Information Blocking Workgroup Meeting #12

Interoperability Matters

4/10/2020

Workgroup Representatives

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

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

Health Information Networks and Service Providers
- Angie Bass, Missouri Health Connect
- Dave Cassel, Carequality
- Laura Danielson, Indiana Health Information Exchange

Healthcare Providers / Physicians
- David Camitta, CommonSpirit, Co-Chair
- Eric Liederman, Kaiser Permanente

Legal, Technology, Standards, and Policy Subject Matter Experts
- Josh Mandel, Microsoft
- Micky Tripathi, MaEHC

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

Public Health
- John Loonsk, APHL

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

Consultant
- Brian Ahier, MITRE Corporation

Federal Government
- Steve Bounds, SSA

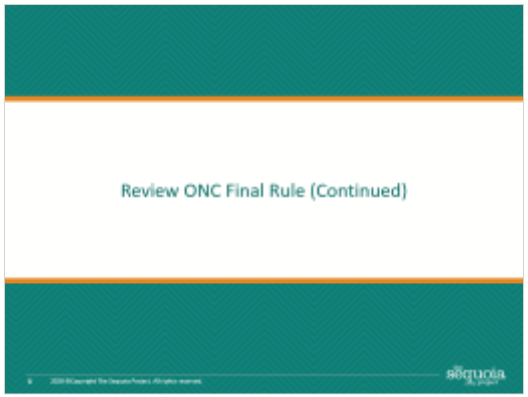
Agenda

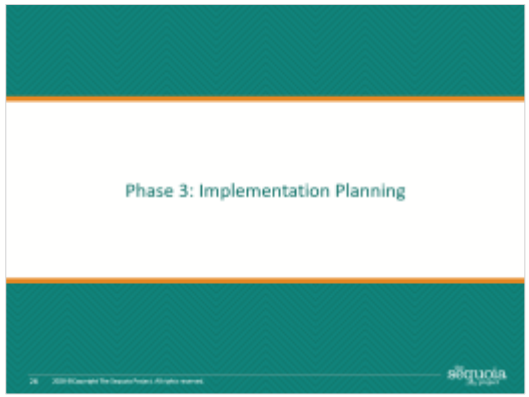
- Welcome and Introductions
- Review of Agenda
- Continue Review ONC of Final Rule
- Implementation Planning: Continue from January Call
  - Final two planning slides
- Additional Phase 3 Priorities
  - Review from March Call
  - Capture key insights, questions and guidance needs
- Next Steps
- Closing

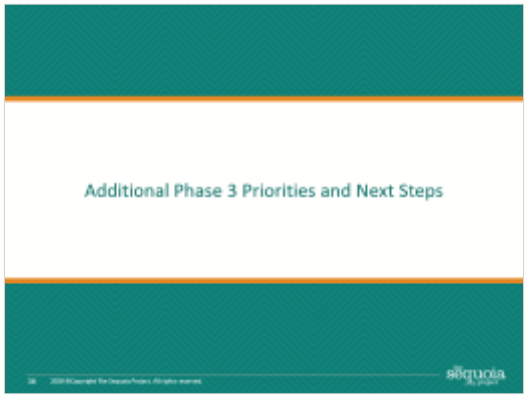
Information Blocking Workgroup: Purpose

- ✓ 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

Organization of this Deck







Review ONC Final Rule (Continued)

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

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

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

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

ONC Final Rule: Key Dates

Key Discussion Points: March 2020

Discussion from March 2020 Meeting

ONC NPRM public comment themes and responses

- ONC did not clarify/or better define “likely”.

Major Changes from NPRM

- Given federal government focus on COVID-19, we cannot expect the Final Rule will be published in the Federal Register any time soon. A delay in publication could be one way to slow down implementation.

Revised Definitions

- HIE/HIN definition: A lot rides on what is meant by “unaffiliated”; are contracted providers affiliated? Note there is some discussion of affiliated in the preamble, including examples (e.g. where a provider organization controls an HIE.).

Finalized Exceptions

- The shift to using case-by-case analysis if an exception is not met, intersects with “know or should have known” – which impacts providers, but not HIT developers.

Discussion from March 2020 Meeting

Preventing Harm Exception

- There is a lot of debate in the provider world about including imaging results and pathology results, not just lab results. Psychiatric notes are another concern. These issues need sorting out.
- Issue for future discussion: Many departments and specialties restrict access to notes created in certain circumstances (e.g., just viewable by the author or a department) Does the decision to restrict notes made at time of their creation count as having been determined on an individual basis by a licensed provider in historical context?

Infeasibility Exception

- Public health emergency: can we invoke this exception during/after the current emergency and push back the 6-month compliance deadline of the Final Rule?
- There is a low likelihood of enforcement actions given current federally declared disaster.

Discussion from March 2020 Meeting

Content and Manner Exception

- Fee requirements will need closer consideration.
- Is there a loophole where parties who use an intermediary can block information sharing? There is a hierarchy test to assess whether it matters:
  - If you are in middle of bilateral exchange as an intermediary, you are not an actor but the other parties would/could be actors
  - Does the Fee Exception apply?

Closing Discussion and Next Steps

- The group contemplated the potential impact of the COVID-19 to its work.
- Monthly calls are scheduled through May. If attention is diverted and work group participation is reduced, we can push the calls further out.

Additional Issues for Review

Requests for Information

- Additional Exceptions
  - ONC had asked whether it should propose, in future rulemaking, a narrow additional information blocking exception for practices needed to comply with TEFCA Common Agreement requirements
    - ONC did not add a new exception related to TEFCA participation in the Final Rule but noted that it received 40 comments on this RFI and may use this feedback in future rulemaking
  - ONC sought comment on potential new exceptions for future rules
    - In Final Rule, ONC addresses multiple comments for new exceptions and states finalized exceptions could address identified issues
- Disincentives for Health Care Providers
  - ONC asked if new disincentives or if modifying disincentives already available under HHS programs and regulations (e.g., provider attestations under incentive programs) would provide more effective deterrents
  - It received many comments for and against such incentives and their structure and extent—these have been shared with HHS agencies for consideration in future rulemaking

Complaint Process and Enforcement

- Cures directs ONC to implement a standard process to submit blocking claims
  - ONC has developed a dedicated complaint process based on experience with the process at https://www.healthit.gov/healthit-feedback and comments
  - ONC will implement ***and evolve*** this complaint process
- ONC's enforcement will focus on certification compliance with a *corrective action plan* approach and it has sole authority (relative to ONC-ACBs) Conditions/ Maintenance of Certification (including information blocking) via "direct review"
- HHS OIG has independent authority to investigate information blocking and false attestations by developers and other actors
- OIG can receive and review public complaints and will provide training to allow investigators to identify blocking allegations as part of fraud and abuse investigations
- OIG will establish policies and procedures to review and triage complaints
- ONC has finalized proposed approach to allow it to coordinate review of a claim of information blocking with OIG or defer to OIG to lead a claim review; finalized approach will also allow ONC to rely on OIG findings for basis of direct review action

Complaint Process and Enforcement

- ONC and OIG are actively coordinating on establishing referral policies and procedures to ensure timely and appropriate flow of information re: information blocking complaints
- They coordinated timing of final rule effective date and start of enforcement, including for Conditions of Certification related to information blocking (6 months from publication)
- CMP enforcement will not begin until set by future OIG notice and comment rulemaking (Proposed Rule published April 2020)
  - Actors are not subject to CMPs until OIG rule final
- At a minimum, enforcement would not begin sooner than the compliance date of the information blocking provision (6 months after publication) and will depend on when the CMP rules finalized
- **Conduct before that time not subject to information blocking CMPs**

Timing and Other Revisions

*During this combined period of 24 months, ONC strongly encourages actors to apply the exceptions to all EHI as if the scope were not limited to EHI identified by the **data elements [not standards]** represented in the USCDI.*

ONC expects actors to use this 18-month delay from the compliance date of the information blocking section of this final rule (45 CFR part 171) (in addition to the 6-month period from the publication date of this final rule to the information blocking compliance date) to practice applying the exceptions to real-life situations and to update their processes, technologies, and systems to adapt to the new information blocking requirements.

