



Information Blocking Workgroup Meeting #11

Interoperability Matters

1/10/2020

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

- Jeff Smith, AMIA

Safety Net Providers / Service Provider

- Jennifer Stoll, OCHIN

Release of Information Company

- Rita Bowen, MROCorp

The Sequoia Project Team

Lindsay Austin, Troutman Sanders Strategies

Steve Gravely, Gravely Group

Shawna Hembree, Program Manager

Mark Segal, Digital Health Policy Advisors

Dawn VanDyke, Director, Marketing Communications

Mariann Yeager, CEO

Agenda

- Welcome and Introductions
- Review of Agenda
- Phase 2 Deliverable Status
- Implementation Planning: Phase 3 Initial Work
- Additional Priorities for Phase 3
- Next Steps
- Closing

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

Information Blocking Workgroup: Phase 2 Recap

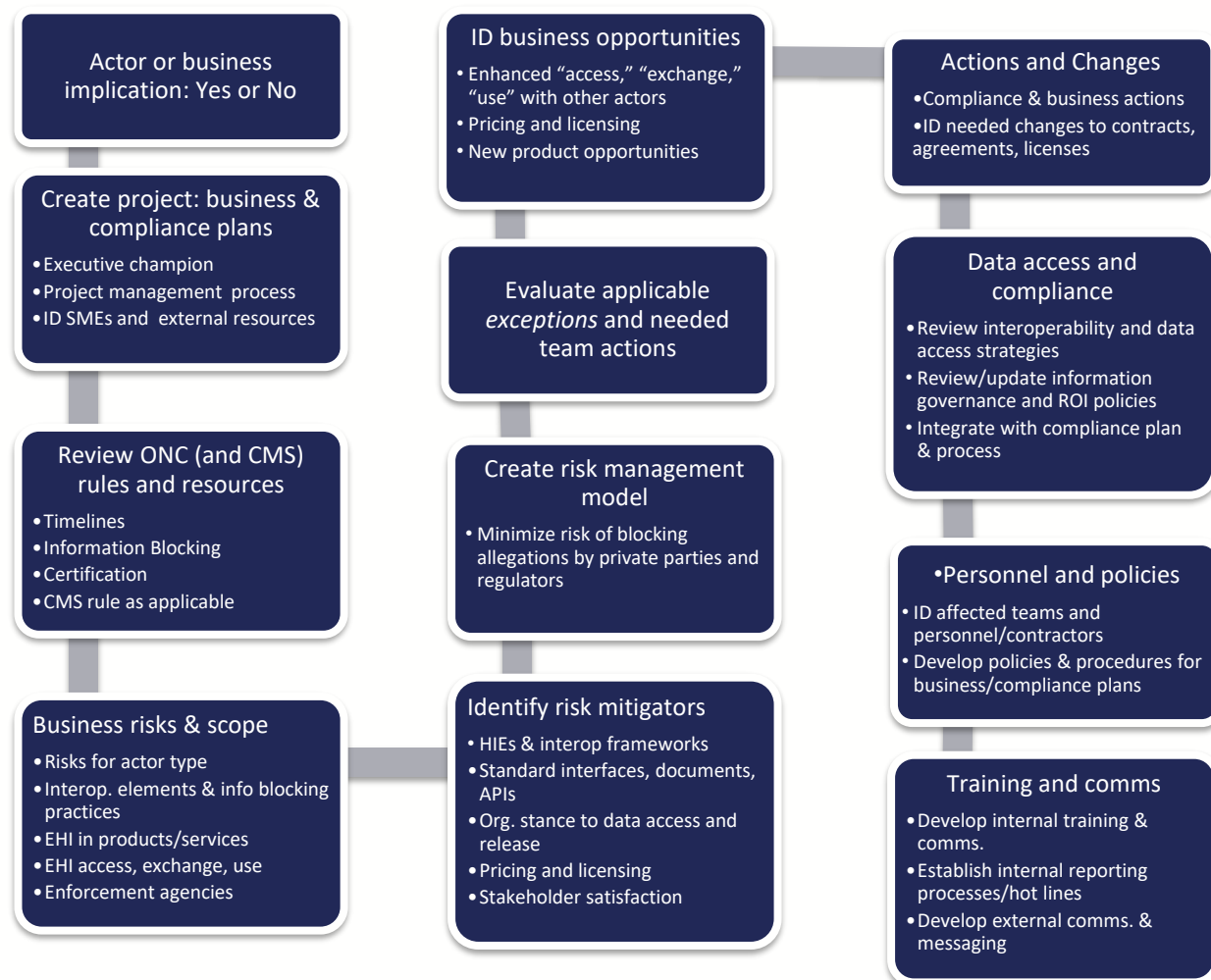
Overall approach: Focus on implementation and compliance implications of ONC proposed rule elements and likely outcomes. Not relitigating comments.

- ✓ 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) – In-person and virtual
- ✓ 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) Compliance Plans (cont.) and Phase 2 Review

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

Phase 3: Implementation Planning

Organization-Wide Information Blocking Plan: Overall Model



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

- ☐ Are you an “actor” and if so for which units of your organization?
 - ☐ If not, are you likely to have market or commercial implications from rule?
 - ☐ If “No” for either aspect of this question, STOP.
- ☐ If “Yes,” create an organizational “information blocking” project or initiative
 - ☐ Business plans (e.g., product, engineering, marketing, commercial, legal, HR/training, communications, etc.)
 - ☐ Compliance plan (complement and integrate with business plans): primarily if “actor”
- ☐ Designate an overall senior executive project owner/champion
 - ☐ Designate business unit project owners as needed
- ☐ Establish a project management process (e.g., PMO)
 - ☐ Create projects as needed
- ☐ Identify/designate/train internal SMEs
- ☐ Identify external resources (legal, compliance, policy, training, etc.)
- ☐ Identify and engage with external industry resources (e.g., associations, interoperability initiatives, experts, colleagues, etc.)

