Information Blocking Workgroup Phase 2: Final Report

Guidance to the Community and Implementation Feedback to HHS

Interoperability Matters

1/23/2020

the sequoia project

Interoperability Matters Guiding Principles

- Reflects public good purpose
- Prioritizes and addresses what will be most impactful to end users
- Leverages important work in government and private sector
- Creates scalable, repeatable processes to address barriers so that interoperability can be fully realized

Interoperability Matters Process

Sequoia Board

- Approves priorities, charters, resources
- Assures alignment with Sequoia mission
- Approves official Sequoia policy positions

Leadership Council

- Facilitates Cooperative
- Recommends priorities to Board
- Charters Workgroups, with Board approval
- Oversees Workgroup process
- Assures Advisory Forum input
- Presents findings, recommendations to Board

Work Group

- Conducts detailed work
- Drafts findings, recommendations
- Enlists input from Public Advisory Forum
- Presents its work to Leadership Council for acceptance

Public Advisory Forum

- Convenes public and private stakeholders
- Advises Leadership Council and Workgroups
- Reflects diverse perspectives
- Is informed of progress
- Support Affinity Groups if consensus or input sought from particular perspective

Interoperability Matters Leadership Council (1)

Organization	Council Member	Alternate
The Badger Group	**Michael Matthews – Co-chair**	
American Medical Association	**Michael Hodgkins – Co-chair**	**Matt Reid**
athenahealth	Kedar Ganta	Greg Carey
Azuba	Bart Carlson	
Bay Health Medical Center	Sue Saxton	Robin Yarnell
Blue Cross Blue Shield Association	Rich Cullen	Matthew Schuller
Cedarbridge Group	Carol Robinson	
Cerner	Hans Buitendijk	
Collective Medical	Vatsala Pathy	Kat McDavitt
CommonSpirit	Sean Turner	Ryan Stewart
Community Care Network of Virginia, Inc	Rene Cabral-Daniels	
CRISP	David Horrocks	Ryan Bramble
Delaware Health Information Network (DHIN)	Jan Lee	Randy Farmer
eClinicalWorks	Navi Gadhiok	Tushar Malhotra
eHealth Exchange	Jay Nakashima	Katie Vizenor
EHNAC	Lee Barrett	Debra Hopkinson
Ellkay LLC	Gupreet (GP) Singh	Ajay Kapare
Epic	Rob Klootwyk	Matt Becker
First Genesis	Joe Chirco	Tom Deloney
Greenway Health	Danny Shipman	

Interoperability Matters Leadership Council (2)

Organization	Council Member	Alternate
HealthCatalyst (formerly Medicity)	Ryan Barry	Jay Starr
Highmark Health	Mitch Kwiatkowski	
HIMSS	Mari Greenberger	Amit Trivedi
HITRUST Alliance	Michael Parisi	Anne Kimbol
ID.me	Blake Hall	Nora Khalili
IHIE	John Kansky	
Intermountain Healthcare	Stan Huff	Sid Thornton
Jackson Community Medical Record	Julie Lowry	
Kaiser Permanente	Jamie Ferguson	Keven Isbell
Kno2	Alan Swenson	Therasa Bell
lifeIMAGE	Matthew Michela	Karan Mansukhani
MedAllies	Holly Miller	John Blair
MedVirigina / Clareto	Steven Leighty	Stephen Hrinda
MiHIN	Drew Murray	Shreya Patel
MRO	David Borden	Rita Bowen
NeHII	Stefanie Fink	
NetSmart	AJ Peterson	
NextGate Solutions	Vince Vitali	

Interoperability Matters Leadership Council (3)

Organization	Council Member	Alternate
NextGen	Dan Werlin	Muhammed Chebli
NYeC	Valerie Grey	Alison Birzon
OCHIN	Jennifer Stoll	Paul Matthews
OneRecord	Jennifer Blumenthal	
Optum	Brian Lumadue	
Orion Health	Kave Henney	
Samsung Electronics	Ricky Choi	Kevin Shim
San Diego Health Connect	Nicholas Hess	Daniel Chavez
Social Security Administration	Stephen Bounds	Jude Soundararajan
Surescripts	Tara Dragert	Kathy Lewis
Sutter Health	Steven Lane	
Stanford Health Care	Matthew Eisenberg	
Updox	Michael Witting	
WOMBA	Moti Mitteldorf	Eli Rowe
Zoll	Greg Mears	

