



Information Blocking Rules Are Here: Now What?

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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

Interoperability Matters Information Blocking Workgroup

Associations and Orgs - health IT community

- Anne Kimbol, HITRUST Alliance
- Mari Greenberger, HIMSS
- Lauren Riplinger, AHIMA
- Scott Stuewe, DirectTrust
- Samantha Burch, AHA

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
- Vince Vitali, NextGate

Informatics

- Jeff Smith, AMIA

Safety Net Providers / Service Provider

- Jennifer Stoll, OCHIN

Release of Information Company

- Rita Bowen, MROCorp

Interoperability Matters Information Blocking Workgroup



Information Blocking Proposed Rule (March 2019)
Information Workgroup Comments to ONC
April 2019



*Phase 2 Topics: Summary of Discussion and
Observations Following Submission of Comments
from*
Information Blocking Workgroup Phase 2: Final Report
***Guidance to the Community and Implementation
Feedback to HHS***
Interoperability Matters
1/23/2020



Review of ONC's Final Rule

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 not meeting certification conditions or false attestations (certified health IT developers) and up to \$1 million civil monetary penalties (CMPs) per violation (developers, HIEs, HINs)*

ONC Interoperability Final Rule: Information Blocking and Certification—March 2020

RIN 0955-AA01

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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:

. . . 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

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 final rule (NPRM at OMB 1/23/2020)
- **HIE/HIN**
 - Combined and narrowed (but still broad applicability and some ambiguity)
- **EHl (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 standards and API criteria
 - Information blocking timing and other Conditions of Certification 6 months after publication

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

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

ONC Final Rule: Key Dates



Actors Defined §171.102

Health Care Providers – <i>Finalized as Proposed</i>	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 – <i>Finalized with minor editorial revisions and one addition</i>	<p>An individual or entity, <u>other than a health care provider that self-develops health IT for its own use</u>, 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).</p> <p><i>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.</i></p>

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 <i>Revised in Final Rule and Combined</i>	<i>Health information network or health information exchange</i> 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 (<u>other than the individual or entity to which this definition might apply</u>) that are enabled to exchange with each other; and (2) That is for a <u>treatment, payment, or health care operations purpose</u> , 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. <i>ONC: “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 individual/entity defined as HIN/HIE, information subject to enforcement not limited to TPO.</i>

HIE and HIN

- ONC combined and narrowed two categories (e.g., removes “substantially influences” which increases focus on actual control or administration)
- Focus on TPO for designation as HIE/HIN
- Maintained “individual” because 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
 - Revision intended to ensure 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” 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) and in public discussion, excludes traditional claims clearinghouses functions

Electronic Health Information §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
- *With narrower EHI definition, “observational health information” not used in Final Rule*
- *EHI limited to USCDI v1 data elements for first 24 months via other Information Blocking and certification provisions*
- *Proposed Rule had RFI on price information in EHI; Final Rule says includes price information if it is PHI in a DRS*



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 <ul style="list-style-type: none"> Address 	Patient Demographics <ul style="list-style-type: none"> Current Address Previous Address Phone Number Phone Number Type Email Address
Provenance <ul style="list-style-type: none"> Author Author Organization Author Time Stamp 	Provenance <ul style="list-style-type: none"> Author Organization Author Time Stamp
Substance Reactions* (including Medication Allergies) <ul style="list-style-type: none"> Substance* Reaction* 	Allergies and Intolerances <ul style="list-style-type: none"> 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*: ability or means necessary to make EHI available for exchange or use
- *Exchange*: ability for EHI to be transmitted between and among different technologies, systems, platforms, or networks
 - Transmission need not be one-way
- *Use*: ability for EHI, once accessed or exchanged, to be understood and acted upon
 - General scope and meaning same as proposed (e.g., includes “write”) 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.