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

- ☐ Review ONC proposed rule, ONC website, industry resources
- ☐ Review ONC (and CMS) final rule
 - ☐ Compliance timelines
 - ☐ Information blocking provisions
 - ☐ As applicable, ONC certification provisions (developers and actors that expect to interact with ONC certified interoperability capabilities)
 - ☐ As applicable, CMS final rule (especially payors and health plans)

Organization-Wide Information Blocking Plan: Adapt to Actor-Type, Organizational Scale, and Organization (3)

- ☐ Identify business risks and scope:
 - ☐ Risks specific to type of actor (e.g., developer, provider, HIE, HIN)
 - ☐ Developers have additional certification-related requirements/risks
 - ☐ Developers, HIEs, HINs have \$1 M/violation maximum fines
 - ☐ Providers: attest for QPP and subject to payment adjustments, OIG, Federal False Claims Act, etc.
 - ☐ Interoperability elements covered by organization
 - ☐ Applicable information blocking practices per:
 - ☐ Definition of information blocking
 - ☐ ONC-identified practices
 - ☐ ONC practice examples
 - ☐ EHI included in organization products or services
 - ☐ Implementation of standards for EHI (e.g., C-CDA, USCDI, HL7® FHIR®, etc.)
 - ☐ Non-standard EHI and how it can be made accessible
 - ☐ Potential external access, exchange, or use of EHI
 - ☐ Current and potential external EHI requesters
 - ☐ Identify enforcement agencies: ONC, OIG, CMS, FTC, etc.
 - ☐ Review organization experience and relationships with agencies

Organization-Wide Information Blocking Plan: Adapt to Actor-Type, Organizational Scale, and Organization (4)

- ☐ Identify risk mitigators, including:
 - ☐ Participation in HIEs and interoperability frameworks
 - ☐ Implementation of standard interfaces, document-types, APIs, messaging, etc.
 - ☐ Organizational stance toward data access and release of information
 - ☐ Pricing and licensing approaches
 - ☐ Stakeholder satisfaction with data sharing/access
 - ☐ Consider stakeholder surveys/outreach
- ☐ Develop a risk management model, such as is used for malpractice, to minimize the risk of allegations of information blocking by:
 - ☐ Private parties
 - ☐ Regulators

Organization-Wide Information Blocking Plan: Adapt to Actor-Type, Organizational Scale, and Organization (5)

- ☐ Evaluate applicable *exceptions* and needed actions by team: initial/ongoing
 - ☐ Privacy: Privacy officer, legal, etc.
 - ☐ Security: Security officer, legal, engineering, etc.
 - ☐ Recovering Costs: CFO/accounting, pricing, marketing, legal, etc.
 - ☐ Evaluate costs and cost accounting and relationship to pricing
 - ☐ Specific CEHRT developer requirements re: APIs
 - ☐ Respond to infeasible requests: Client services, product, engineering, etc.
 - ☐ Need process to identify and handle timely
 - ☐ RAND licensing: legal, licensing, pricing, product, marketing
 - ☐ Identify licensed interoperability elements
 - ☐ Maintaining and Improving Health IT Performance: CIO, engineering, legal, etc.
 - ☐ Need to review/revise SLAs

Organization-Wide Information Blocking Plan: Adapt to Actor-Type, Organizational Scale, and Organization (6)

- ❑ Identify business opportunities (even if not an “actor”)
 - ❑ Enhanced “access,” “exchange,” “use” with other actors
 - ❑ e.g., access data from an EHR or HIE or to write to an EHR
 - ❑ Pricing and licensing opportunities
 - ❑ New product opportunities

Organization-Wide Information Blocking Plan: Adapt to Actor-Type, Organizational Scale, and Organization (7)

- ☐ Identify needed/desired compliance and business actions
 - ☐ Identify owners
 - ☐ Conduct and update gap analyses
- ☐ Identify needed changes to contracts, agreements, licenses
 - ☐ Develop process to revise: legal, commercial, client services
- ☐ Review interoperability and data access strategies, including use of:
 - ☐ Standards (HHS adopted, industry consensus, etc.)
 - ☐ APIs (FHIR and other)
 - ☐ Apps (developed by organization and those that connect with your HIT)
 - ☐ App stores, including licensing a pricing policies
 - ☐ Write access to your HIT by external apps/applications
- ☐ Review/update information governance and release of information policies
 - ☐ HIM and contractors

Organization-Wide Information Blocking Plan: Adapt to Actor-Type, Organizational Scale, and Organization (8)

- ☐ **Integrate with compliance plan and process**
- ☐ Identify affected teams and personnel, including contractors
 - ☐ Likely very wide across the organization
- ☐ Develop policies and procedures reflecting business and compliance plans
 - ☐ Including documentation of actions and events
- ☐ Develop internal training and communications process
 - ☐ Track and document training by relevant team members
- ☐ Establish internal reporting processes/hot lines
 - ☐ Concerns with information blocking risk
 - ☐ Internal
 - ☐ External (e.g., business partners, competitors, etc.)
 - ☐ Reporting mentions of “information blocking” in commercial or other external discussions
- ☐ Develop external communications and messaging strategy
 - ☐ General on organization approach to information blocking/interoperability
 - ☐ Addressing public complaints

Additional Phase 3 Priorities

Additional Phase 3 Priorities: Open Discussion

Next Steps

Next Steps

- Finalize Phase 2 PowerPoint Deliverable this month
 - Shared with Interoperability Matters Leadership Council and Workgroup
 - Convey to Sequoia Project Board
 - Share with HHS, Public Forum participants and the broader stakeholder community
- Review Final Rule
 - Implementation, compliance, and educational needs
- Communicate to ONC and OIG as needed in 2020
- Calls scheduled through May 2020

Closing Discussion

Interoperability Matters


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

Appendix 1: Information Blocking Comments to ONC

Status Update


- Sequoia comment letters submitted May 2019
 - CMS Interoperability NPRM
 - ONC Cures NPRM
- Information Blocking Workgroup Findings and Recommendations
 - Accepted by Sequoia board
 - Included with public comment letters from Sequoia and Carequality

ONC received 2,013 comments, many/most? on price transparency





Your Voice in Federal Decision-Making

Home Help Resources Contact U

Interoperability 

Advanced Search

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

Docket Folder Summary  [View all documents and comments in this Docket](#)

Docket ID: HHS-ONC-2019-0002 Agency: Department of Health and Human Services (HHS)

Summary:


The rulemaking would implement certain provisions of the 21st Century Cures Act, including conditions and maintenance of certification requirements for health information technology (IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric healthcare providers and reasonable and necessary activities that do not constitute information blocking. The rulemaking would also modify the 2015 Edition health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.