Prioritizing Issues With The Biggest Potential Benefit

Current Work

- Patient Matching
- Information Blocking

Future Work

- Data Quality
- The next major challenge

Information Blocking Workgroup

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

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

Information Blocking Workgroup—Phase 1

- Information Blocking Workgroup findings and recommendations on the March 2019 ONC 21st Century Cures Proposed Rule
  - Accepted by the Sequoia Board
  - Included with public comment letters from The Sequoia Project

Information Blocking Workgroup—Phase 2

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

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

Information Blocking: Looking Ahead

- Most provisions proposed to be effective 60 days after final rule
- Others: proposed to be effective 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
- The Community will need implementation guidance to meet legislative and regulatory intent and reduce compliance uncertainty and costs

Phase 2 Topics: Summary of Discussion and Observations

Phase 2 Report Overview

- The main body of this report summarizes discussion points and observations from Workgroup members
- Background detail on each topic is in Appendix 2

HIE/HIN and Other Key Definitions

Implementation & Compliance Implications/Needs

HIEs/HIN Definitions: HITAC Proposed Revisions

- Definitions too confusing, even for expert likely more confusing in actual practice
- Proposed revisions positive, but still concerns, especially with broad EHI definition
- HITAC proposed revised HIE definition clearer, category overlap removed
  - Unusual to be an HIE if not an HIN.
- Revised HIN definition improved but still too broad, continued use of "or" between criteria underscores broad definition
- Guidance essential for final definitions., including likely scenarios
- Essential to understand how definitions are used by enforcement agencies, such as OIG, ONC, and CMS and whether they have consistent interpretations
- Definitions will be used in other regulations and policies, like TEFCA
- Some broad scope may not matter (e.g., an EHR Developer that is a HIN would have no additional enforcement exposure)
- But, a health plan, not an "actor," could be an HIE or HIN and subject to regulations.
- Will take years for implications of definitions and other elements of enforcement to become clear, through cases and enforcement decisions
  - 25+ years for clarity around fraud and abuse/Stark/Anti-Kickback Statute/ Federal False Claims Act enforcement
- Risk of paralysis in organizational decision-making from policy ambiguity; clarity in definitions essential
- Common theme: definition breadth and overlap has real and practical implications.
- The Workgroup can provide tools and perspectives to help organizations deal with ambiguity

Implementation & Compliance Implications/Needs

HIEs/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**

Implementation & Compliance Implications/Needs

HIEs/HIN Definitions

Exceptions

- Unclear which likely most relevant to broad HIE/HIN definitions
- Exceptions proposed by ONC because they promote a public interest/ greater good, not to reduce actor burden and not as safe harbors
- March 2019 CMS interoperability proposed rule has detailed contractual requirements for health plans for interoperability but no exceptions, which plans may need

Provisions likely to be especially challenging or with unique in application to broadly defined HINs or HIEs

- Limits on non-standard technology
- Pricing requirements/exceptions
- Contracting rules (e.g., RAND terms)
- Documentation requirements – many organizations that may be included as HIEs and HINs are less experienced with compliance-related documentation requirements
- "Individuals" defined as HIEs or HINs

Implementation and Compliance Implications/Needs

Interoperability Elements and HIEs/HINs: Organizational Priorities

- Actors and *potential Actors* should think about all issues associated with information blocking compliance
- Plan for the worst case
- Challenging to ensure that smaller clinician practices obtain needed compliance expertise and resources
  - Some clinician practices may be HIE/HIN
- Implementing certain exceptions will require organizational policies and procedures *and* need to integrate these into workflows
  - e.g., "minimum necessary" sub-exception requirements exceed what HIPAA requires
- Think about information blocking implications and obligations for parties with which you do business; threats and opportunities
- Physicians, other clinicians, and provider organizations will continue to view themselves as stewards of patient information and have concerns about vetting apps and API access, despite OIG guidance on HIPAA right of access
- Some organizations may face high volume of requests for information and will have challenges in handling volume
- Ambiguity in definitions and policies will make planning for compliance harder (e.g., actors, EHI vs. PHI, etc.)
- Audits may later show what you thought was best and sufficient effort not good enough, leading to unexpected liability

Information Blocking Practices

Implementation and Compliance Implications and Needs

Are the ONC examples unambiguous and sufficiently specific?