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

Information Blocking Practices: Final Rule

- Did not revise Proposed Rule examples but added *new* examples
- Finalized purposes for access, exchange, or use for which interference will *almost always implicate* information blocking
 - e.g., patient access to EHI, treatment and care coordination
- Focus on actors with *control* over interoperability elements

Business Associate Agreements: Final Rule Discussion

- If actor permitted to provide access, exchange, or use of EHI under HIPAA Privacy Rule (or other law), actor must provide access, exchange, or use so long as not prohibited by law (assuming no exception is available)
- While information blocking provision does not require actors to violate a BAA, a BAA or its SLAs must not be used in a discriminatory manner to forbid or limit disclosures permitted by Privacy Rule
- Both actors/BAA parties subject to information blocking provision

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

- An actor may want to engage an entity for services (e.g., use of a CDS application that require CDS App Developer to enter into a BAA with a provider and, to gain access and use of EHI held by another BA of the provider (e.g., EHR developer of certified health IT), CDS Developer required by EHR developer to enter into a contract to access its EHR technology.
 - “[C]ontracts 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

- A FHIR service base URL (i.e., “FHIR endpoints”) 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
- Slowing or delaying access, exchange, or use of EHI could constitute an “interference” and implicate information blocking; for example, scoping and architecture questions could constitute interference and implicate information blocking if not necessary to enable access, exchange, or use of EHI and utilized as a delay tactic

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

- App vetting and “education”
 - Practices that educate patients about app privacy and security of and parties to whom a patient chooses to receive EHI may be reviewed by OIG or ONC if information blocking claimed
 - ONC: unlikely these practices would interfere with access, exchange, and use if information:
 - Focuses on current privacy and/or security risks posed by the technology or the third-party developer of the technology
 - Factually accurate, unbiased, objective, and not unfair or deceptive
 - Provided in a non-discriminatory manner
 - **An actor may not prevent an individual from deciding to provide EHI to a technology developer or app despite risks noted regarding the app or developer**
 - Actors may establish processes to notify a patient, call to a patient’s attention, or display in advance whether developer of app that patient is about to authorize to receive EHI has attested whether the its privacy policy and security practices meet “best practices”
 - ONC provides minimum app privacy notice criteria and examples



Exceptions

Information Blocking: Finalized Exceptions

- ONC revised per comments, framed as questions, added eighth exception, provides guidance and examples, and divides 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 exception conditions
- *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., 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 other person
- The actor must have reasonable belief that the practice will ~~directly and substantially reduce likelihood of harm (special focus on physical harm)~~
- 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 risk of harm that practice intended to reduce
- Must implement *organizational policy* that meets certain requirements *or* be based on *individualized assessment of risk in each case*
- Likely challenges to policies to delay release of test results to patients

Privacy Exception

- An actor may engage in practices that protect privacy of EHI
- Must satisfy at least one of four sub-exceptions that address scenarios recognizing existing privacy laws and practices:
 - Preconditions prescribed by ~~privacy~~ laws not satisfied;
 - Developer of certified health IT not covered by HIPAA [i.e., developer not a BA for a patient-facing product or service] but implements documented and transparent privacy policies;
 - Denial of individual's request for ePHI in circumstances provided in 45 CFR 164.524(a)(1) and (2) [unreviewable grounds for denying patient right of access]; or
 - 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

Privacy Exception (continued)

- General conditions apply to ensure practices tailored to specific privacy risk or interest being addressed and implemented in *consistent and non-discriminatory manner*
- Information blocking provision may require actors to provide access, exchange, or use in situations where 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
- To determine if actor's privacy policies and procedures and actions satisfy applicable conditions, when actor's operations subject to multiple laws with inconsistent preconditions, they will satisfy requirements of subsections if actor has adopted policies and procedures to address the *more restrictive preconditions*