ONC Certification and Information Blocking

Maintenance of Certification: Information Blocking

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

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

Conditions of Certification: Information Blocking §170.401 – Finalized as Proposed

- As a *Condition of Certification (CoC)* and to maintain such certification, a health IT developer must not take any action that constitutes information blocking as defined in Cures
  - In some cases, these go beyond API certification criteria, for example, after 24 months, information blocking focuses on revised EHI definition rather than USCDI and *use* includes *write* and extends beyond the proposed new API certification criteria
  - Fee and transparency requirements are part of API CoC
- Provision subject to finalized information blocking exceptions
- No Maintenance of Certification beyond ongoing compliance
- This provision and several other new Conditions and Maintenance of Certification implemented six months after Final Rule publication

Conditions of Certification: Information Blocking: Assurances– Finalized With Revisions

- *Condition of Certification*: A health IT developer must provide assurances to the Secretary (unless for Exceptions) that it will not take any action that constitutes information blocking or any other action that may inhibit the appropriate exchange, access, and use of EHI.
  - 170.402(a)(1) [information blocking] has six-month delayed compliance date
- A health IT developer must ensure its certified health IT conforms to full scope of the applicable certification criteria
- Developers of certified health IT must provide assurances they have made certified capabilities available in ways that enable them to be implemented and used in production for intended purposes
- ONC: Information blocking policies do not require providers to implement Health IT Modules certified to API technical requirements but other programs, like CMS MIPS and PIP, may require use of this technology

API: Read and Write

Certification

- As was proposed, final certification criterion only requires mandatory support for "read" access, though ONC anticipates that a future version of this criterion that could include "write" requirements (for example, to aid decision support) once FHIR-based APIs are widely adopted.
- ONC encourages industry to advance "write" capabilities and standards

Information Blocking

- Proposed Rule stated: *". . . 'use' includes the ability to read, write, modify, manipulate, or apply EHI to accomplish a desired outcome or to achieve a desired purpose, while "access" is defined as the ability or means necessary to make EHI available for use. As such, interference with "access" would include, for example, an interference that prevented a health care provider from writing EHI to its health IT or from modifying EHI stored in health IT, whether by the provider itself or by, or via, a third-party app.*
- Final Rule eliminated specific reference to "write" in "use" definition, but states:
  - " 'acted upon' within the final definition encompasses the ability to read, write, modify, manipulate, or apply the information from the proposed definition."
  - " 'use' is bi-directional. . . Thus, an actor's practice could implicate the information blocking provision not only if the actor's practice interferes with the requestor's ability to read the EHI (one-way), but also if the actor's practice interferes with the requestor's ability to write the EHI (bi-directional) back to a health IT system."

ONC Rule: Summing Up

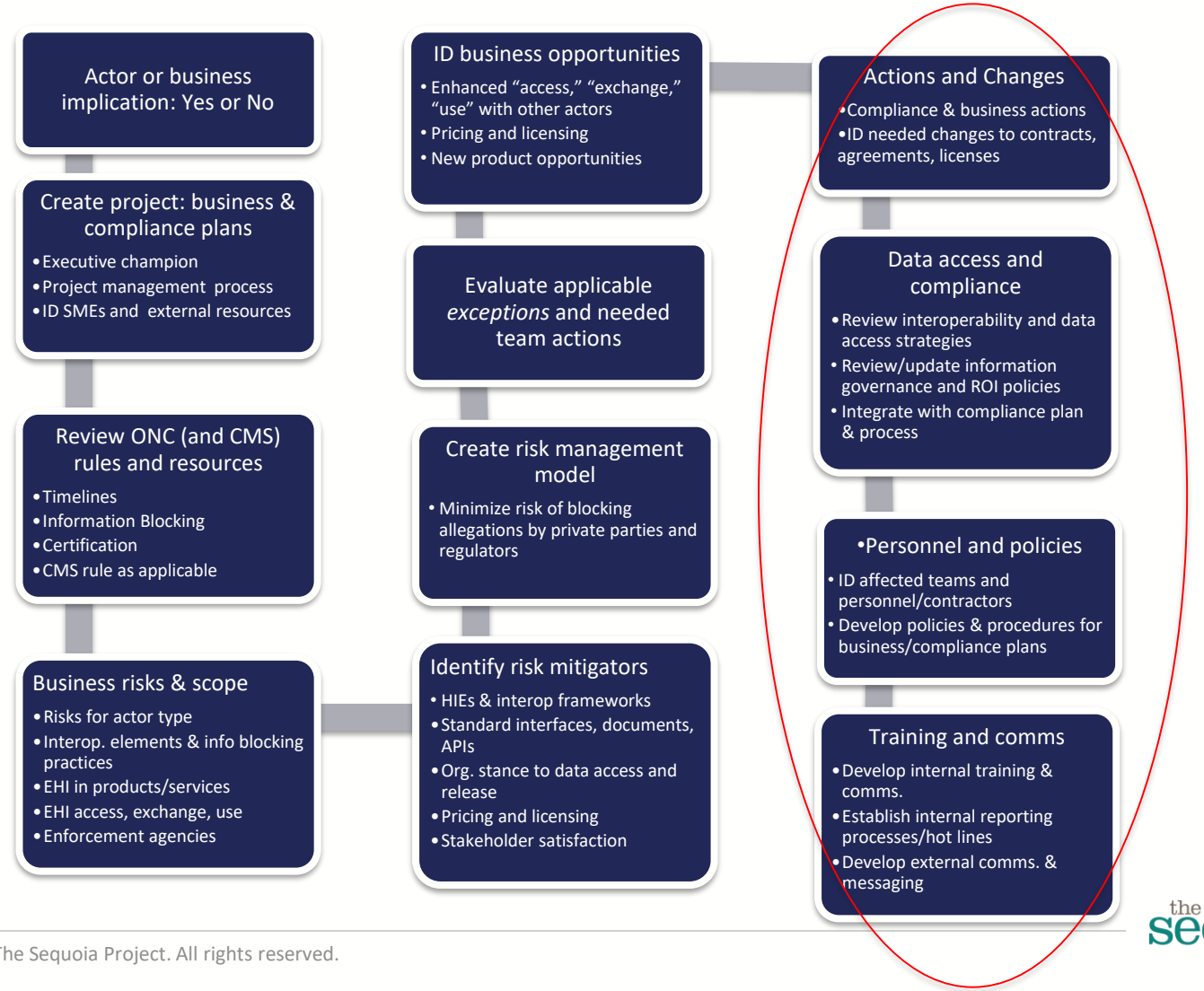
Information Blocking: Looking Ahead

- Final Rule retained key provisions but with material revisions, more flexibility and relaxed timing
- A few certification provisions effective 60 days after publication
- Information blocking compliance six months (or more) after publication, not sixty days
- Others: effective 24 months after Final Rule publication (e.g., USCDI v1, API technology criteria) or 36 months (i.e., EHI data export)

- ➢ Extended period of regulatory and compliance uncertainty
- ➢ Scarcity of qualified legal advice and lack of guidance and case law to support legal interpretations
- ➢ Community needs implementation guidance to meet legislative and regulatory intent and reduce compliance uncertainty and costs

Phase 3: Implementation Planning

Organization-Wide Information Blocking Plan: Overall Model



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

- ❑ Are you an "actor" and if so for which units of your organization?
  - ❑ If not, are you likely to have market or commercial implications from rule?
  - ❑ If "No" for either aspect of this question, STOP.
- ❑ If "Yes," create an organizational "information blocking" project or initiative
  - ❑ Business plans (e.g., product, engineering, marketing, commercial, legal, HR/training, communications, etc.)
  - ❑ Compliance plan (complement and integrate with business plans): primarily if "actor"
- ❑ Designate an overall senior executive project owner/champion
  - ❑ Designate business unit project owners as needed
- ❑ Establish a project management process (e.g., PMO)
  - ❑ Create projects as needed
- ❑ Identify/designate/train internal SMEs and project "champions" and influencers
  - ❑ Identify and mitigate staff misalignments between HIPAA focus on information protection and Cures focus on information sharing – may require cultural/professional reorientation
  - ❑ Create change management process for shift from HIPAA focus to HIPAA/Cures balance
- ❑ Identify external resources (legal, compliance, policy, training, etc.)
- ❑ Identify and engage with external industry resources (e.g., associations, interoperability initiatives, experts, colleagues, etc.)