[Take a Tour!](#)

[Sign up for Email Alerts](#)


2,013

Comments [View All](#) (1,880)




Please see attached comment letter (uploaded file) regarding the Illinois Health and Hospital Association's comments on the 21st Century Cures Act: Proposed..." 

[View Comment](#) Submitter Name: Sandy Kraiss Posted: 06/06/2019 ID: HHS-ONC-2019-0002-1873




I recently had cataract surgery on both eyes, and while my eye doctor told me what the charges would be for the actual surgery, I didn't know how much extra..."


[View Comment](#) Submitter Name: Julia Ingram Posted: 06/06/2019 ID: HHS-ONC-2019-0002-1866




Please make price transparency a reality. People need to be able to know what they will pay for their prescription drugs."

[View Comment](#) Submitter Name: Susan Hoare Posted: 06/06/2019 ID: HHS-ONC-2019-0002-1872



Please find the attached comment letter from the American College of Osteopathic Family Physicians (ACOPP)." 

[View Comment](#) Submitter Name: Anonymous Anonymous Posted: 06/06/2019 ID: HHS-ONC-2019-0002-1845



I am 100% in support of price transparency. It is way past time for Congress to step and lead re this issue in support of our president and the citizens of our..."

[View Comment](#) Submitter Name: Martin Owens Posted: 06/06/2019 ID: HHS-ONC-2019-0002-1860

Common ONC NPRM public comment themes

- Imposes a significant burden on actors
 - Complexity of exceptions
 - Ambiguity of terms
 - Cost of compliance
- Definition of Information Blocking too broad and might be struck down by courts upon review
 - “Likely” to interfere is too vague
 - ONC should provide specific examples so Actors can develop realistic compliance programs
- Definition of HIE and HIN confusing
 - Consider a single definition
- Adoption of EHI widely panned
 - ONC urged to stick with PHI
- Burden of Proof and Standard of Proof
 - Burden on Actors to prove that they did NOT info block
 - Documentation burden on providers, especially hospitals, a real concern
 - Standard too high, if you miss one part of an exception then you are outside the exception

Common ONC NPRM public comment themes

- Proposed Exceptions
 - Categories right but requirements too detailed and rigid
 - Some see exceptions as loopholes and others as too restrictive
 - A new “TEFCA exception” popular
- Pricing/contracting limits too restrictive, requiring too much documentation, and could distort markets; refine (e.g., focus on “basic access”)
- Should developers who are information blocking actors only be those who develop CEHRT (and subject to penalties) and conversely, should all products developed by developers of CEHRT be regulated?
- RAND creates “severe disincentive” for established developers to create new solutions
 - RAND for licensing terms needs much further study

Common ONC NPRM public comment recommendations

- ONC should revise NPRM and submit for second round of comments
- Effective Date should be delayed to enable Actors to modify practices
 - Suggested timelines vary from 12 months to 36 months after publication
- ONC should make clear what practices are not acceptable
- ONC should make clear the enforcement mechanism(s)
- ONC should develop a process for ongoing clarification of the rule

FTC



Office of Policy Planning
Bureau of Economics
Bureau of Competition

RIN 0955-AA01

Department of Health & Human Services
Office of the National Coordinator for Health Information Technology
Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule

The staff of the Federal Trade Commission ("FTC" or "Commission") Office of Policy Planning, Bureau of Economics, and Bureau of Competition ("FTC staff" or "we")¹ appreciate the opportunity to comment on the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, RIN 0955-AA01 ("NPRM").²

We recognize the potential benefits of interoperability and of easier sharing of health care information.³ Both can foster innovation and competition in health information technology ("HIT") and health care diagnosis, delivery and treatment. This benefits consumers financially and in better health care outcomes. We support ONC's efforts to achieve these important objectives.

As the NPRM acknowledges, FTC staff provided informal technical assistance to ONC staff during the drafting process.⁴ We appreciate the open dialogue between the agencies' staffs as ONC worked to accomplish the various policy goals identified by Congress in the 21st

¹ These comments reflect the views of FTC staff. They do not necessarily represent the views of the FTC or of any Commissioner; the Commission has, however, voted to authorize staff to submit these comments.

² 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Criteria, 84 Fed. Reg. 7424, 7424 (proposed Mar. 4, 2019) (to be codified at 45 CFR Parts 170 and 171) [hereinafter NPRM].

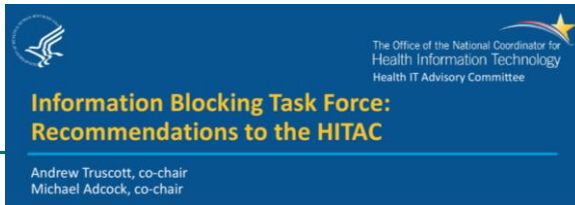
³ See, e.g., Fed. Trade Comm'n Staff Comment Before the Office of the National Coordinator for Health Information Technology, regarding its Draft Shared Nationwide Interoperability Roadmap for Health Information Technology Systems (Apr. 2015), https://www.ftc.gov/system/ftc_documents/advocacy_documents/ftc-staff-comment-on-the-national-coordinator-for-health-information-technology-regarding-the-draft-1504-roadmap-health.pdf.

⁴ NPRM at 7523.