- Examples generally reasonable given underlying statutory and regulatory definitions of information blocking, recognizing areas of ambiguity
- In many ways, examples appear to be catalog of complaints to ONC from stakeholders and can be understood as high priority concerns that will/should motivate enforcement and compliance; there are, however, specific issues per the below points:
  - Recognize/clarify that definition of *Electronic Health Information* (EHI), central to these practices, is not limited to information used for treatment
  - "Promptness" (e.g., for security vetting) is subjective and subject to fact situations
    - General concern if term in a practice example, like "promptness", does not have a corresponding reference in an exception
  - Another issue relates to the ONC practice example for information release, when a provider has capability to do same-day release but takes several days:
    - Such a delay could be reasonable, for example if provider must deal with flawed authorization form, missing key elements in release or a bad signature; and
    - Technical and even process capability may not offset situational specifics

Implementation and Compliance Implications and Needs:

Do you disagree with any of ONCs identified practices?

- Need clarification on whether state or local government would be *Actors (e.g.,* an HIE or HIN), and subject to enforcement
  - If so, several practices would be problematic for government public health agencies
- References to "optional" vs. "required" aspects of standards examples do not align well with how optionality viewed in implementation guides or world of implementers; for example, "optional" generally viewed as optional.
  - Implementation guides usually specific to use case(s)
  - What if optional extension not used exactly as described in the standard or the required part of the standard is not used exactly as prescribed
  - General point: examples and enforcement need more nuanced view of how standards are implemented
- With respect to "[h]ealth system policy requiring consent to exchange EHI for treatment even though not required by law," workgroup members emphasized that multiple federal and state laws at play and important for OIG and ONC to coordinate with SAMSHA (42 CFR Part 2) and state agencies to reduce confusion on how to interpret and harmonize non-HIPAA privacy regulations, which could affect information blocking
  - Is failure of EHR to segregate Part 2 data, which could hinder interoperability (e.g., all data for a patient excluded from exchange), information blocking?
  - Decision on whether to segment at record or data element level could affect ability to exchange data

Implementation and Compliance Implications and Needs:

Do you disagree with any of ONCs identified practices?

- In addition, a vendor may build a capability that a client (e.g., provider or HIE/HIN) chooses to not acquire or implement (e.g., data segmentation)
  - Is provider decision not to acquire or use a capability information blocking, especially when there are cost and ROI considerations for deploying specific capabilities (e.g., the cost to a provider to implement data tagging and segmentation)?
- What is a vendor's obligation to develop and offer capabilities that could enhance interoperability, especially support for certain regulatory requirements?
- Important to recognize that a provider's conservative approach to HIPAA compliance may be well within accepted legal and compliance approaches, especially given concerns with OCR enforcement of HIPAA requirements
  - How will OCR compliance concerns be balanced with OIG/ONC compliance concerns?
- Cures and information blocking regulations may eliminate flexibility in implementation of HIPAA and 42 CFR Part 2 and other privacy and security regulations, some of which have conflicting imperatives (e.g., protect information vs. release information)

Implementation and Compliance Implications and Needs:

Are there examples where "likely" standard especially problematic?

- Concern when "likely" standard in ONC information blocking definition is paired with "knowledge" standards, which are applied differently by type of actor
  - Challenging for HIE (as intermediary) to know which "likely" interpretation to follow; their own or members', which may have different preferences and policies
- HIPAA sometimes authorizes release of information outside of Treatment, Payment or Operations, such as for research via an Institutional Review Board (IRB)
  - Can an outside organization cite its *own IRB* as a rationale to demand exchange?
- "Likely" already coming into play
  - Some companies are demanding immediate information release based on what responding provider views as deficient authorization forms
  - At what point does vetting equal information blocking, especially given "likely" standard?
  - From the Release of Information Vendor perspective, there are times when bad actors submit authorizations for release

Implementation and Compliance Implications and Needs:

Are needed examples missing?