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

- ❑ Review ONC proposed and rule
- ❑ Review ONC (and CMS) final rule, ONC website, industry resources
  - ❑ Compliance timelines
  - ❑ Information blocking provisions
  - ❑ As applicable, ONC certification provisions (developers and actors that expect to interact with ONC certified interoperability capabilities)
  - ❑ As applicable, CMS final rule (especially payors and health plans)
- ❑ Review OIG guidance and other material
- ❑ Review 2019 Stark/AKS proposed rules re: information blocking provisions
- ❑ Reconcile (sometimes conflicting) regulatory standards for data release: HIPAA (protect data) & Cures (share data/no information blocking)
  - Don't rely on providers' EHR/HIT vendors for this process – they cannot do it alone

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

- Identify business risks and scope:
  - Note: much of this risk assessment activity is standard practice or underway: fine tune after Final Rule
  - Risks specific to type of actor (e.g., developer, provider, HIE, HIN)
    - Developers have additional certification-related requirements/risks
    - Developers, HIEs, HINs have $1 M/violation maximum fines – need guidance on specifics, such as how "violation" defined
    - Providers: attest for QPP and subject to payment adjustments, OIG, Federal False Claims Act, etc.
  - Interoperability elements covered by organization
  - Applicable information blocking practices per:
    - Definition of information blocking
    - ONC-identified practices
    - ONC practice examples
  - EHI included in organization products or services
    - Implementation of standards for EHI (e.g., C-CDA, USCDI, HL7® FHIR®, etc.)
    - Non-standard EHI and how it can be made accessible
  - Potential external access, exchange, or use of EHI
    - Current and potential external EHI requesters
    - Consider academic (e.g., approved IRB) and private researcher requests and Business Associate requests
      - Note that IRB waiver access route is permitted but not required under HIPAA, patient authorization and/or HIPAA permitted purpose still required, and deidentified data (per HIPAA) is not EHI (and therefore not subject to information blocking prohibition)
  - Identify enforcement agencies: ONC, OIG, CMS, FTC, etc.
    - Review organization experience and relationships with agencies
  - Develop tailored scenarios for data access requests, apply regulation/guidance, seek guidance

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

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

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

- ❑ Evaluate finalized applicable *exceptions* and needed actions by team: initial/ongoing
  - ❑ Preventing Harm: Legal, etc.
  - ❑ Privacy: Privacy officer, legal, etc.
  - ❑ Security: Security officer, legal, engineering, etc.
  - ❑ Infeasibility: Client services, product, engineering, etc.
    - ❑ Need process to identify and handle timely
  - ❑ Performance: CIO, engineering, legal, etc.
    - ❑ Need to review/revise SLAs
  - ❑ Content & Manner: Engineering, CFO, legal, licensing, pricing, product, marketing
  - ❑ Fees: CFO/accounting, pricing, marketing, legal, etc.
    - ❑ Evaluate costs and cost accounting and relationship to pricing
    - ❑ Specific CEHRT developer requirements re: APIs
    - ❑ Note: need more clarity/guidance on “reasonable” costs and fees
  - ❑ Licensing: legal, licensing, pricing, product, marketing
    - ❑ Identify licensed interoperability elements

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

- ❑ Identify business opportunities (even if not an "actor")
  - ❑ Enhanced "access," "exchange," "use" with other actors
    - ❑ e.g., access data from an EHR or HIE or to write to an EHR
  - ❑ Pricing and licensing opportunities
  - ❑ New product opportunities
  - ❑ Focus on identified consumer/patient needs

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

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

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

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

Additional Phase 3 Priorities and Next Steps

Additional Phase 3 Priorities: From January and March 2020 Calls

- ❑ Review the ONC Final Rule
  - ❑ Provide implementation/compliance guidance and education
- ❑ Seek sub-regulatory guidance from HHS
  - ❑ OIG/ONC guidance/clarification re: information blocking status of data requests from researchers and industry, especially IRB waiver requests and data partnership requests/business associates
- ❑ Seek questions from the public, perhaps through a dedicated email box; aggregate/submit to HHS/OIG/ONC
- ❑ Address consumer/patient need for clarity re: information blocking
- ❑ Identify/develop priority scenarios; work with agencies on clarity
- ❑ Provide implementation guidance and resource materials

Key Questions from Public Webinars and the Workgroup

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

- Do Public Health programs meet the definition of an HIE/HIN and therefore become subject to the information blocking requirements?
  - Some programs (e.g., immunization registries) collect data from multiple sources (multiple provider organizations) and share with providers. Does this qualify as facilitating exchange by more than two entities?
- How does this Rule apply to Payers (e.g., health insurance companies)?
- How do the ONC information blocking rules apply (and to be implemented by) entities that may not have a direct patient/provider relationship, such as a laboratory or consulting physician?
- Do the requirements apply to only entities with data subject to HIPAA or data outside of HIPAA (that may have been disclosed by a HIPAA-covered entity)?
- Clearinghouses exchange far more data than just claims. Does the exclusion of clearinghouses include any information exchanged by health care clearinghouses, or just claim data?

EHI and USCDI

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

Access, Exchange, Use

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

Key Questions from Webinars and the Workgroup

Is it Information Blocking?

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

Key Questions from Webinars and the Workgroup

Fee Exception

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

Implementation and Enforcement Dates

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

Key Questions from Webinars and the Workgroup

Closing Discussion and Next Steps

- Identify implementation, compliance, education needs
- Communicate to ONC and OIG as needed in 2020

Interoperability Matters

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

Appendix 1: Final Rule Materials from the March 2020 Meeting

Information Blocking Workgroup: Phase 2/3 Recap

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

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

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

21st Century Cures: Information Blocking (Section 4004)

A **practice** that:

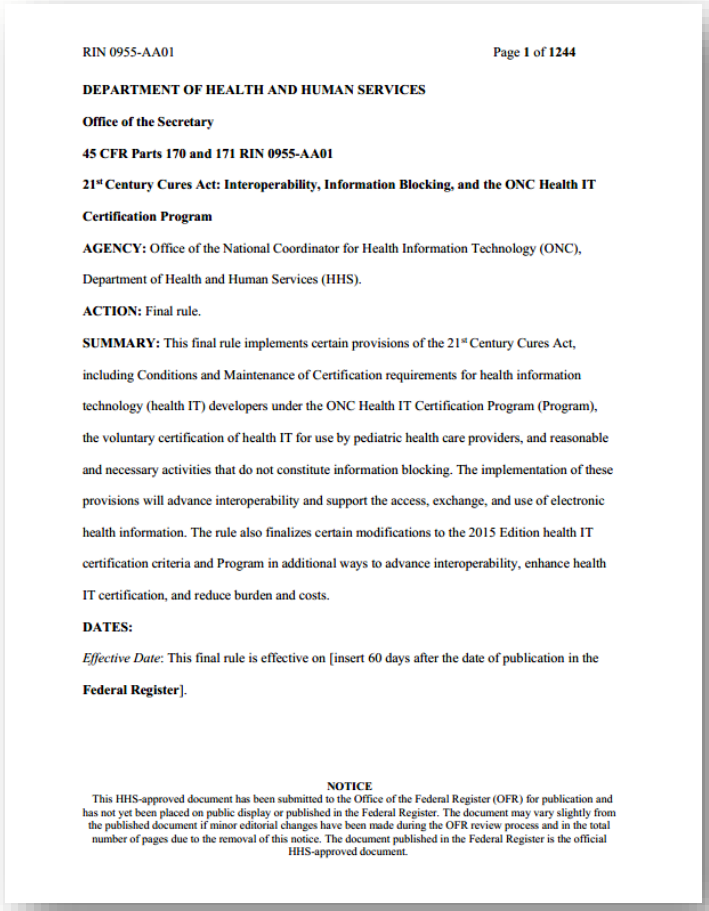
- Except as required by law or specified by the Secretary per ***rulemaking), likely*** to ***interfere with, prevent, or materially discourage access, exchange, or use*** of ***electronic health information*** (EHI); and
- If conducted by a **health IT *developer***, exchange, or network, developer,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