Our goal in providing technical assistance has been to help ensure that the final rule does not inadvertently distort competition or inhibit conduct that is affirmatively procompetitive and consumer friendly. We set out below some additional areas where the information-blocking rule and accompanying exceptions could be further refined to help minimize unintended consequences. These suggestions may help clarify the final rule so that the exceptions do not inadvertently prohibit "activities that are innocuous, or even beneficial."⁶

1. We acknowledge the considerable work the Department and ONC have done to identify and clarify exceptions to the information blocking prohibition; however, consider whether additional and more fully developed examples of permissible conduct, as observed in HIT and EHI use and development, could clarify safe harbors for conduct that does not harm competition or consumer welfare.
2. Consider adjusting the definition of EHI, so that it applies more narrowly to the information that is the focus of the statute, such as the information needed for patient treatment and HIT interoperability.
3. Consider (a) clarifying when market pricing is not deemed information blocking, and (b) providing additional leeway for market pricing and certain ordinary refusals (or failures) to deal under the "recovering costs reasonably incurred,"⁷ "responding to requests that are infeasible,"⁸ and the "licensing of interoperability elements on fair and reasonable terms"⁹ safe harbors.
4. Consider narrowing the proposed definition of "developers of certified HIT" so that regulatory restrictions apply to certified HIT, but not for all of its products, services, conduct, or practice, "including practices associated with any of the developer or offeror's health IT products that have not been certified under the Program."¹⁰

HITAC: Examples of Comments to ONC



June 3, 2019

Donald Rucker, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Rucker:

The Health Information Technology Advisory Committee (HITAC) asked the HITAC Notice of Proposed Rulemaking (NPRM) Task Forces to provide recommendations on the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program proposed rule. The recommendations were provided by the following Task Forces: Information Blocking Task Force; the Conditions and Maintenance of Certification Task Force; the Health IT for the Care Continuum Task Force; and the U.S. Core Data for Interoperability (USCDI) Task Force. This transmittal offers these recommendations, which are informed by the deliberations among the Task Force subject matter experts. These recommendations were reviewed, discussed and approved for transmittal by the full HITAC at the March 19, April 10, April 25, May 13, and May 22, 2019 meetings.

Information Blocking Task Force Recommendations

The Health Information Technology Advisory Committee (HITAC) requested that the Information Blocking Task Force (IB TF) provide recommendations to the HITAC regarding the proposals in the Cures Act Notice of Proposed Rulemaking related to information blocking. The Task Force recommendations were reviewed, deliberated, and approved by the full HITAC. This transmittal letter offers these recommendations, which the HITAC wishes to advance to the ONC for consideration.

We believe that there are several aspects of these recommendations which warrant additional exploration to ascertain the impact upon different stakeholder groups, and to provide guidance to them. This is not a suggestion to defer any recommendations, but to provide additional clarity to those stakeholder groups and to assist in the adoption of the 21st Century Cures Act and ensuring the benefits thereof. It is our profound belief that HITAC is best positioned as the agent to assist in this regard.

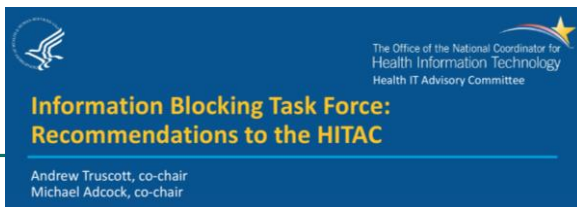
As co-chairs of the HITAC, we wish to thank ONC for the opportunity to serve in this fundamental role supporting the success of ONC's Proposed Rule and the rulemaking process and promoting improved patient outcomes through information sharing. The discussions of the HITAC have been exhaustive, in no small part due to the diligence and expertise demonstrated by the ONC staff assigned to support this task force. We thank them for their contributions.

Please consider the attached recommendations from the HITAC. Each recommendation is individually numbered, and where recommendations have been removed compared to prior late-stage drafts, we have preserved the original numbering to promote appropriate version control.

HITAC NPRM Recommendations | 2

- **Recommendations 1 (HIE definition) & 2 (HIN definition): “Substantially influences”**
 - *Health Information Exchange* or *HIE* means: Any entity who is not considered a Provider, Health Information Network, or Health IT Developer performing the access, exchange, transmittal, processing, handling, or other such use of Electronic Health Information.
 - *Health Information Network* or *HIN* means an individual or entity that satisfies one or several of the following— (1) Determines, oversees, administers, controls, or sets policies or makes agreements that define business, operational, technical, or other conditions or requirements for Health Information Exchange between or among two or more individuals or entities, or (2) Provides, manages, or controls any technology or service that enables or facilitates Health Information Exchange between or among two or more individuals or entities.

HITAC: Examples of Comments to ONC



June 3, 2019

Donald Rucker, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Rucker:

The Health Information Technology Advisory Committee (HITAC) asked the HITAC Notice of Proposed Rulemaking (NPRM) Task Forces to provide recommendations on the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program proposed rule. The recommendations were provided by the following Task Forces: Information Blocking Task Force; the Conditions and Maintenance of Certification Task Force; the Health IT for the Care Continuum Task Force; and the U.S. Core Data for Interoperability (USCDI) Task Force. This transmittal offers these recommendations, which are informed by the deliberations among the Task Force subject matter experts. These recommendations were reviewed, discussed and approved for transmittal by the full HITAC at the March 19, April 10, April 25, May 13, and May 22, 2019 meetings.

Information Blocking Task Force Recommendations

The Health Information Technology Advisory Committee (HITAC) requested that the Information Blocking Task Force (IB TF) provide recommendations to the HITAC regarding the proposals in the Cures Act Notice of Proposed Rulemaking related to information blocking. The Task Force recommendations were reviewed, deliberated, and approved by the full HITAC. This transmittal letter offers these recommendations, which the HITAC wishes to advance to the ONC for consideration.

We believe that there are several aspects of these recommendations which warrant additional exploration to ascertain the impact upon different stakeholder groups, and to provide guidance to them. This is not a suggestion to defer any recommendations, but to provide additional clarity to those stakeholder groups and to assist in the adoption of the 21st Century Cures Act and ensuring the benefits thereof. It is our profound belief that HITAC is best positioned as the agent to assist in this regard.