Security Exception

- An actor may implement measures to promote security of EHI if:
 - Directly related to safeguarding EHI confidentiality, integrity, and availability
 - Tailored to specific security risks
 - Implemented in a consistent and non-discriminatory manner
 - Implementing organizational security policy that meets certain requirements or based on individualized determination of risk and response in each case
- ONC takes *fact-based approach* to allow actors to implement policies, procedures, and technologies appropriate for its size, structure, risks to individuals' EHI
- 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 request for access, exchange, or use due to events beyond their 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 of 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 actor’s practice is non-discriminatory and actor provides same access, exchange, or use to its companies or to customers, suppliers, partners, and others 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
 - Period of unavailability or performance degradation could be outside parameters of SLAs without being “longer than necessary” in totality of applicable circumstances and, therefore, without necessarily constituting information blocking [Unclear if exception still applies or if 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 app (including but not only patient-facing apps) that is negatively affecting health IT performance, if practice is—(1) For a period of time no longer than necessary to resolve negative impacts; (2) Implemented in consistent and non-discriminatory manner; and (3) consistent with existing SLAs, where applicable
- Harm, Security, or Infeasibility-related practices are addressed by those exceptions



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

Content and Manner Exception (New)

- New exception, addressing 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, *all 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 (Continued)

- *Alternative manner.* If actor does not fulfill request *in any manner requested* because technically unable or cannot reach terms with requestor (intended as 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 paragraph if technically unable to fulfill request in manner identified in a paragraph, using:
 - A. Technology certified to standard(s) adopted in Part 170 (ONC certification) *specified by requestor*
 - B. Content and transport standards *specified by requestor* and published by the Federal Government or an ANSI accredited SDO
 - C. Mutually agreeable alternative machine-readable format, including means to interpret EHI
 - Any fees charged by actor in fulfilling request must satisfy Fee Exception
 - Any license of interoperability elements 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*

Fees Exception (Continued)

- 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 API fees must comply with all requirements of such conditions for all practices and at all relevant times
- *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 if it licenses such elements on *reasonable and non-discriminatory terms (RAND)-per conditions (uses concepts of reasonable and necessary but not RAND model)*
 - *Negotiating a license* conditions: 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

Licensing Exception (Continued)

- 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 sought license solely to develop 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 information blocking provision by amending contracts or agreements to eliminate or void any clauses that contravene this provision
- See Proposed Rule for *practices* that could implicate information blocking
- *New Manner and Content Exception materially relaxes fee regulation*



Additional Issues

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 complaint process based on comments and experience with <https://www.healthit.gov/healthit-feedback>
 - ONC will implement **and evolve** this complaint process
- ONC's enforcement to focus on certification compliance, with *corrective action plan* approach, and it has sole authority (relative to ONC-ACBs) for 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 train 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 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 at OMB since 1/23/2020)
 - 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**



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 certification, a health IT developer must not take any action that constitutes information blocking as defined in Cures
 - In some cases, these conditions 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 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 developer must ensure its certified health IT conforms to full scope of the applicable certification criteria
- Developers must provide assurances they have made certified capabilities available in ways that enable them to be implemented and used in production for intended purposes
- 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



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



Compliance Plans

Why is Compliance Important?

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

OIG Compliance Program Framework

Seven Elements

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

Why Use the OIG framework?

- For over 10 years, healthcare industry organizations have built their compliance programs using the OIG model compliance plans
- Using the OIG elements also makes sense because the OIG is responsible for enforcing violations of the Information Blocking Rule (along with ONC)
- This framework is based on Federal Sentencing Guidelines for Organizations, widely by U.S. Federal Courts in a variety of cases