Information Blocking: Penalties and Enforcement

- Health Care Providers: Enforcement by CMS and the HHS OIG based on CMS incentive program attestations—*Penalties for false attestations*
- Health IT Developers, HIEs, HINs: Enforcement by ONC and/or HHS OIG—*Penalties for false attestations (certified developers) and up to $1 million civil monetary penalties (CMPs) per violation (developers, HIEs, HINs)*

In general enforcement per ONC Final Rule 6 months after Final Rule (CMPs – also after OIG proposed and final rule)

ONC Interoperability Final Rule: Information Blocking and Certification



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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 170 and 171 RIN 0955-AA01

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

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule implements certain provisions of the 21st Century Cures Act, including Conditions and Maintenance of Certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. The implementation of these provisions will advance interoperability and support the access, exchange, and use of electronic health information. The rule also finalizes certain modifications to the 2015 Edition health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.

DATES:

Effective Date: This final rule is effective on [insert 60 days after the date of publication in the **Federal Register**].

NOTICE

This HHS-approved document has been submitted to the Office of the Federal Register (OFR) for publication and has not yet been placed on public display or published in the Federal Register. The document may vary slightly from the published document if minor editorial changes have been made during the OFR review process and in the total number of pages due to the removal of this notice. The document published in the Federal Register is the official HHS-approved document.

Final Rule—and not Interim Final Rule with Comments or Supplemental Notice of Proposed Rulemaking, as some requested:

It has been three years since the Cures Act was enacted and information blocking remains a serious concern. This final rule includes provisions that will address information blocking and cannot be further delayed.

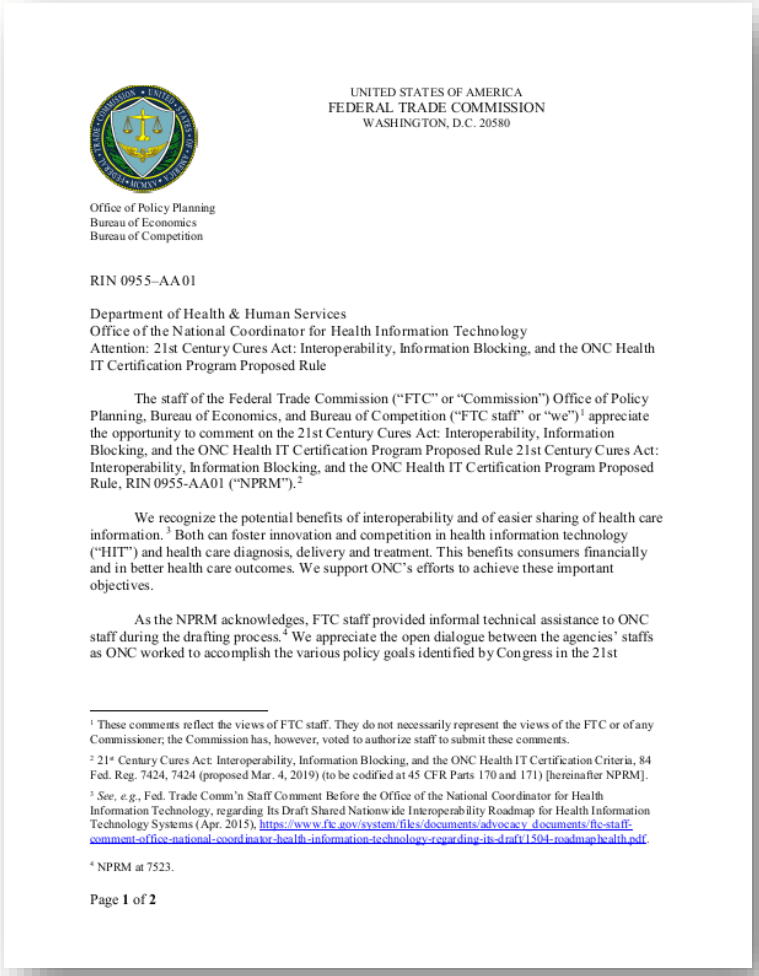
We have taken multiple actions to address some expressed concerns regarding the timing of the Conditions and Maintenance of Certification requirements as well as the comprehensiveness of the information blocking proposals.

We continue to receive complaints and reports alleging information blocking from a wide range of stakeholders.

ONC NPRM Public Comment Themes and Responses

- ✓ Significant burdens on actors
- ❖ Revise NPRM and submit for second set of comments
- ✓ Delay Effective Date to enable changes
- ✓ Clarify enforcement
- ✓ Exceptions: Categories right but some see loopholes, others as too restrictive
- ❖ Blocking defined too broadly
- ✓ HIE/HIN definitions confusing
- ✓ Narrow EHI definition; use ePHI
- ✓ Pricing/contracting too restrictive, excessive documentation, could distort markets
  - ✓ Final Rule relaxes, including in new Content & Manner Exception

FTC Comments on Proposed Rule Addressed



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.

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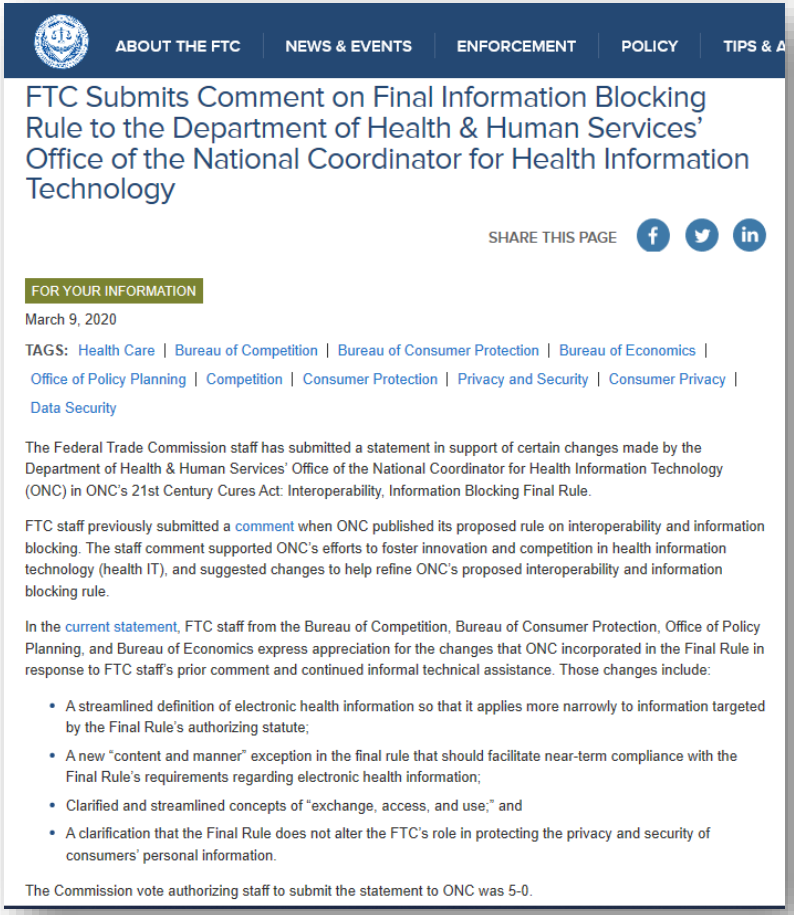

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FTC Submits Comment on Final Information Blocking Rule to the Department of Health & Human Services' Office of the National Coordinator for Health Information Technology

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FOR YOUR INFORMATION

March 9, 2020

TAGS: Health Care | Bureau of Competition | Bureau of Consumer Protection | Bureau of Economics | Office of Policy Planning | Competition | Consumer Protection | Privacy and Security | Consumer Privacy | Data Security

The Federal Trade Commission staff has submitted a statement in support of certain changes made by the Department of Health & Human Services' Office of the National Coordinator for Health Information Technology (ONC) in ONC's 21st Century Cures Act: Interoperability, Information Blocking Final Rule.