As co-chairs of the HITAC, we wish to thank ONC for the opportunity to serve in this fundamental role supporting the success of ONC's Proposed Rule and the rulemaking process and promoting improved patient outcomes through information sharing. The discussions of the HITAC have been exhaustive, in no small part due to the diligence and expertise demonstrated by the ONC staff assigned to support this task force. We thank them for their contributions.

Please consider the attached recommendations from the HITAC. Each recommendation is individually numbered, and where recommendations have been removed compared to prior late-stage drafts, we have preserved the original numbering to promote appropriate version control.

HITAC NPRM Recommendations | 2

- **Recommendation 33:** The HITAC recommends that ONC distinguish between **Basic Access** and **Value-Added Access, Exchange, and Use** . . .
- **Recommendation 35:** The HITAC recommends that ONC distinguish between IPR that are *essential* to access and IPR that allow for value-added services . . .
- **Recommendation 36:** The HITAC recommends that allowed fees for basic access be on a pure direct cost recovery basis only . . .
- **Recommendation 37:** The HITAC recommends that allowed fees for access, exchange and use essential IPR be set on a RAND-basis . . .
- **Recommendation 38:** The HITAC recommends no further restrictions on permitted fees . . .

Looking Ahead

- Comment period closed ~~May 3~~
June 3
- Final Rule likely by late Fall but timing uncertain
- Most provisions effective 60 days after final rule
- Others: 26 months after final rule (e.g., API technology criteria)
- Timing for specific provisions could change in final rule or after
- Final Rule will likely retain key provisions but with material revisions, more flexibility and relaxed timing
- Extended period of regulatory and compliance uncertainty
- Scarcity of qualified legal advice and a lack of guidance and case law to support legal interpretations
- Community will need implementation guidance to meet legislative and regulatory intent and reduce compliance uncertainty and costs

Appendix 2: Background on Phase 2 Topics Addressed in this Report



HIEs/HINs and Related Key Definitions

Information Blocking: ONC §171.103

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 but ONC has RFI on including price information within EHI with regard to information blocking

Interoperability Element §171.102

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

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

ONC HITAC on HIE and HIN

HIE

- *Health Information Exchange or HIE* means: ~~a Any individual or entity who is not considered a Provider, Health Information Network, or Health IT Developer performing the that enables access, exchange, transmittal, processing, handling or other such use of e-Electronic Health Information primarily between or among a particular class of individuals or entities or for a limited set of purposes.~~

“We recognize that there are multiple uses of the terms “Health Information Network” (HIN) and “Health Information Exchange” (HIE) across the healthcare ecosystem. Having the terms overlap within the Proposed Rule is likely to cause a degree of confusion. We recommend making the following changes to the definitions of HIN and HIE:”

HIN

Health Information Network or HIN means an individual or entity that satisfies one or ~~both~~ **several** of the following— (1) Determines, oversees, administers, controls, or sets ~~substantially influences~~ policies or makes agreements that define business, operational, technical, or other conditions or requirements for Health Information Exchange enabling or facilitating access, exchange, or use of electronic health information between or among two or more **unaffiliated** individuals or entities. (2) Provides, manages, or controls ~~or substantially influences~~ any technology or service that enables or facilitates Health Information Exchange the access, exchange, or use of electronic health information between or among two or more **unaffiliated** individuals or entities.

Selected ONC Information Blocking Examples Relevant to Broadly Defined HIEs and HINs

- An HIN's participation agreement prohibits entities that receive EHI through the HIN from transmitting that EHI to entities who are not participants of the HIN.
- A health IT developer of certified health IT refuses to license an API's interoperability elements, to grant the rights necessary to commercially distribute applications that use the API's interoperability elements, or to provide the related services necessary to enable the use of such applications in production environments.
 - *What if an HIE or HIN has proprietary APIs or interoperability tools and methods??*
- An 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.
- An EHR developer of certified health IT charges customers a fee to provide interfaces, connections, data export, data conversion or migration, or other interoperability services, where the amount of the fee exceeds the actual costs that the developer reasonably incurred to provide the services to the particular customer(s).
 - *What if a broadly defined HIE or HIN charges fees for such or similar services that exceed costs?*
- A health IT developer of certified health IT adheres to the "required" portions of a widely adopted industry standard but chooses to implement proprietary approaches for "optional" parts of the standard when other interoperable means are readily available.
 - *Are "proprietary" implementations of APIs or other technologies by broadly defined HIEs and HINs information blocking? How is non-standard to be defined? Is a non-FHIR Restful API non-standard?*

Actors and Other Definitions: Workgroup Comments-Phase 1

- The definition of an *actor* is critical because it exposes organizations to penalties and the regulatory implications of defined *practices* and *exceptions*.
- The proposed definition of an *HIN* is too broad and could include organizations that are not networks; it should be more narrowly focused:
 - For example, health plans, technology companies that handle *EHI*, and standards developing organizations (SDOs) or organizations that develop recommended interoperability policies are not networks and could, inappropriately, be included in the proposed definition.
 - Should receipt of health IT incentive program payments or federal stimulus payments be a determinant of whether an organization is an HIE or an HIN?
- The definition of an *HIE* includes *individuals*, which is difficult to understand, and, as with the *HIN* definition, could sweep in individuals or organizations that are not actually HIEs.
- The distinction between HIEs and HINs is unclear; HIEs should be viewed as a subset of HINs; ONC should therefore consider combining the two types of actors into one combined definition.
- The HIT *developer* definition needs more clarity on whether its application includes all *interoperability elements* under the control of the developer.
 - In addition, the definition is too broad as it could bring in companies that only have one product certified against one or a very few criteria, for example a quality reporting module.
 - The definition would also seem to inappropriately include organizations like value-added resellers in its focus on “offers” certified health IT.
- ONC should consider defining EHI to equal PHI as defined by HIPAA.



Information Blocking Practices

Information Blocking: ONC §171.103

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 but ONC has RFI on including price information within EHI with regard to information blocking

Interoperability Element §171.102

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.

