



# Information Blocking Workgroup Meeting #9

## Interoperability Matters

*11/8/2019*

# 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

# Agenda

- Welcome and Introductions
- Review of Agenda
- Recap: Recovering Costs/RAND Licensing
- Role of Compliance Plans in healthcare organizations
- Discuss possible compliance framework for Information Blocking
- Preview of 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: Agenda—Phase 2

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

- ✓ Meeting 1 (6/20) Review comments submitted and proposed workplan
- ❖ No July Call
- ✓ 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 (or review Final Rule Out)**
- Deliverable: Summary of Meetings 2-5: Guidance to the Community and Implementation Feedback to ONC
- Meeting 6 (12/13) Review Final Rule or TBD

# October Topic Recap: 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?

# Implementation and Compliance Implications and Needs

## *Likely additional documentation burdens for cost-based pricing*

- This approach to pricing would be 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” subject 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)
- Uncertain on accounting granularity needed: more granular = greater burden
- Pricing and accounting 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
- 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 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
- 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
- Impossible for developers to know which customers will want technology under development when pricing determined as part of go-to-market plan
- 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 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 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*

- Very low familiarity with RAND licensing among workgroup members and this lack of familiarity likely widespread across community of actors
- While often used by Standards Development Organizations which incorporate the intellectual property of third parties 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 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
- Unclear if intent 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
- Great need for clarity on scope of the interoperability elements (e.g., API or interface vs entire EHR) to which exception relevant
- Need to respond to licensing requests in 10 business days will be challenge (similar to need for timely response for “infeasible requests” exception)
- Organizations that primarily license IP could face major business model challenges, with need for non-discrimination conflicting with complex licensing scenarios
- Patent infringement subject to treble damages, reinforcing complexity of IP licensing



# Implementation and Compliance Implications and Needs:

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

- For both pricing and contracting, key issue is when liability for information blocking in context of finalized exceptions begins – 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, need processes to review “timely” or within 10 business days as applicable
- Requests for EHI/interoperability element may come from many “actors” not specified in the final rule and in unanticipated forms and channels
- More generally, need to establish and document processes for timely handling



# 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 ?

## Next Steps

- December call will continue discussion regarding compliance plan framework and review of Phase 2 work to date

# Closing Discussion



## Registration Now Open!

The Sequoia Project's Annual Member Meeting will feature discussions of ONC's Trusted Exchange Framework and Common Agreement, health IT disaster response planning, innovations in patient identity management, clinical content quality and accuracy, and more. The meeting will provide an opportunity to connect with senior leadership, members, and government officials while addressing key health information sharing issues.

# Interoperability Matters

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

## Appendix 2: Project Background


# Information Blocking Comments to ONC

# Status Update

- Sequoia comment letters submitted
  - 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

HomeHelpResourcesContact 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 (ACOFPP)." 

[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 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 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 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



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")<sup>1</sup> 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").<sup>2</sup>

We recognize the potential benefits of interoperability and of easier sharing of health care information.<sup>3</sup> 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.<sup>4</sup> We appreciate the open dialogue between the agencies' staffs as ONC worked to accomplish the various policy goals identified by Congress in the 21st

<sup>1</sup> 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.

<sup>2</sup> 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].

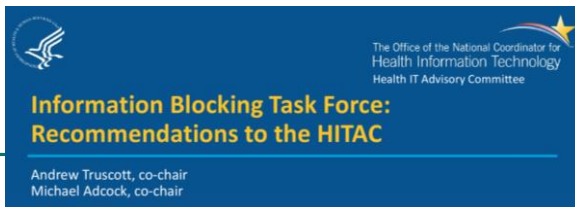
<sup>3</sup> See, e.g., Fed. Trade Comm'n Staff Comment Before the Office of the National Coordinator for Health Information Technology, regarding its Draft Shared Nationwide Interoperability Roadmap for Health Information Technology Systems (Apr. 2015), [https://www.ftc.gov/system/files/documents/advocacy\\_documents/ftc-staff-comment-on-the-national-coordinato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

<sup>4</sup> 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."<sup>6</sup>

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,"<sup>7</sup> "responding to requests that are infeasible,"<sup>8</sup> and the "licensing of interoperability elements on fair and reasonable terms"<sup>9</sup> 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."<sup>10</sup>

# 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 21<sup>st</sup> 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 21<sup>st</sup> 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.