FTC staff previously submitted a comment when ONC published its proposed rule on interoperability and information blocking. The staff comment supported ONC's efforts to foster innovation and competition in health information technology (health IT), and suggested changes to help refine ONC's proposed interoperability and information blocking rule.

In the current statement, FTC staff from the Bureau of Competition, Bureau of Consumer Protection, Office of Policy Planning, and Bureau of Economics express appreciation for the changes that ONC incorporated in the Final Rule in response to FTC staff's prior comment and continued informal technical assistance. Those changes include:

- A streamlined definition of electronic health information so that it applies more narrowly to information targeted by the Final Rule's authorizing statute;
- A new "content and manner" exception in the final rule that should facilitate near-term compliance with the Final Rule's requirements regarding electronic health information;
- Clarified and streamlined concepts of "exchange, access, and use;" and
- A clarification that the Final Rule does not alter the FTC's role in protecting the privacy and security of consumers' personal information.

The Commission vote authorizing staff to submit the statement to ONC was 5-0.

Actors Defined §171.102

Health Care Providers – *Finalized as Proposed*	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 – *Finalized with minor editorial revisions and one addition*	An individual or entity, other than a health care provider that self-develops health IT for its own use, that develops or offers health information technology (as that term is defined in 42 U.S.C. 300jj(5)) and which has, at the time it engages in a practice that is the subject of an information blocking claim, one or more Health IT Modules certified under a program for the voluntary certification of health information technology that is kept or recognized by the National Coordinator pursuant to 42 U.S.C. 300jj-11(c)(5) (ONC Health IT Certification Program). *Note: This explicit addition had been implied by other provisions of the proposed rule, which indicate that provider self-developers will be treated as providers for information blocking purposes.. ONC notes that self-developers will be subject to applicable certification provisions, including those related to information blocking.*

Actors Defined §171.102

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
Health Information Network or Health Information Exchange ***Revised in Final Rule and Combined***	*Health information network or health information exchange* means an individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of electronic health information: (1) Among more than two unaffiliated individuals or entities (other than the individual or entity to which this definition might apply) that are enabled to exchange with each other; and (2) That is for a treatment, payment, or health care operations purpose, as such terms are defined in 45 CFR 164.501 regardless of whether such individuals or entities are subject to the requirements of 45 CFR parts 160 and 164. *ONC: "the narrower definition of HIN/HIE in this final rule should clearly exclude entities that might have been included under the proposed definitions, such as social networks, internet service providers, and technology that solely facilitates the exchange of information among patients and family members". Once an individual or entity is defined as an HIN or HIE, information subject to information blocking enforcement not limited to TPO.*

HIE and HIN

- ONC combined and narrowed two categories (e.g., removes "substantially influences")
- Focus on TPO only
- Maintained inclusion of "individual" as that term is in Cures
- Clarifies: must be exchange among more than two unaffiliated individuals or entities, *besides HIN/HIE*, that are enabled to exchange with each other
  - ONC states that revision ensures that definition does not unintentionally cover "essentially bilateral exchanges" in which intermediary "simply" performing a service on behalf of one entity in providing EHI to one or more entities and no "actual exchange" taking place among all entities (e.g., acting as intermediary between two entities where first sends non-standardized data to be converted by intermediary into standardized data for receiving entity)
- ONC retains, as proposed, as functional definition without specific exclusions
  - ONC notes that narrower definition of HIN/HIE should "clearly exclude entities that might have been included under proposed definitions (e.g., social networks, ISPs, and technology that solely facilitates exchange of information among patients and family members

Electronic Health Information Defined §171.102

- Electronic protected health information (defined in HIPAA) to the extent that it would be included in a designated record set ~~, and any other information that:~~
  - ~~Identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual; and~~
  - ~~Is transmitted by or maintained in electronic media (defined in 45 CFR 160.103) that;~~
  - ~~Relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.~~
- ~~Not limited to information created or received by a provider~~
- As proposed, does not include de-identified health information
- Proposed Rule had an RFI on including price information within EHI with regard to information blocking; Final Rule says may or may not include price information, issue is whether it is PHI in a DRS

Electronic Health Information Defined §171.102

- Electronic protected health information as defined in 45 CFR 160.103 to the extent that it would be included in a designated record set as defined in 45 CFR 164.501, regardless of whether the group of records are used or maintained by or for a covered entity as defined in 45 CFR 160.103, but EHI shall not include:

  (1) Psychotherapy notes as defined in 45 CFR 164.501; or

  (2) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

  Note: Given narrower definition of EHI, term "observational health information" not used in the Final Rule. EHI limited to USCDI v1 for first 24 months via other Information Blocking and certification provisions

United States Core Data for Interoperability

FEBRUARY 2020 • VERSION 1

Table 1:
Data Class and Data Element Changed from NPRM
Data class is cell header. Data elements are bulleted.

Changed Data Elements NPRM to USCDI v1	
Proposed USCDI	**Final Cures Rule (USCDI v1)**
Patient Demographics • Address	**Patient Demographics** • Current Address • Previous Address • Phone Number • Phone Number Type • Email Address
Provenance • Author • Author Organization • Author Time Stamp	**Provenance** • Author Organization • Author Time Stamp
Substance Reactions* (including Medication Allergies) • Substance* • Reaction*	**Allergies and Intolerances** • Substance (Medication) • Substance (Drug Class) • Reaction

USCDI v1 Summary of Data Classes and Data Elements

Allergies and Intolerances
- Substance (Medication)
- Substance (Drug Class)
- Reaction

Assessment and Plan of Treatment
- Assessment and Plan of Treatment

Care Team Members
- Care Team Members

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals
- Patient Goals

Health Concerns
- Health Concerns

Immunizations
- Immunizations

Laboratory
- Tests
- Values/Results

Medications
- Medications

Patient Demographics
- First Name
- Last Name
- Previous Name
- Middle Name (incl Middle Initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address

Problems
- Problems

Procedures
- Procedures

Provenance
- Author Time Stamp
- Author Organization

Smoking Status
- Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a Patient's Implantable Device(s)

Vital Signs
- Diastolic Blood Pressure
- Systolic Blood Pressure
- Body Height
- Body Weight
- Heart Rate
- Respiratory Rate
- Body Temperature
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2 - 20 Years)
- Weight-for-length Percentile (Birth - 36 Months)
- Head Occipital-frontal Circumference Percentile (Birth - 36 Months)

Information Blocking: Key Definitions §171.102: Simplified

- *Access:* the ability or means necessary to make EHI available for exchange or use~~, including the ability to securely and efficiently locate and retrieve information from any and all source systems in which the information may be recorded or maintained~~
- *Exchange:* the ability for electronic health information to be transmitted ~~securely and efficiently~~ between and among different technologies, systems, platforms, or networks ~~in a manner that allows the information to be accessed and used~~ *[Note: transmission need not be one-way]*
- *Use:* the ability ~~of health IT or a user of health IT to access relevant~~ for electronic health information, once accessed or exchanged, to be understood and acted upon ~~to comprehend the structure, content, and meaning of the information; and to read, write, modify, manipulate, or apply the information to accomplish a desired outcome or to achieve a desired purpose~~ *[Note: the general scope and meaning of the definition (e.g., write) is the same as proposed and use, like transmission, can be bi-directional]*

Interoperability Element §171.102: Simplified

- *Interoperability element* means hardware, software, integrated technologies or related licenses, technical information, privileges, rights, intellectual property, upgrades, or services that:

  (1) May be *necessary* to access, exchange, or use electronic health information; and

  (2) Is *controlled by the actor*, which includes the ability to confer all rights and authorizations necessary to use the element to enable the access, exchange, or use of electronic health information.