Practices: Selected, Edited ONC Examples

Restrictions on Access, Exchange, or Use

- Requiring consent to exchange EHI for treatment even though not required by law
- Developer refuses to share technical information needed to export data
- HIN restriction on end-user sharing EHI with non-HIN members
- Vendor only provides EHI in PDF on termination of customer agreement
- Developer of certified health IT refuses to license interoperability elements reasonably necessary for others to develop and deploy software that works with health IT

Practices: Selected, Edited ONC Examples

Limiting or Restricting the Interoperability of Health IT

- Actor deploys technological measures that restrict ability to reverse engineer to develop means for extracting and using EHI in the technology
- Hospital directs EHR developer to configure technology so users cannot easily send electronic referrals to unaffiliated providers, even when the user knows Direct address and/or identity of the unaffiliated provider
- 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
- Provider has capability to provide same-day access to EHI but takes several days to respond

Practices: Selected, Edited ONC Examples

Impeding Innovations and Advancements in Access, Exchange, or Use or Health IT-Enabled Care Delivery

- Developer of certified health IT requires third-party apps to be “vetted” for security but does not vet promptly
- Developer of certified health IT refuses to license interoperability elements that other applications require to access, exchange, and use EHI in the developer’s technology
- Provider engages integrator to develop interface engine but its license with EHR developer prohibits it from disclosing technical documentation integrator needs to perform the work [without broad non-compete]
- Health system insists local physicians adopt its EHR platform, which provides limited connectivity with competing hospitals and threatens to revoke admitting privileges for physicians that do not comply
- 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

Practices: Selected, Edited ONC Examples

Rent-Seeking and Other Opportunistic Pricing Practices

- Developer of certified health IT charges customers a fee exceeding their costs for interfaces, connections, data export, data conversion or migration, other interoperability services
- Developer of certified health IT charges more to export or use EHI in certain competitive situations or purposes
- Developer of certified health IT interposes itself between customer and third-party developer, insisting that developer pay licensing fee, royalty, or other payment [not related to costs] for permission to access EHR or documentation
- Analytics company provides services to customers of developer of certified health IT and developer insists on revenue sharing that exceeds its reasonable costs

Practices: Selected, Edited ONC Examples

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
- Even where no federally adopted or identified standard exists, if a particular implementation approach has been broadly adopted in a relevant industry segment, deviations from that approach would be suspect unless strictly necessary to achieve substantial efficiencies.
- Developer of certified health IT implements C-CDA for TOC summary receipt but only sends summaries in a proprietary or outmoded format
- Developer of certified health IT adheres to “required” portions of widely adopted standard but implements proprietary approaches for “optional” parts of the standard when other interoperable means are available

Practices: Workgroup Comments-Phase 1

- The definition of *interoperability elements* is very broad (beyond certified health IT) and interacts with the identified information blocking practices and actors (and other aspects of the information blocking requirements) to create a very broad and complex web of compliance risk.
- Although part of the Cures statute, the term “likely” in the regulatory definition of information blocking, without a commonly understood definition or one in the proposed rule is problematic.
 - It could lead to an ongoing a large number of commercially motivated allegations of information blocking, even without any actual blocking.
 - Actions and capabilities associated with patient matching might trigger the “likely” level of risk.
 - ONC should define “likely” as “highly probable,” backed up with examples of actual information blocking.
- There is a need to allow for due diligence as distinct from simply delaying access and such diligence should not need an exception (e.g., the security exception) to avoid implicating or being judged as information blocking. The need to vet external locations of exchange includes but is not limited to apps (e.g. networks).
 - In lieu of a focus on “vetting” of apps and other points of exchange by providers, CARIN Alliance suggests a focus on apps needing to be “centrally registered” by an EHR or a health plan. This approach allows a light 'vetting' process of the app but also allows the app to gain access to all client end points following registration without providers needing or wanting to vet every app. https://www.carinalliance.com/wp-content/uploads/2019/02/CARIN_Private-and-Secure-Consumer-Directed-Exchange_021019.pdf
 - It would be desirable if there can be a central point where apps are certified/vetted to achieve efficiencies for plans/providers/Vendors/app developers. If organizations want to do other vetting, that would be permitted of course, but at minimum CMS and ONC should release a White List for apps that they have vetted, and preferably also a Black List from the FTC if there is not a full fledged certification process. There is concern from some participants that being simply “registered” with a plan will not determine if it is a legitimate request, from a legitimate organization, with a legitimate scope of data elements.

Practices: Workgroup Comments-Phase 1

- The focus on non-standard implementations, combined with the broad definitions of actors, could pose challenges for certain organization, such as clinical registries, which have historically needed some non-standard implementations to achieve their intended purpose. In addition, we ask ONC to provide additional examples of non-standard implementations beyond those on p. 7521, for when applicable adopted standards exist and when they do not.
- There should be “safe harbor” provisions for some practices without the need to use an exception with all of its specificity.
- The nature of this rule and the underlying issue being addressed is leading ONC to assume actors have bad intent, and to err on the side of ensuring that there are no loopholes for these bad actors to exploit. This approach is understandable, but it casts such a wide net that there is a strong chance of collateral damage and pulling in those who are acting in good faith. It should be possible to relax some of the language in the practices and exceptions (e.g., “all things at all times and if no alternatives”), perhaps language that references acting in good faith and an allowance for “one off” cases in a gray area.



Recovering Costs/RAND Licensing

Exception: Recovering Costs Reasonably Incurred

- Actor may recover costs it reasonably incurs, in providing access, exchange, or use of EHI
- Fees must be:
 - charged on basis of *objective and verifiable criteria uniformly applied* to all similarly situated persons and requests;
 - *related to the costs* of providing access, exchange, or use; and
 - *reasonably allocated among all customers* that use the product/service
- Fees must not be based:
 - in any part on whether requestor is a *competitor*, potential competitor, or will be using EHI to facilitate competition with the actor;
 - on *sales, profit, revenue*, or other value that the requestor derives or may derive *that exceed the actor's reasonable costs*; or
 - *anti-competitive* or other impermissible criteria
- Certain costs excluded from this exception, such as costs that are *speculative or subjective or associated with electronic access by an individual to their EHI*

Issues: Documentation? “Related” to costs vs. equal to costs? Profit – not in regulatory language?
Unintended consequences?

