Interoperability Matters Leadership Council

5/19/2020

Leadership Council Members

Organization	Council Member	Alternate
American Medical Association	**Michael Hodgkins – Co-chair**	**Matt Reid**
athenahealth	Kedar Ganta	Greg Carey
Azuba	Bart Carlson	
Bay Health Medical Center	Sue Saxton	Robin Yarnell
Blue Cross Blue Shield Association	Rich Cullen	Matthew Schuller
Cedarbridge Group	Carol Robinson	
Cerner	Hans Buitendijk	
Collective Medical	Vatsala Pathy	Kat McDavitt
CommonSpirit	Sean Turner	Ryan Stewart
Cenevia	Rene Cabral-Daniels	
CRISP	David Horrocks	Ryan Bramble
Delaware Health Information Network (DHIN)	Jan Lee	Randy Farmer
eClinicalWorks	Navi Gadhiok	Tushar Malhotra
eHealth Exchange	Jay Nakashima	
EHNAC	Lee Barrett	Debra Hopkinson
Epic	Rob Klootwyk	Matt Becker
First Genesis	Joe Chirco	Tom Deloney
Greenway Health	Amy Ming	Sherry De Cuba
HealthCatalyst	Ryan Barry	Jay Starr

Leadership Council Members, cont.

Organization	Council Member	Alternate
Highmark Health	Mitch Kwiatkowski	
HIMSS	Mari Greenberger	Amit Trivedi
HITRUST Alliance	Michael Parisi	Anne Kimbol
Humana	Nancy Beavin	
ID.me	Blake Hall	Nora Khalili
IHIE	John Kansky	
Intermountain Healthcare	Stan Huff	Sid Thornton
Jackson Community Medical Record	Julie Lowry	
Kaiser Permanente	Jamie Ferguson	Keven Isbell
Kno2	Alan Swenson	Therasa Bell
lifeIMAGE	Matthew Michela	Karan Mansukhani
MedAllies	Holly Miller	
MedVirigina / Clareto	Steven Leighty	Stephen Hrinda
MIB	Jas Awla	Jane Severson Kelly
MiHIN	Drew Murray	Shreya Patel
MRO	David Borden	Rita Bowen
NeHII	Stefanie Fink	
Netsmart	AJ Peterson	
NextGate Solutions	Norm Carnick	

Leadership Council Members, cont.

Organization	Council Member	Alternate
NextGen	Dan Werlin	Muhammed Chebli
NYeC	Valerie Grey	Alison Birzon
OCHIN	Jennifer Stoll	Paul Matthews
OneRecord	Jennifer Blumenthal	
Optum	Brian Lumadue	Veridiana Croce
Orion Health	Chad Peterson	Jeffrey Turpin
San Diego Health Connect	Nicholas Hess	Daniel Chavez
Santa Cruz HIO	Bill Beighe	
Social Security Administration	Stephen Bounds	Jude Soundararajan
Surescripts	Tara Dragert	Kathy Lewis
Sutter Health	Steven Lane	
Stanford Health Care	Matthew Eisenberg	Matt Abram
Updox	Michael Witting	
WOMBA	Moti Mitteldorf	Eli Rowe

New Members – WELCOME!

- Cedarbridge
- Collective Medical
- Cenevia
- EHNAC
- Highmark Health
- Humana
- MedAllies
- Sutter Health

Agenda

- Review Agenda
- Leadership Council Co-Chair Nominations [Inform]
- Information Blocking Workgroup
  - Phase 3 Updates [Inform]
  - Enforcement Discretion/OIG Proposed Rule and Draft Sequoia Project Comments [Inform/Advise]
  - Implementation and Compliance Resources [Advise]
- Other Updates [Inform]
  - New Project: Data Quality and Usability
  - RCE
- Future Meetings [Inform]

Leadership Council Co-Chair Nomination Process

- Nominations open for Leadership Council co-chair slot held by Michael Matthews
- Interested and qualified Council members should submit nomination, including name, organization, resume/bio to interopmatters@sequoiaproject.org by **Close of Business May 20, 2020**
- Time commitment
  - 1-3 hours monthly, inclusive of Leadership Council meetings and preparation (approximately every other month) and Interoperability Matters workgroups and Public Advisory Forum meetings
- Questions: interopmatters@sequoiaproject.org

Qualifications

- Representative of full Sequoia Project member organization
- Serving on Leadership Council
- Subject matter expertise, leadership, facilitation skills
- Co-chairs should represent different stakeholder groups
  - Provider organizations, physicians, others
  - Health information networks (HIN)
  - Developers or technology service providers
  - Health plans
  - Consumer interests
  - Standards development organizations/initiatives

Duties include

- Leading/facilitating Council efforts, including development and maintenance of deliverables and assigning deliverables
- Facilitating meetings and enabling balanced opportunities for Council members to contribute
- Conducting work in an efficient manner, per the work plan
- Meeting with staff before Council meetings to prepare agenda and discussion topics