Note: The first part of the definition draws on PHSA definition of health IT

Interoperability element is a key concept of API and Information Blocking provisions, for example relative to licensing

Information Blocking Practices

- § 171.102: “an act or omission by an actor”
- Must be *likely to interfere with, prevent, or materially discourage* the access, exchange, or use of EHI
- ONC did not revise Proposed Rule examples but added *additional examples*
- ONC finalized purposes for access, exchange, or use for which interference will *almost always implicate* information blocking
- Focus on actors with *control* over interoperability elements

Business Associate Agreements: Final Rule Discussion

- "We designed the final rule to operate in a manner consistent with the framework of the HIPAA Privacy Rule and other laws providing privacy rights for patients. Foremost, we do not require the disclosure of EHI in any way that would not already be permitted under the HIPAA Privacy Rule (or other federal or state law). However, if an actor is *permitted* to provide access, exchange, or use of EHI under the HIPAA Privacy Rule (or any other law), then the information blocking provision would require that the actor provide that access, exchange, or use of EHI so long as the actor is not prohibited by law from doing so (assuming that no exception is available to the actor)."
- While the information blocking provision does not require actors to violate a BAA, a BAA or its associated service level agreements must not be used in a discriminatory manner by an actor to forbid or limit disclosures that otherwise would be permitted by the Privacy Rule.
  - For example, a BAA entered into by one or more actors that permits access, exchange, or use of EHI by certain health care providers for treatment should generally not prohibit or limit the access, exchange, or use of the EHI for treatment by other health care providers of a patient.

Business Associate Agreements: Final Rule Discussion

- Both the provider(s) who initiated the BAA and the BA who may be an actor under the information blocking provision (e.g., a health IT developer of certified health IT) would be subject to the information blocking provision in the instance described above.
  - To illustrate the potential culpability of a BA, a BA with significant market power may have contractually prohibited or made it difficult for its covered entity customers to exchange EHI, maintained by the BA, with health care providers that use an EHR system of one of the BA's competitors.
  - To determine whether there is information blocking, the actions and processes (e.g., negotiations) of the actors in reaching the BAA and associated service level agreements would need to be reviewed to determine whether there was any action taken by an actor that was likely to interfere with the access, exchange, or use of EHI, and whether the actor had the requisite intent.
  - If the BA has an agreement with the covered entity to provide EHI to a third party that requests it and the BA refuses to provide the access, exchange, or use of EHI to a requestor in response to the request received by the CE, the BA (who is also an actor under the information blocking provision) may have violated the information blocking provision unless an exception applied.

Additional Edited ONC Examples in Final Rule: Restrictions on Access, Exchange, or Use That Might Implicate Information Blocking

- An actor (e.g., a health care provider that is a covered entity under HIPAA) may want to engage an entity for services (e.g., use of a clinical decision support application ("CDS App Developer")) that require the CDS App Developer to enter into a BAA with the health care provider and, in order to gain access and use of the EHI held by another BA of the health care provider (e.g., EHR developer of certified health IT), the CDS App Developer is required by the EHR developer of certified health IT to enter into a contract to access its EHR technology.
- An entity may offer an application that facilitates patients' access to their EHI through an API maintained by an actor (e.g., EHR developer of certified health IT) that is a BA of a health care provider that is a covered entity under HIPAA.
- A health care provider may request EHI from an actor that is a BA of another health care provider under HIPAA, such as an EHR developer of certified health IT or HIN, that is contracted to make EHI available for treatment purposes.

ONC clarifies: "contracts and agreements can interfere with the access, exchange, and use of EHI through terms besides those that specify unreasonable fees and commercially unreasonable licensing terms".

Additional Edited ONC Examples in Final Rule: Limiting or Restricting the Interoperability of Health IT

- Publication of "FHIR service base URLs" (i.e., "FHIR endpoints")
  - A FHIR service base URL cannot be withheld by an actor as it (just like many other technical interfaces) is necessary to enable the access, exchange, and use of EHI.
  - In the case of patients seeking access to their EHI, the public availability of FHIR service base URLs is an absolute necessity and without which the access, exchange, and use of EHI would be prevented. Thus, any action by an actor to restrict the public availability of URLs in support of patient access would be more than just likely to interfere with the access, exchange, or use of EHI; it would prevent such access, exchange, and use. Accordingly, as noted in § 170.404(b)(2), a Certified API Developer must publish FHIR service base URLs for certified API technology that can be used by patients to access their electronic health information.
- Slowing or delaying access, exchange, or use of EHI could constitute an "interference" and implicate information blocking provision; for example, scoping and architecture questions could constitute interference and implicate information blocking if they are not necessary to enable access, exchange, or use of EHI and are being utilized as a delay tactic

Additional Edited ONC Examples in Final Rule: Limiting or Restricting the Interoperability of Health IT

- An actor's refusal to register a software application that enables a patient to access their EHI would effectively prevent its use given that registration is a technical prerequisite for software applications to be able to connect to certified API technology
  - Such refusals in the context of patient access unless otherwise addressed in this rule would be highly suspect and likely to implicate information blocking
- There is often specific information that may be necessary for certain actors, such as health care providers, to effectively access, exchange, and use EHI via their Certified EHR Technology and certified Health IT Modules. A health care provider's "direct address" is an example of this kind of information.
  - If this information were not made known to a health care provider upon request, were inaccessible or hidden in a way that a health care provider could not identify (or find out) their own direct address, or were refused to be provided to a health care provider by a health IT developer with certified health IT, we would consider all such actions to be information blocking because knowledge of a direct address is necessary to fully engage in the exchange of EHI.
- To the extent that a legal transfer of IP to an individual or entity that is not an actor is intended to facilitate circumvention of the information blocking provision, *transfer itself* by an actor could be considered interference with the access, exchange, or use of EHI

Additional Edited ONC Examples in Final Rule: Impeding Innovations and Advancements in Access, Exchange, or Use or Health IT-Enabled Care Delivery

- Vetting and "education" re: apps
  - *This final rule also supports and strongly encourages providing individuals with information that will assist them in making the best choice for themselves in selecting a third-party application.*
  - Practices that purport to educate patients about the privacy and security practices of applications and parties to whom a patient chooses to receive their EHI may be reviewed by OIG or ONC, as applicable, if there was a claim of information blocking. However, we believe it is unlikely these practices would interfere with the access, exchange, and use of EHI if they meet certain criteria.
    - Foremost, the information provided by actors must focus on any current privacy and/or security risks posed by the technology or the third-party developer of the technology.
    - Second, this information must be factually accurate, unbiased, objective, and not unfair or deceptive.
    - Finally, the information must be provided in a non-discriminatory manner. For example, all third-party apps must be treated the same way in terms of whether or not information is provided to individuals about the privacy and security practices employed. To be clear, an actor may not prevent an individual from deciding to provide its EHI to a technology developer or app despite any risks noted regarding the app itself or the third-party developer.
  - For example, actors may establish processes where they notify a patient, call to a patient's attention, or display in advance (as part of the app authorization process with certified API technology) whether the third-party developer of the app that the patient is about to authorize to receive their EHI has attested in the positive or negative whether the third party's privacy policy and practices (including security practices such as whether the app encrypts the EHI) meet certain "best practices" set by the market for privacy policies and practices.
  - ONC provides minimum app privacy notice criteria and examples

App Privacy Notices: Minimum Criteria

At a minimum, as it relates to the above, all third-party privacy policies and practices should adhere to the following:

1) *The privacy policy is made publicly accessible at all times, including updated versions;*
2) *The privacy policy is shared with all individuals that use the technology prior to the technology's receipt of EHI from an actor;*
3) *The privacy policy is written in plain language and in a manner calculated to inform the individual who uses the technology;*
4) *The privacy policy includes a statement of whether and how the individual's EHI may be accessed, exchanged, or used by any other person or other entity, including whether the individual's EHI may be sold at any time (including in the future); and*
5) *The privacy policy includes a requirement for express consent from the individual before the individual's EHI is accessed, exchanged, or used, including receiving the*
6) *individual's express consent before the individual's EHI is sold (other than disclosures required by law or disclosures necessary in connection with the sale of the application or a similar transaction).*

Exceptions

Revised/Final Policy Considerations for Exceptions

1. Exceptions are limited to certain activities important to the successful functioning of the U.S. health care system, including *promoting public confidence in health IT infrastructure* by *supporting the privacy and security* of EHI, and *protecting patient safety and promoting competition and innovation* in health IT and its use to provide health care services to consumers
2. Each is intended to address a *significant risk that regulated individuals and entities* (i.e., health care providers, health IT developers of certified health IT, health information networks, and health information exchanges) *will not engage in these reasonable and necessary activities because of potential uncertainty* regarding whether they would be considered information blocking
3. Each is *intended to be tailored*, through *appropriate conditions*, so that it is *limited to the reasonable and necessary activities* that it is designed to exempt

Information Blocking: Finalized Exceptions

- ONC revised the exceptions per comments, framed as questions, added an eighth exception, provides more guidance and examples in the Preamble, and divides exceptions into two categories:
  1. Not fulfilling requests to access, exchange, or use EHI
  2. Procedures for fulfilling requests to access, exchange, or use EHI
- Documentation requirements are in final exception conditions
- Final Rule creates a safe-harbor approach: *Failure to meet conditions of an exception does not mean a practice is information blocking, only that it would not have guaranteed protection from CMPs or disincentives, and would be evaluated on case-by-case basis (e.g., for level of impact, intent, knowledge)*

Exceptions: Not Fulfilling Requests to Access, Exchange, or Use EHI

Preventing Harm Exception

- *Final Rule revises and aligns with HIPAA Privacy Rule harm standards (§ 164.524(a)(3))*
- An actor may engage in practices that are reasonable and necessary to prevent *harm* to a patient or another person
- The actor must have a reasonable belief that the practice will ~~directly and~~ substantially reduce the likelihood of harm (~~special focus on physical harm~~) to a patient or another person
  - Note: focus on "life or physical safety" retained where practice likely to, or does, interfere with patient's access, exchange, or use of their own EHI (per HIPAA 164.524(a)(3)(i). Otherwise, "substantial harm" standard
- Practice must be no broader than necessary to substantially reduce the risk of harm practice is implemented to reduce
- Practice must implement an *organizational policy* that meets certain requirements *or* based on *individualized assessment of risk in each case*
  - Likely challenges to policies to delay release of test results to patients

§ 171.201 Preventing Harm Exception — When will an actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to prevent harm not be considered information blocking?

An actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to prevent harm will not be considered information blocking when the practice meets the conditions in paragraphs (a) and (b) of this section, satisfies at least one condition (subparagraph) from each of paragraphs (c), (d) and (f) of this section, and also meets the condition in paragraph (e) of this section when applicable.

(a) *Reasonable belief.* The actor engaging in the practice must hold a reasonable belief that the practice will substantially reduce a risk of harm to a patient or another natural person that would otherwise arise from the access, exchange, or use of electronic health information affected by the practice. For purposes of this section, "patient" means a natural person who is the subject of the electronic health information affected by the practice.

(b) *Practice breadth.* The practice must be no broader than necessary to substantially reduce the risk of harm that the practice is implemented to reduce.

(c) *Type of risk.* The risk of harm must:

(1) Be determined on an individualized basis in the exercise of professional judgment by a licensed health care professional who has a current or prior clinician-patient relationship with the patient whose EHI is affected by the determination; *or*

(2) Arise from data that is known or reasonably suspected to be misidentified or mismatched, corrupt due to technical failure, or erroneous for another reason.

(d) *Type of harm.* The type of harm must be one that could serve as grounds for a covered entity (as defined in § 160.103 of this title) to deny access (as the term "access" is used in part 164 of this title) to an individual's protected health information under:

(1) Section 164.524(a)(3)(iii) of this title where the practice is likely to, or in fact does, interfere with access, exchange, or use (as these terms are defined in § 171.102) of the patient's EHI by their legal representative (including but not limited to personal representatives recognized pursuant to 45 CFR 164.502) and the practice is implemented pursuant to an individualized determination of risk of harm consistent with (c)(1) of this section; [substantial harm]

(2) Section 164.524(a)(3)(ii) of this title where the practice is likely to, or in fact does, interfere with the patient's or their legal representative's access to, use or exchange (as these terms are defined in § 171.102) of information that references another natural person and the practice is implemented pursuant to an individualized determination of risk of harm consistent with paragraph (c)(1) of this section; [substantial harm]

(3) Section 164.524(a)(3)(i) of this title where the practice is likely to, or in fact does, interfere with the patient's access, exchange, or use (as these terms are defined in § 171.102) of their own EHI, regardless of whether the risk of harm that the practice is implemented to substantially reduce is consistent with paragraph (c)(1) or (c)(2) of this section; or [life or physical safety]

Privacy Exception

- An actor may engage in practices that protect the privacy of EHI
- An actor must satisfy *at least one of four* discrete sub-exceptions that address scenarios that recognize existing privacy laws and privacy-protective practices:
  1. Preconditions prescribed by ~~privacy~~ laws not satisfied;
  2. Health IT developer of certified health IT not covered by HIPAA [i.e., developer not a BA for a patient facing product or service] but that implement documented and transparent privacy policies;
  3. Denial of an individual's request for their electronic protected health information in the circumstances provided in 45 CFR 164.524(a)(1) and (2) [unreviewable grounds for denying patient right of access]; or
  4. Respecting an individual's request not to share information.
- Actors need not provide access, exchange, or use of EHI in a manner not permitted under the HIPAA Privacy Rule
- General conditions apply to ensure that practices are tailored to the specific privacy risk or interest being addressed and implemented in a *consistent and non-discriminatory manner*
- ONC emphasizes that information blocking provision may require that actors provide access, exchange, or use of EHI in situations where the HIPAA Rules would not require access of similar information; the HIPAA Privacy Rule *permits*, but does not *require*, covered entities to disclose ePHI in most circumstances
- Some Documentation requirements aligned with OIG safe harbor and HIPAA Privacy Rule documentation requirements (sub-exception 1) and examples of EHR-based documentation provided

§ 171.202 Privacy Exception — When will an actor's practice of not fulfilling a request to access, exchange, or use electronic health information in order to protect an individual's privacy not be considered information blocking?

(b) *Sub-Exception – Precondition not satisfied.* To qualify for the exception on the basis that state or federal law requires one or more preconditions for providing access, exchange, or use of electronic health information have not been satisfied, the following requirements must be met—

(1) The actor's practice is tailored to the applicable precondition not satisfied, is implemented in a consistent and non-discriminatory manner, and either:

(i) Conforms to the actor's organizational policies and procedures that:

(A) Are in writing;

(B) Specify the criteria to be used by the actor to determine when the precondition would be satisfied and, as applicable, the steps that the actor will take to satisfy the precondition; and

(C) Are implemented by the actor, including by providing training on the policies and procedures; or

(ii) Are documented by the actor, on a case-by-case basis, identifying the criteria used by the actor to determine when the precondition would be satisfied, any criteria that were not met, and the reason why the criteria were not met.

(2) If the precondition relies on the provision of a consent or authorization from an individual and the actor has received a version of such a consent or authorization that does not satisfy all elements of the precondition required under applicable law, the actor must:

(i) Use reasonable efforts within its control to provide the individual with a consent or authorization form that satisfies all required elements of the precondition or provide other reasonable assistance to the individual to satisfy all required elements of the precondition; and

(ii) Not improperly encourage or induce the individual to withhold the consent or authorization.