Exception: Licensing Interoperability Elements on Reasonable and Non-Discriminatory Terms

- Actor that controls technologies or other interoperability elements that are necessary to enable access to EHI will not be information blocking so long as it licenses such elements on *reasonable and non-discriminatory terms (RAND)*
 - RAND terms often used by SDOs
- License can impose *reasonable royalty* but *must include appropriate rights* so licensee can develop, market, and/or enable use of interoperable products and services
- License terms must be based on *objective and verifiable criteria* that are *uniformly applied and must not be based on impermissible criteria*, such as whether the requestor is a potential competitor

Issues: Documentation? Unintended consequences? “Reasonable”? Scope of this requirement – EHRs?

Recovering Costs Reasonably Incurred: Workgroup Comments-Phase 1

- There was strong support for ONC's proposal to provide free API access to an individual who requests access to their EHI through a consumer-facing application and ONC should consider whether this approach could be extended to public health access.
- There were varying views regarding prohibition of fees for patient access:
 - Some noted that prohibition on any fees that do not meet this very detailed exception is too complex (both preamble and regulatory text) and interferes too much with market operations and could reduce investment in needed interoperability solutions. They suggest that ONC revise the exception to shift from an emphasis on cost recovery to a focus on the shared goal, central to 21st Century Cures, that pricing should not be a deterrent to information sharing.
 - Some also were concerned with the breadth of the prohibition on fees “based in any part on the electronic access by an individual or their personal representative, agent, or designee to the individual’s electronic health information,” particularly the reference to “designees.” They noted that data accessed in this way by commercial “designees” (e.g., apps) has economic value with costs associated with its provision. Prohibiting any such fees to designees (as opposed to the individual) as part of the information blocking provision, beyond API certification requirements, could reduce investment in interoperability capabilities and overall availability of information. In addition, this issue has important interaction effects with the companion CMS interoperability proposed rule if payers, who are required and encouraged to create APIs are unable to recover costs because they have been defined as HIEs or HINs as part of this rule.
- There was concern with a high burden for hospitals to comply with this exception.

Recovering Costs Reasonably Incurred: Workgroup Comments-Phase 1

- We ask ONC to clarify what individuals and entities are subject to the prohibition of fees for individual access and how to determine if an entity is actually an individual's designees for data sharing. More generally we ask ONC to clarify whether consent to share information to be interpreted as equivalent to actual patient direction to share?
- Many terms in this exception are subjective (e.g., "reasonable). We ask ONC to provide clear definitions in the final rule and associated guidance.
 - In particular, we ask ONC to provide more guidance on the allowance for "reasonable profit" in the preamble (p. 7538) and to explicitly include such an allowance in the regulatory text.
- ONC states that the method to recover costs "[m]ust not be based on the sales, profit, revenue, or other value that the requestor or other persons derive or may derive from the access to, exchange of, or use of electronic health information, including the secondary use of such information, that exceeds the actor's reasonable costs for providing access, exchange, or use of electronic health information." The preamble (p. 7539) further states that "such revenue-sharing or profit-sharing arrangements would only be acceptable and covered by the exception if such arrangements are designed to provide an alternative way to recover the costs reasonably incurred for providing services." *The term "alternative" is confusing and could be read to imply that this method is an alternate to another simultaneously offered method of cost recovery, which we do not believe is ONC's intent; we ask ONC to clarify.*

Recovering Costs Reasonably Incurred: Workgroup Comments-Phase 1

- The disallowance for costs that are “due to the health IT being designed or implemented in non-standard ways that unnecessarily increase the complexity, difficulty or burden of accessing, exchanging, or using electronic health information” requires further clarification. In particular, ONC should recognize that there are often multiple actors and actor-types involved in an implementation. A given actor could face higher costs as a result of non-standard implementations by another actor (e.g., a provider, a developer or vice versa). Such costs incurred as a result of non-standard design or implementation by another actor should be able to be reflected in fees.
- This exception should be expanded to clarify that costs associated with research, including costs from non-standard implementations due to research needs, should be able to be reflected in fees.
- There was interest and uncertainty as to how rapidly useful pricing information can be included in this exception.

Reasonable and Non-Discriminatory Terms (RAND)

Licensing: Workgroup Comments-Phase 1

- Overall, we ask ONC to simplify this exception and its scope and to provide more guidance on RAND licensing and its implementation.
- We request that ONC address the potential for unintended consequences; for example, some health IT delivery models might have fees eligible for the RAND licensing exception and others would only be eligible for 171.204, with the potential for higher net financial returns under one model or the other, a preference that is not intended (and should not be) as a matter of public policy.
- The preamble discussion of this exception is complex and will require very technical and fact-specific steps by actors, including establishment of “reasonable” royalties.
- We ask ONC to consider the combined implications and timing to assess feasibility, licensing implications and enter a negotiation for licensing within a 10-day timeframe.

Reasonable and Non-Discriminatory Terms (RAND)

Licensing: Workgroup Comments-Phase 1

- In addition, given the extensive use of licenses as one element of commercial health IT software offerings, we ask ONC to clarify which software licenses would need to (be revised to) meet this exception to avoid information blocking (i.e., will *all* software licenses need to be converted to RAND terms or only those that focus on specific intellectual property rights, and in what timeframe?). For example, would licenses for EHRs presented to providers be subject to this provision or only licenses for specific IP (e.g., code sets) or APIs licensed by an EHR developer to an application developer? We also ask ONC to recognize that this exception, if it requires changes to virtually all health IT software licenses, is likely to have far reaching and very disruptive impacts on the market for health IT software, including a high compliance and documentation burden.
- We ask ONC to clarify its definition of “royalty” and which fees associated with licenses software would be consider a royalty and which would not, and hence only eligible for the exception at 171.204.