- Vendors charging providers for development or implementation of data segmentation capabilities or other regulatory support
- More definition needed re: “reasonable” costs/fees
- Need examples of "without special effort" and for actor use of third-party developers that may have "all or nothing” consent policies
- Need examples that address *writing* to an EHR as “use” of EHI
  - Writing is much more complex than read access, from a technical, operational and health information management (HIM) perspective
  - Latter issue goes to important role of the HIM function in validating information entered into medical record (e.g., via app or HIE)
- Is an unreadable C-CDA information blocking and what makes a C-CDA unreadable, the vendor implementation or the sending organization’s documentation practices?
- General recognition/concern that information blocking will be “weaponized” via private party negotiations, creating de facto, but private sector, enforcement
- With these and similar examples, ONC and OIG would have extensive discretion on which practices to deem information blocking and select for enforcement

Recovering Costs/RAND Licensing

Implementation and Compliance Implications and Needs

Likely additional documentation burdens for cost-based pricing

- This approach to pricing would be a major departure from current practice
- General concern: could be a burden and have a chilling effect on development, especially for developers and HIEs
  - But likely not for providers or others do not charge for information release
- Level of burden driven in part by extent of "interoperability elements" that are ultimately found subject to information blocking in ONC final rule and needing exception (e.g., API used for data access vs. entire EHR)
- Uncertainty on accounting granularity needed: more granular = greater burden
- Pricing and accounting are under review by organizations given proposed rule
- Required detailed cost accounting could reduce services from developers, etc.
- Uncertainty/concern whether and at what level costs would need to be disclosed to/auditable by regulators and especially data requesters
- "Reasonableness" will depend on facts and circumstances per ONC—who needs to be convinced pricing is reasonable and what documentation needed?

Implementation and Compliance Implications and Needs

Likely additional documentation burdens for cost-based pricing

- May need detailed information on customers and their competitors to ground cost/price documentation in factors like "similarly situated," (e.g., bed size data)
- Will be very challenging to be consistent across all "similarly situated" clients given variability of circumstances, especially for development and implementation costs
- Cost data are proprietary and unclear how this exception addresses that issue
- Potential anti-trust issues for cost disclosure to competitors (e.g., issue of input price disclosure – see https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/dealings-competitors/price-fixing)
- How often will pricing need to be revised as costs are recovered over time?
- How long should cost recovery take, especially as customers leave and arrive and products/services are updated – issue of dynamic vs. static cost structure?
- Need to address cost recovery for non-standard development and implementation, which will be unavoidable in many cases (and need clarity on what costs for "non-standard" implementations are defined/recoverable)
- *To avoid unintended consequences, ONC should consider a higher-level approach focusing on non-discriminatory, transparent and consistent pricing (allowing "apples to apples" comparisons), without need for detailed cost accounting. Cures would permit such an approach as HHS has wide discretion on exceptions (recognizing pricing concerns were major driver for underlying Cures provisions)*

Implementation and Compliance Implications and Needs:

Terms likely to be most problematic (e.g. "reasonable")

- Need very clear definition of terms, especially "reasonable" costs
- Ambiguity around key terms, and broader pricing-related exception issues, could have a chilling effect to business entry and conduct
- *A higher-level focus on pricing transparency can offset need for terms needed for detailed cost accounting approach*

Implementation and Compliance Implications and Needs:

Issues with cost allocation across customers

- Cost allocation across customers will very challenging and need to account for allocation and reflect in prices could radically alter business practices
- Will be impossible for developers to know which customers will want technology under development when pricing is determined as part of go-to-market plans
- Should costs only be allocated over actual customers or over the potential, applicable customer base?
- If development for one client, but potentially applicable for others, need way to price that does not penalize this one client or lead to unsustainable pricing given market dynamics (are cross-subsides prohibited?)
- *Again, a higher-level focus on non-discrimination could obviate the need for detailed cost allocation*

Implementation and Compliance Implications and Needs:

Pricing based on customer size as preferred approach

- Non-profit pricing is partially grounded in expected costs but also reflects need to be able to invest in future projects
- Pricing based on customer/member size (e.g., revenue, employees, number of beds, etc.) common for non-profits (e.g., industry collaboratives and HIEs)
- Customer size can be a reasonable proxy for level of support effort an organization will require
- Pricing by customer size can reflect concern with fairness/ability to pay
- Non-profits would need to invest in more detailed cost and market analyses to rigorously assess role of size as cost proxy and fairness issues

Implementation and Compliance Implications and Needs:

Familiarity with RAND licensing

- There is very low familiarity with RAND licensing among workgroup members and this lack of familiarity is likely widespread across the community of Actors
- While often used by Standards Development Organizations (SDOs) that incorporate third party intellectual property into the standard, it is not clear that RAND is a good fit for terms of licenses to software that developers are selling to customers in a commercial marketplace