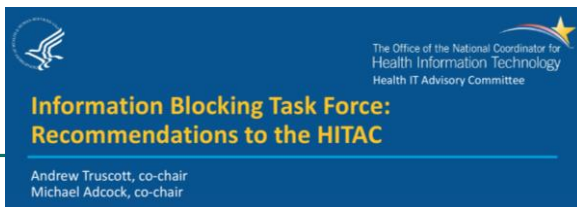
As co-chairs of the HITAC, we wish to thank ONC for the opportunity to serve in this fundamental role supporting the success of ONC's Proposed Rule and the rulemaking process and promoting improved patient outcomes through information sharing. The discussions of the HITAC have been exhaustive, in no 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 21<sup>st</sup> 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 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 21<sup>st</sup> 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



# August Topic: HIEs/HINs and Related Key Definitions





# Definitions Providing Context for Discussion of HIE and HIN

# 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)

- Per §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

<b>Health Care Providers</b>	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.
<b>Health IT Developers of Certified Health IT</b>	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 <del>information blocking claim</del> , health information technology (one or more) certified under the ONC Health IT Certification Program
<b>Health Information Exchanges</b>	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
<b>Health Information Networks</b>	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

# 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 Findings

- 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.



# Questions for the Workgroup

## ***HIN Definitions***

- *There is a broad consensus among commenters that the definitions of HIE/HIN is too vague and overlapping. Did the HITAC proposed revisions adequately address these concerns?*
- *What organizations could be included as HIEs or HINs that might not expect to be?*
- *Which kinds of potential HIEs and HINs should be planning for final rules that might not expect to be subject to these provisions?*
- *Which exceptions are likely to be most relevant to broad HIE and HIN definitions?*
- *Are there specific information blocking provisions or expectations that are likely to be especially challenging or unique in application to broadly defined HINs or HIEs (e.g., an SDO, a health plan, an interoperability services provider)?*

# Questions for the Workgroup

## Interoperability Elements and HIEs/HINs

- *If ONC does not narrow this definition, how should we approach this from a compliance perspective?*
- *Will every HIE/HIN and other Actor needs to review and update all of its policies and procedures that relate to “access, use or exchange” of EHI?*
- *If so, this seems like a massive level of effort. How can we safely triage this work to concentrate on the most important first?*

# 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 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.
- 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 vendors;
- **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
- Recent 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 & 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 find themselves HIE or HINs
- 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
- Important for organizations to think about information blocking implications and obligations for parties with which they 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

# September Topic: Information Blocking Practices



# 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.*



## 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: 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: 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 Findings

- 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](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 Findings

- 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.



# Questions for the Workgroup

## ***Practices***

- *Are the ONC examples unambiguous and sufficiently specific?*
- *Do you disagree with any of ONCs identified practices?*
- *Are there examples where the “likely” standard will be especially problematic?*
- *Are needed examples missing?*
- *Are examples for certain actors especially problematic?*
- *What additional types of guidance using examples or similar materials likely to be needed for compliance planning?*

# Implementation and Compliance Implications and Needs: Thoughts for Workgroup Discussion

# Appendix 1: ONC Information Blocking Practices Examples

# Practices: ONC Examples

## Restrictions on Access, Exchange, or Use

1. Formal restrictions through contract or license terms, EHI access policies, organizational policies and procedures, or other instruments or documents that relate to EHI or health IT.
2. Exercising IP rights or other rights.
3. Health system policy requiring consent to exchange EHI for treatment even though not required by law.
4. EHR developer refuses to share technical information needed to export data.
5. HIN restriction on end-user sharing EHI with non-HIN members.
6. Health system citing HIPAA as a reason that it cannot share EHI when that is not the case.
7. EHR vendor only provides EHI in PDF format upon termination of an agreement with a customer.
8. An EHR developer sues to prevent a clinical data registry from providing interfaces to physicians who use the developer's EHR technology and wish to submit EHI to the registry. The EHR developer claims that the registry is infringing the developer's copyright in its database because the interface incorporates data mapping that references the table headings and rows of the EHR database in which the EHI is stored.
9. A health IT developer of certified health IT refuses to license interoperability elements that are reasonably necessary for the developer's customers, their IT contractors, and other health IT developers to develop and deploy software that will work with the certified health IT.
10. An EHR developer ostensibly allows third-party developers to deploy apps that are interoperable with its EHR system. However, as a condition of doing so, the third-party developers must provide their source code and grant the EHR developer the right to use it for its own purposes—terms that almost no developer would willingly accept.