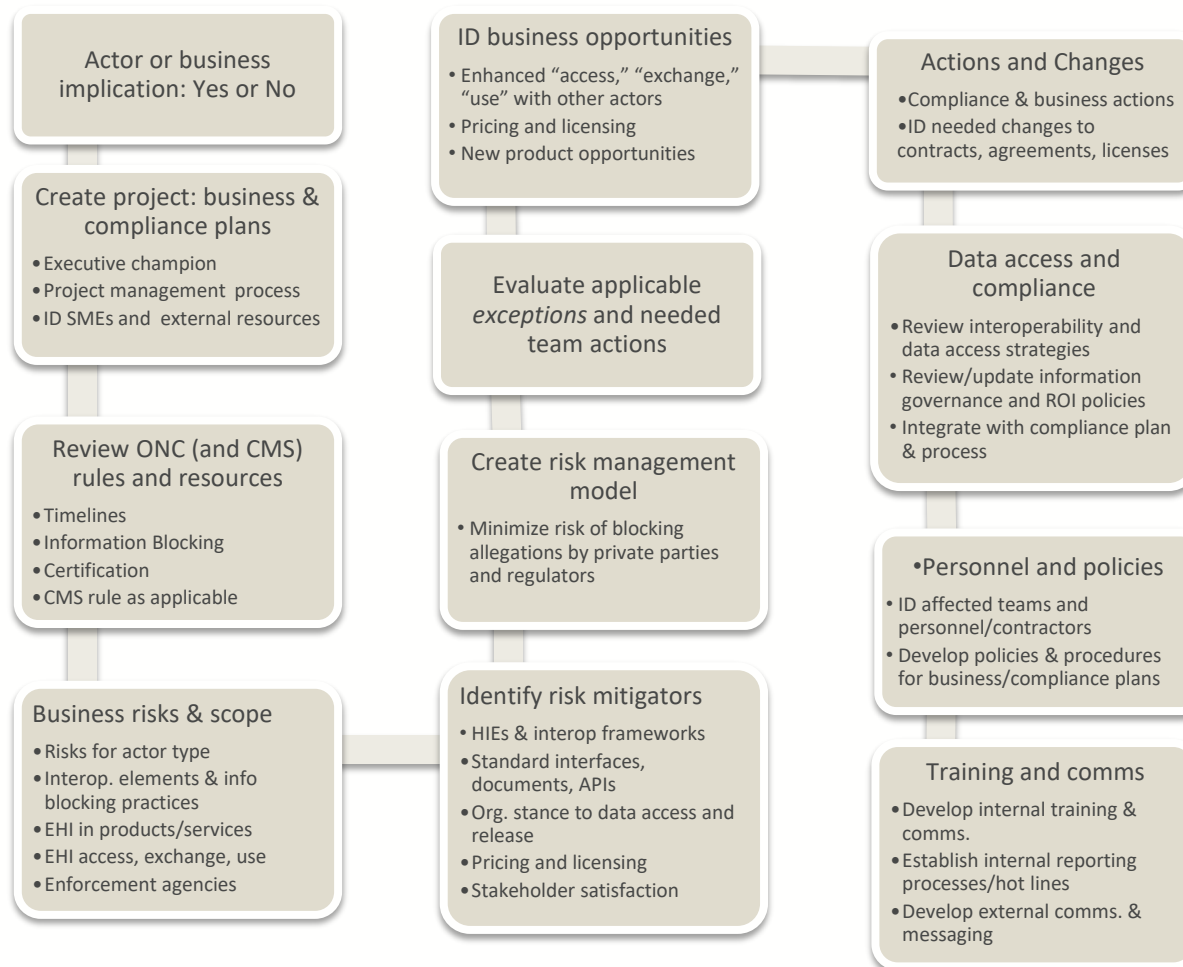


Implementation Plans

Implementation Planning

- Organizations that are Actors or will interact with Actors will need a formal plan to implement operational and business responses to ONC Final Rule
- Implementation Plan should integrate with Compliance Plan

Organization-Wide Information Blocking Plan: Model



Organizational Opportunities

- Cures will also provide opportunities for innovative healthcare organizations and health IT developers
- Organizational responses to information blocking and API requirements, as well as new standards like the USCDI, will enable greater access to data and integration of apps with existing health IT
- Increased data access and integration will enable a broader “app economy,” new technology approaches, data for artificial intelligence/machine learning, and broader and more useful provider and patient access to data



Questions

Interoperability Matters

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