Reasonable and Non-Discriminatory Terms (RAND)

Licensing: Workgroup Comments-Phase 1

- We ask ONC to clarify whether, *in all cases*, fees that might be associated with software are also eligible for the alternate exception under 171.204. The preamble (p. 7549) states that “[f]inally, the actor must not condition the use of interoperability elements one requirement or agreement to pay a fee of any kind whatsoever unless the fee meets either the narrowly crafted condition to this exception for a reasonable royalty, or, alternatively, the fee satisfies the separate exception proposed in § 171.204, which permits the recovery of certain costs reasonably incurred”.
- We also ask ONC to clarify whether an actor that licenses an interoperability element and chooses to use the exception at 171.204 for fees, would also need to use this exception, as there are many non-monetary aspects of this exception.
- We ask ONC to address an actor’s obligation to license intellectual property that they do not yet have and to clarify that inability to honor such a request could be met by the feasibility exception and would not require use of this one as well.

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 to for the business to continue operating in good standing”
- Modern compliance emerged around 1991 when US Sentencing Commission updated its Federal Sentencing Guidelines
- US Federal Sentencing Commission sets rules that US 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
- Bona fide compliance plan is a mitigating factor for a sentencing
- FSGO identifies components of a bona-fide compliance plan

Compliance in healthcare

- Driven by increased enforcement of federal “fraud and abuse “ laws by the US Dept. of Justice and the HHS Office of Inspector General (OIG) beginning in early 1990s
- False Claims Act applies to any claim for payment under a federal program like Medicare, Medicaid, Tricare and others - so everyone is affected
- Series of high profile “national enforcement actions” by DOJ/OIG in 1980s and 1990s
- OIG has published in Federal Register “model” compliance plans for healthcare beginning in 1998 for many types of healthcare orgs, including:
 - Hospitals
 - Physicians
 - Nursing facilities
 - Clinical labs
 - DME suppliers
 - Third party billing companies
 - Home Health and Hospice
 - Medicare Choice Plans
- For some developers, there are FDA regulations which cover similar elements

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

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

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
 - Analogous state laws
3. Facilities and Staff rules and regulations
4. Patient Safety
5. Corrective Action Plans – as required
6. Medical and Medicaid incentive programs (MU, QPP, MIPS, etc)

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

- **Healthcare Payor** 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. Data privacy and security
- **HINs, HIEs, and other networks** 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, corrective action plans (as required)

Information Blocking Compliance Framework

- Using the 7 elements used by the OIG in its model compliance plans, lets discuss a compliance framework for Information Blocking
- 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 FSGO which has been used widely by the US Federal Courts in a variety of cases

Information Blocking Compliance Framework

- A framework is a good start, but there will be challenges
- For organizations that already have robust compliance programs, these are often spread across the organization with different leaders and structures
- This might complicate Information Blocking compliance since it cuts across so many disciplines
- For HIEs, interoperability vendors, software developers, and others that are subject to the final Information Blocking Rule but have not developed compliance programs, could be a heavy lift

Information Blocking Compliance Framework

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

- These will need to be very specific and cover "interoperability elements," "practices," and exceptions, especially ensuring that exceptions are met and documented
- Who is responsible for creating these written standards of conduct?
- Do these folks understand the Information Blocking Rule?
- Who will approve the standards of conduct?
- Who is responsible for keeping the standards of conduct up to date?

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,
 - Where does the Information Blocking compliance function reside?
 - Consider that 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 complying with the Information Blocking Rule?

Information Blocking Compliance Framework

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

- Need to identify and apply to organizational functions and individuals that influence “interoperability elements” and “practices” (e.g., HIM, release of information, development, pricing and licensing, legal, interface engineers, 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 records of all education and training is essential

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 conversant in Information Blocking
- 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

- Generally means that complaints must be investigated thoroughly and not “swept under the rug”
- Key issue - Did we violate the Information Blocking Rule?
- How will an Actor implement this since Information Blocking might be driven by policy rather than any single individual’s wrongdoing?
- For smaller companies, discipline can be an issue

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
- For example, if Information Blocking complaints are always found to be without merit

Key Considerations for Discussion

- Overall impressions of how your organization will approach compliance for the Information Blocking Rule
- Key challenges that you can see
- What is your #1 concern regarding compliance ?

November Topic Recap/Continuation: Developing a Compliance Framework for the Information Blocking Rule

Information Blocking Compliance

- Last month, we discussed that Actors will need to prepare for enforcement of the Information Blocking Rule by ONC and the OIG
- Assuring compliance with the Information Blocking Rule is a key part of this effort
- We reviewed how compliance programs emerged in healthcare in the 1990s in response to federal government investigations
- We discussed that health care providers, payors, HINs and software developers approach compliance differently
- Compliance is often “siloed” in different parts of the organization.
 - Fraud and Abuse compliance is in one department, HIPAA compliance is in another department, technology compliance in yet another department
- Information Blocking cuts across different parts of the organization, which makes compliance a challenge

OIG Compliance Program Framework – Seven 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

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

COMMENTS

Confusion about what this means

Concerns about the burden on smaller organizations that may lack the resources to develop these materials

Information Blocking Compliance Framework

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

COMMENTS

Who is the “owner” of Information Blocking?

Do current compliance officers have the expertise?

Information Blocking Compliance Framework

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

COMMENTS

Actors will need time after publication of the Final Rule to ramp up their compliance efforts before enforcement actions begin

Education must extend beyond the Actor's staff and include customers, partners, vendors and others

Information Blocking Compliance Framework

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

COMMENTS

No specific comments

Information Blocking Compliance Framework

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

COMMENTS-

Will compliance with the Information Blocking Rule favor larger Actors and disadvantage smaller Actors?

Information Blocking Compliance Framework

Element #6 - Monitoring the compliance program for effectiveness

COMMENTS

No specific comments

Information Blocking Compliance Framework

Element #7 - Investigate and remediate systemic problems

COMMENTS

No specific comments

Continued Discussion

- Additional thoughts about how your organization plans to approach compliance with the information blocking rule
- Are there specific things about the information blocking rule that will make it more difficult to incorporate into your existing compliance programs?
- Other thoughts?