# Practices: ONC Examples

## Limiting or Restricting the Interoperability of Health IT

11. Disabling or restricting the use of a capability that enables users to share EHI with users of other systems or to provide access to EHI to certain types of persons or for certain purposes that are legally permissible.
12. An actor configures or otherwise implements technology in ways that limit the types of data elements that can be exported or used from the technology.
13. Configuring capabilities in a way that removes important context, structure, or meaning from the EHI, or that makes the data less accurate, complete, or usable for important purposes for which it may be needed.
14. Implementing capabilities in ways that create unnecessary delays or response times, or that otherwise limit the timeliness of EHI accessed or exchanged.
15. An actor deploys technological measures that limit or restrict the ability to reverse engineer the functional aspects of technology in order to develop means for extracting and using EHI maintained in the technology.
16. A health system implements locally-hosted EHR technology certified to proposed § 170.315(g)(10) (the health system acts as an API Data Provider as defined by § 170.102). As required by proposed § 170.404(b)(2), the technology developer provides the health system with the capability to automatically publish its production endpoints (i.e., the internet servers that an app must “call” and interact with in order to request and exchange patient data).
17. The health system chooses not to enable this capability, however, and provides the production endpoint information only to apps it specifically approves. This prevents other applications—and patients that use them—from accessing data that should be made readily accessible via standardized APIs.

# Practices: ONC Examples

## Limiting or Restricting the Interoperability of Health IT

18. A hospital directs its EHR developer to configure its technology so that users cannot easily send electronic patient referrals and associated EHI to unaffiliated providers, even when the user knows the Direct address and/or identity (i.e., National Provider Identifier) of the unaffiliated provider.
19. An EHR developer that prevents (such as by way of imposing exorbitant fees unrelated to the developer's costs, or by some technological means) a third-party clinical decision support (CDS) app from writing EHI to the records maintained by the EHR developer on behalf of a health care provider (despite the provider authorizing the third-party app developer's use of EHI) because the EHR developer: (1) offers a competing CDS software to the third-party app; and (2) includes functionality (e.g., APIs) in its health IT that would provide the third party with the technical capability to modify those records as desired by the health care provider.
20. Although an EHR developer's patient portal offers the capability for patients to directly transmit or request for direct transmission of their EHI to a third party, the developer's customers (e.g., health care providers) choose not to enable this capability.
21. A health care provider has the capability to provide same-day access to EHI in a form and format requested by a patient or a patient's health care provider but takes several days to respond.
22. 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.

## Practices: ONC Examples

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

23. An EHR developer of certified health IT requires third-party applications to be “vetted” for security before use but does not promptly conduct the vetting or conducts the vetting in a discriminatory or exclusionary manner.
24. A health IT developer of certified health IT refuses to license interoperability elements that other software applications require to efficiently access, exchange, and use EHI maintained in the developer’s technology.
25. An EHR developer of certified health IT maintains an “app store” through which other developers can have “apps” listed that run natively on the EHR developer’s platform. However, if an app “competes” with the EHR developer’s apps or apps it plans to develop, the developer requires that the app developer grant the developer the right to use the app’s source code.
26. A health care provider engages a systems integrator to develop an interface engine. However, the provider’s license agreement with its EHR developer prohibits it from disclosing technical documentation that the systems integrator needs to perform the work. The EHR developer states that it will only permit the systems integrator to access the documentation if all of its employees sign a broad non-compete agreement that would effectively bar them from working for any other health IT companies.