Implementation and Compliance Implications and Needs:

Software typically sold via a license that could be subject to RAND

- Much health IT software is sold via a new or existing license
- Compliance will likely increase costs of doing business
- Regulators and actors will need clarity on when cost vs. RAND exception apply and whether any opportunity for strategic choice to rely on one or the other
- It is unclear if the focus of this exception is specific IP (e.g., a code set, patent, or proprietary API) or broader access to all IP associated with interoperability elements in any way
- There is a great need for clarity on scope of the interoperability elements (e.g., API or interface vs entire EHR) to which exception relevant
- The need to respond to licensing requests in 10 business days will be a challenge (similar to need for timely response for “infeasible requests” exception)
- Organizations that primarily license IP could face major business model challenges, with the need for non-discrimination conflicting with complex licensing scenarios
- Patent infringement is subject to treble damages, reinforcing IP licensing complexity

Implementation and Compliance Implications and Needs:

How long will it take to review/revise pricing and licensing?

- For both pricing and contracting, the key issue is when liability for information blocking in context of finalized exceptions begins – the effective date of final rule or will there be a grace period or "learning year"?
- Time needed for review will depend on scope of interoperability elements subject to exceptions – three (3) months is best case even if very narrowly defined but more likely will be a year or more for contract and price review and revision
- If must revisit all agreements and pricing, will be very complex and time consuming – there will be an initial period and additional ongoing review for new ***and*** existing contracts and prices
- For contracting and infeasible exceptions, will need processes to review "timely" or within 10 business days as applicable
- External requests for EHI/interoperability element may come from many sources not specified in the Final Rule and in unanticipated forms and channels
- More generally, will need to establish and document processes for timely handling

Implementation Planning for the Information Blocking Rule

Implementation Planning

- Organizations that are “Actors” or that will interact with “Actors” will want to have a formal plan to implement their operational and business response to the ONC information blocking Final Rule
- The Workgroup had an initial discussion of this topic at the end of its Phase 2 work and will continue with a deeper dive in early 2020, considering the ONC Final Rule
- The next two slides are a high-level overview of the organizational steps to be considered in developing an information blocking implementation plan

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 an 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 teams
- ❑ 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**

Developing a Compliance Framework for the Information Blocking Rule

Information Blocking Compliance

- Actors will need to prepare for enforcement of the Information Blocking Final Rule by ONC and the HHS OIG
- Assuring compliance with the Information Blocking Final Rule is a key part of this Workgroup effort
- Compliance programs emerged in healthcare in the 1990s in response to various federal government investigations
- Health care providers, payors, HINs and software developers approach compliance differently
- Compliance is often "siloed" in different parts of an organization.
  - e.g., 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
- A useful starting point for compliance planning is the HHS OIG Compliance Program Framework

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

- There is uncertainty about what is required by this element.
- There are concerns about burdens 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 organization's "owner" of Information Blocking?
- Do current compliance officers have expertise for this topic?

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 stand-up compliance efforts before enforcement begins.
- 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

- Actors will need an internal "alert strategy" when information blocking concerns arise internally or through interactions with external entities (e.g., customers, business partners, entities seeking data access, exchange, or use).

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 Final Rule favor larger Actors and disadvantage smaller Actors?

Information Blocking Compliance Framework

Element #6 - Monitoring the compliance program for effectiveness

COMMENTS

- It will be essential to monitor the compliance program for effectiveness and needed enhancements.

Information Blocking Compliance Framework

Element #7 - Investigate and remediate systemic problems

COMMENTS

- It will be essential to have processes in place to identify, investigate, and correct organizational issues with information blocking.

Additional Discussion

- It will take several years and case experience to give many healthcare organizations and actors confidence with compliance with information blocking exceptions.
- Nonetheless, enforcement agencies will seek to communicate their expectations regarding information compliance to allow near-term enforcement.
- It will be a major challenge to shift organizational cultures for HIPAA-related data stewardship to reflect the imperatives to prevent information blocking.
- The current variability in understanding of HIPAA will reinforce this challenge and is also likely to occur regarding information blocking.
- It will be essential for organizations to have an effective response to complaints that are received.
- Existing government and private sector organizations already have some of these challenges and experiences regarding data requests and we can learn from them.
- The need to monitor compliance plan effectiveness can be met, in part, by looking to existing compliance audits and experience with Corporate Integrity Agreements.
- It will be important to address any individual staff member-level liability for information blocking, especially as some definitions of Actors reference “individual or entity”.