(3) For purposes of determining whether the actor's privacy policies and procedures and actions satisfy the requirements of subsections (b)(1)(i) and (b)(2) above when the actor's operations are subject to multiple laws which have inconsistent preconditions, they shall be deemed to satisfy the requirements of the subsections if the actor has adopted uniform privacy policies and procedures to address the more restrictive preconditions.

Security Exception

- An actor may implement measures to promote the security of EHI—Practice must be:
  - Directly related to safeguarding confidentiality, integrity, and availability of EHI
  - Tailored to specific security risks
  - Implemented in a consistent and non-discriminatory manner
  - implementing an organizational security policy that meets certain requirements or based on individualized determination regarding risk and response in each case
- ONC takes a *fact-based approach* to allow each actor to implement policies, procedures, and technologies appropriate for its size, structure, risks to individuals' EHI
- The intent is to prohibit practices that "purport to promote the security of EHI but that are unreasonably broad and onerous on those seeking access to EHI, not applied consistently across or within an organization, or otherwise may unreasonably interfere with access, exchange, or use of EHI"
- Would apply to security practices exceeding minimum HIPAA Security Rule conditions

Infeasibility Exception

- An actor may decline to provide access, exchange, or use of EHI in a manner that is *infeasible*
- ~~Complying with the request must impose a *substantial burden on the actor that is unreasonable under the circumstances* (taking into account the cost to the actor, actor's resources, etc.)~~
- Conditions:
  1. Actor cannot fulfill the request for access, exchange, or use of EHI due to events beyond the actor's control, namely a natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority;
  2. Actor cannot unambiguously segment the requested EHI from other EHI; or
  3. Infeasible under the circumstances as demonstrated by contemporaneous documentation consistent and non-discriminatory consideration of several revised factors *including new Content and Manner Exception (which includes some aspects of proposal like "reasonable alternative")* and whether the actor's practice is non-discriminatory and the actor provides the same access, exchange, or use of EHI to its companies or to its customers, suppliers, partners, and other persons with whom it has a business relationship.
- Actor must ~~*timely*~~ *respond* to infeasible requests within ten business days of receipt of request
- Two factors that may not be considered in the determination: (1) whether the manner requested would have facilitated competition with the actor; and (2) whether the manner requested prevented the actor from charging a fee or resulted in a reduced fee.

Health IT Performance Exception

- An actor may make health IT under its control temporarily unavailable to perform maintenance or improvements to the health IT
- The actor to whom health IT is provided must agree to unavailability, via service level agreement (SLA) or similar agreement or in each event
  - Obligations differ if health IT vendor or provider
  - ONC notes that a period of health IT unavailability or performance degradation could be outside the parameters of SLAs without being "longer than necessary" in the totality of applicable circumstances and, therefore, without necessarily constituting information blocking as defined in § 171.103 [Unclear if exception still applies or this becomes a case-by-case issue]
- An actor must ensure that the health IT is unavailable for no longer than necessary to achieve the maintenance or improvements
- An actor may take action against a third-party application (including but not limited to patient-facing apps) that is negatively impacting the health IT's performance, provided that the practice is—(1) For a period of time no longer than necessary to resolve any negative impacts; (2) Implemented in a consistent and non-discriminatory manner; and (3) Consistent with existing SLAs, where applicable.
- Harm, Security, or Infeasibility (e.g., disaster)-related practices addressed by those respective exceptions

Exceptions: Procedures for Fulfilling Requests to Access, Exchange, or Use EHI

Content and Manner Exception (New)

- New exception, addressing some elements of proposed Feasibility Exception, with two alternative ("or") conditions
- *Content condition* –An actor must respond to request to access, exchange, or use electronic health information with
  - EHI in *USCDI data elements for* up to 24 months after Final Rule publication; and
  - On and after 24 months after publication date, a*ll EHI* as (re)defined in § 171.102
- *Manner condition*
  - *Manner requested*. (i) Actor must fulfill request per Content Condition in any manner requested, unless technically unable or *cannot reach terms with requestor* If actor fulfills such a request described in any manner requested:
    - **Any fees charged in fulfilling the response *need not* satisfy Fee Exception (i.e., could be "market rate); and**
    - **Any license of interoperability elements granted in fulfilling the request *need not* satisfy Licensing Exception**

Content and Manner Exception (New)

- *Alternative manner*. If actor does not fulfill request in any manner requested because technically unable or cannot reach terms with requestor (intended as a high bar), actor must fulfill request in an alternative manner, as follows:
  - Without unnecessary delay in following order of priority, starting with (A) and only proceeding to next consecutive paragraph if technically unable to fulfill request in manner identified in a paragraph.
    A. Using technology certified to standard(s) adopted in Part 170 (ONC certification) specified by requestor.
    B. Using content and transport standards specified by requestor and published by the Federal Government or an ANSI accredited SDO
    C. Using mutually agreeable alternative machine-readable format, including means to interpret EHI
  - Any fees charged by actor in fulfilling request must satisfy the Fee Exception
  - Any license of interoperability elements granted by the actor in fulfilling request must satisfy Licensing Exception
- If still unable to fulfill request, use Infeasibility Exception

Fees ~~Costs~~ Exception

- In setting fees for providing access, exchange, or use of EHI, an actor may charge fees, including a "reasonable profit margin," if they are:
  - charged on basis of *objective and verifiable criteria uniformly applied* to all ~~substantially similar~~ or similarly situated persons and requests;
  - *related to the costs* of providing access, exchange, or use; and
  - *reasonably allocated among all similarly situated ~~customers~~ persons or entities that* use the product/service [intended to allow approaches like sliding fee scales per comments]
  - based on costs not otherwise recovered for same instance of service to a provider and third party
  - not based in any part on whether requestor is a *competitor*, potential competitor, or will be using EHI to facilitate competition with the actor; and
  - not based on *sales, profit, revenue*, or other value requestor derives or may derive, ~~including secondary use of such information,~~ [intent remains] *that exceed the actor's reasonable costs*
  - not based on *costs that led to creation of IP, if the actor charged a royalty for that IP* per § 171.303 and royalty included development costs for IP creation
  - costs actor incurred due to the health IT being *designed or implemented in non-standard way,* unless requestor agreed to fees associated with non-standard approach
  - certain costs associated with *intangible assets* other than actual development or acquisition costs
  - *opportunity costs* unrelated to access, exchange, or use of EHI; or
  - based on *anti-competitive or other impermissible criteria*
- Costs excluded from exception: *some* data export, electronic access by individual to EHI, fees prohibited by 45 CFR 164.524(c)(4)) [HIPAA Privacy Rule]
- Health IT developers subject to Conditions of Certification on fees must comply with all requirements of such conditions for all practices and at all relevant times
- *Note: new Manner and Content Exception materially relaxes fee regulation*

Licensing Exception

- An 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)*~~ *per conditions (uses concepts of reasonable and necessary in specific ways but not RAND model)*
  - *Negotiating a license* conditions: timeliness begin license negotiations with requestor within 10 business days from receipt of request and negotiate (in good faith) license within 30 business days from receipt
  - *Licensing* conditions: includes scope of rights; reasonable, non-discriminatory royalty and terms (including an actor may not charge a royalty for IP if the actor recovered any development costs pursuant to the Fee Exception that led to the creation of the IP); prohibited collateral terms; permitted NDA terms
  - *Additional conditions* relating to provision of interoperability elements to prohibit various forms of impeding licensee's efforts to use licensed elements
- ONC emphasizes in Final Rule that actor would *not need to license all of their IP* or license interoperability elements per this exception to a firm that requested a license solely for that firm's use in developing its own technologies and not to meet *current* needs for exchange, access or use of *EHI* to which it had a *"claim"* for *specific patients or individual access*
- ONC expects actors to take *immediate steps to come into compliance* with the information blocking provision by amending their contracts or agreements to eliminate or void any clauses that contravene the information blocking provision
- See Proposed Rule for *practices* that could implicate information blocking
- *Note: new Manner and Content Exception materially relaxes fee regulation*