## Practices: ONC Examples

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

28. A hospital is working with several health IT developers to develop an application that will enable ambulatory providers who use different EHR systems to access and update patient data in the hospital's EHR system from within their ambulatory EHR workflows. The inpatient EHR developer, being a health IT developer of certified health IT, pressures the hospital to abandon this project, stating that if it does not it will no longer receive the latest updates and features for its inpatient EHR system.
29. A health IT developer of certified health IT discourages customers from procuring data integration capabilities from a third-party developer, claiming that it will be providing such capabilities free of charge in the next release of its product. In reality, the capabilities it is developing are more limited in scope and are still 12-18 months from being production-ready.
30. A health system insists that local physicians adopt its EHR platform, which provides limited connectivity with competing hospitals and facilities. The health system threatens to revoke admitting privileges for physicians that do not comply.
31. 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.



## Practices: ONC Examples

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

- 32. A health care provider imposes one set of fees and terms to establish interfaces or data sharing arrangements with several registries and exchanges, but offers another more costly or significantly onerous set of terms to establish substantially similar interfaces and arrangements with an HIE or HIN that is used primarily by health plans that purchase health care services from the provider at negotiated reduced rates.
- 33. A health IT developer of certified health IT charges customers fees, throttles speeds, or limits the number of records they can export when exchanging EHI with a regional HIE that supports exchange among users of competing health IT products but does not impose like fees or limitations when its customers exchange EHI with enterprise HIEs that primarily serve users of the developer's own technology.
- 34. As a condition of disclosing interoperability elements to third-party developers, an EHR developer requires third-party developers to enter into business associate agreements with all of the EHR developer's covered entity customers, even if the work being done is not for the benefit of the covered entities.
- 35. A health IT developer of certified health IT takes significantly longer to provide or update interfaces that facilitate the exchange of EHI with users of competing technologies or services.

# Practices: ONC Examples

## Rent-Seeking and Other Opportunistic Pricing Practices

36. Certain practices that artificially increase the cost and expense associated with accessing, exchanging, and using EHI will implicate the information blocking provision. An actor may seek to extract profits or capture revenue streams that would be unobtainable without control of a technology or other interoperability elements that are necessary to enable or facilitate access, exchange, or use of EHI.
37. 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).
38. An EHR developer of certified health IT charges a fee to perform an export using the EHI export capability proposed in § 170.315(b)(10) for the purposes of switching health IT systems or to provide patients access to EHI.
39. An EHR developer of certified health IT charges more to export or use EHI in certain situations or for certain purposes, such as when a customer is transitioning to a competing technology or attempting to export data for use with a HIE, third-party application, or other technology or service that competes with the revenue opportunities associated with the EHR developer's own suite of products and services.

# Practices: ONC Examples

## Rent-Seeking and Other Opportunistic Pricing Practices

40. An EHR developer of certified health IT interposes itself between a customer and a third-party developer, insisting that the developer pay a licensing fee, royalty, or other payment in exchange for permission to access the EHR system or related documentation, where the fee is not reasonably necessary to cover any additional costs the EHR developer incurs from the third-party developer's activities.
41. An analytics company provides services to the customers of an EHR developer of certified health IT, including de-identifying customer EHI and combining it with other data to identify areas for quality improvement. The EHR developer insists on a revenue sharing arrangement whereby it would receive a percentage of the revenue generated from these activities in return for facilitating access to its customers' EHI, which turns out to be disadvantageous to customers. The revenue the EHR developer would receive exceeds its reasonable costs of facilitating the access to EHI.

# Practices: ONC Examples

## Non-Standard Implementation Practices

- 42. An EHR developer of certified health IT implements the C-CDA for receiving transitions of care summaries but only sends transitions of care summaries in a proprietary or outmoded format.
- 43. 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.
- 44. An actor chooses not to adopt, or to materially deviate from, relevant standards, implementation specifications, and certification criteria adopted by the Secretary under section 3004 of the PHSA.
- 45. 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.
- 46. An EHR developer of certified health IT implements the C-CDA for receiving transitions of care summaries but only sends transitions of care summaries in a proprietary or outmoded format.
- 47. 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.



## Recovering Costs/RAND Licensing

# Recovering Costs Reasonably Incurred: Findings

## §171.204

- 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: Findings

## §171.204

- 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: Findings

## §171.204

- 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: Findings §171.206

- 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: Findings §171.206

- 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: Findings §171.206

- 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.

# Implementation and Compliance Implications and Needs: Thoughts for Workgroup Discussion



# Compliance Plans

# Implementation and Compliance Implications and Needs: Thoughts for Workgroup Discussion