Next Steps

Next Steps

- Finalize Phase 2 Power Point Deliverable by January 2020
  - Share with Interoperability Matters Leadership Council, Workgroup, and Sequoia Project Board
  - Share with HHS
  - Share with Public Forum participants and the broader stakeholder community
- Phase 3: Review the Final Rule and identify and address priority implementation topics and approaches in 2020

Interoperability Matters

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

Appendix 1: Information Blocking Proposed Rule (March 2019) Comments to ONC

Common ONC Proposed Rule 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

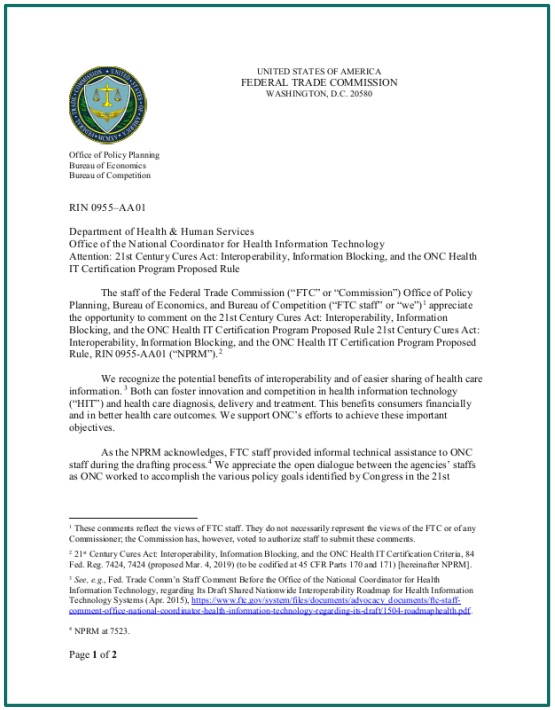
Common ONC Proposed Rule Public Comment Themes

- Proposed Exceptions
  - Categories right, requirements too detailed and rigid
  - Some see exceptions as loopholes, some as too restrictive
  - New “TEFCA exception” favored
- 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 Proposed Rule Comment Recommendations

- ONC should revise NPRM and seek second round of comments
- ONC should delay the effective date to enable Actors time to modify practices
  - Suggested timelines vary from 12 to 36 months after publication in the Federal Register
- ONC should make clear what practices are unacceptable
- ONC should make enforcement mechanism(s) clear
- ONC should develop a process for ongoing clarification of information blocking regulations

FTC



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

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/files/documents/advocacy_documents/ftc-staff-comment-office-national-coordinator-health-information-technology-regarding-its-draft/1504-roadmaphealth.pdf.

[4] NPRM at 7523.

Page **1** of **2**

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]

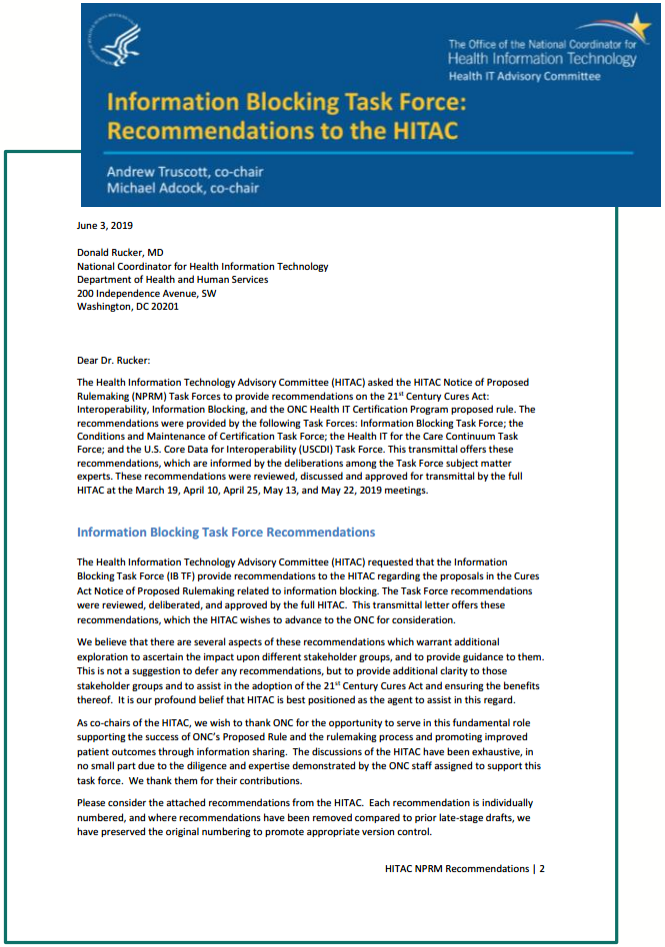
1. We acknowledge the considerable work the Department and ONC have done to identify and clarify exceptions to the information blocking prohibition; however, consider whether additional and more fully developed examples of permissible conduct, as observed in HIT and EHI use and development, could clarify 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



The Office of the National Coordinator for Health Information Technology
Health IT Advisory Committee

Information Blocking Task Force: Recommendations to the HITAC

Andrew Truscott, co-chair
Michael Adcock, co-chair

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.

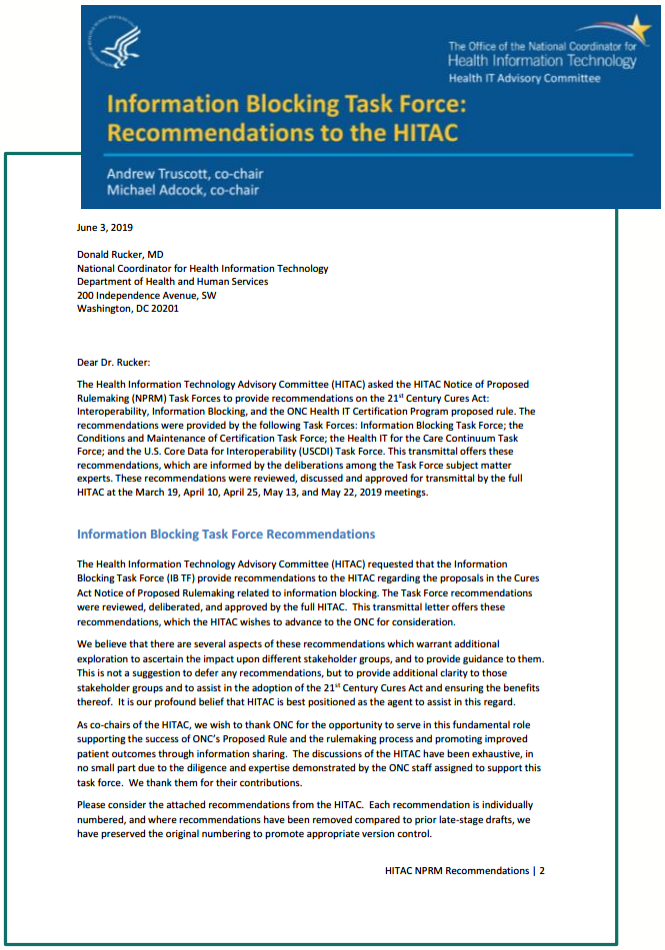
As co-chairs of the HITAC, we wish to thank ONC for the opportunity to serve in this fundamental role supporting the success of ONC's Proposed Rule and the rulemaking process and promoting improved patient outcomes through information sharing. The discussions of the HITAC have been exhaustive, in no 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



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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 . . .

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 applicable 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 A~~~~n~~~~y 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 ~~h~~ Health ~~i~~ 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 & Other Definitions: Workgroup Phase 1 Comments

- 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 polices 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 Phase 1 Comments

- 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 Phase 1 Comments

- 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 Phase 1 Comments

- 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 Phase 1 Comments

- 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 Phase 1 Comments

- 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 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 Phase 1 Comments

- 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 Phase 1 Comments

- 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 DOJ/OIG “national enforcement actions” in 1980s/90s
- 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, FDA regulations 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 decentralized organizational approach might complicate Information Blocking compliance since it cuts across so many disciplines
- HIEs, interoperability vendors, software developers, and others that are subject to the final Information Blocking Rule but have not developed compliance programs could face 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 written standards of conduct and do these individuals understand the Information Blocking Rule?
- Who will approve standards of conduct?
- Who is responsible for keeping 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
- There should be 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 element since Information Blocking might be driven by policy rather than any single individual's wrongdoing?
- For smaller companies, staff 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

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, questions may be raised about your compliance program