Information Blocking Workgroup
Phase 3

Workgroup Representatives

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

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

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

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

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

Public Health
- John Loonsk, APHL

Developers
- Cherie Holmes-Henry, EHRA/NextGen
- Noah Nuechterlein, Epic
- Josh Mast, Cerner
- Jennifer Stoll, OCHIN
- Micky Tripathi, Arcadia.io
- Rita Bowen, MROCorp

Consultant
- Brian Ahier, MITRE Corporation

Federal Government
- Steve Bounds, SSA

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

Phase 3 Priorities

- ❑ Review ONC Final Rule
- ❑ Seek sub-regulatory guidance from HHS (ONC/OIG)
- ❑ Seek questions from public via a dedicated email box— aggregate and submit to HHS/OIG and 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

Information Blocking Workgroup: Agenda—Phase 3

- ✓ Meeting #11 (1/10/2020)
- ✓ Meeting #12 (3/20/2020)
- ✓ Members-Only Webinar on Final Rules (3/25/2020)
- ✓ Public Webinar on Final Rules (3/31/2020)
- ✓ Meeting #13 (4/10/2020)
- ✓ Public Webinar: Extended Q&A (4/17/2020)
- ✓ Meeting #14 (5/8/2020)
- Meetings through end of 2020

Phase 3 Activities To-Date

- Review Phase 2 deliverables
- Plan for Phase 3
- Review ONC Final Rule
- Begin implementation planning
- ID priority questions on Final Rule
- Review enforcement discretion and OIG Proposed Rule
- Provide suggestions for compliance and implementation resources

Focus on implementation and compliance implications of ONC Final Rule.

Information Blocking Rules: Formal Publication and Enforcement Discretion

Summary of Recent Actions

ONC

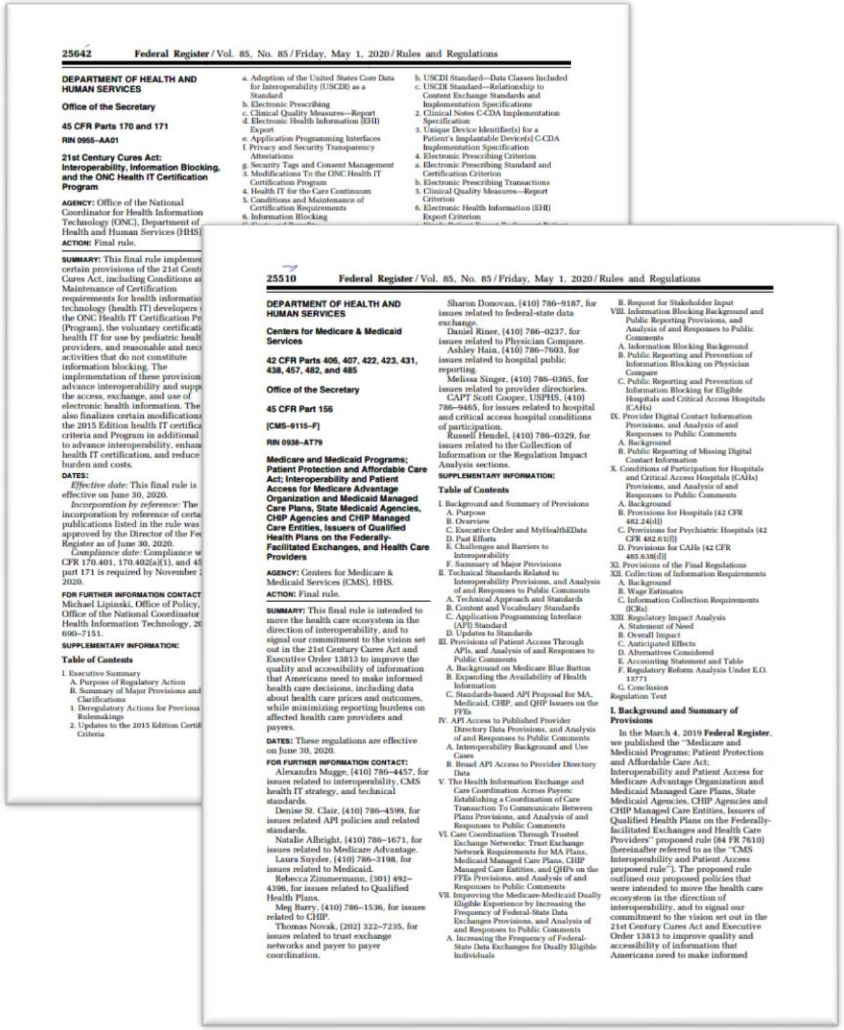
- Publication in Federal Register: 5/1/2020
- Enforcement discretion for Final Rule certification (not information blocking)

CMS

- Publication in Federal Register: 5/1/2020
- Final Rule modified from March version: ADT CoP pushed out by six months
- Enforcement discretion (some provisions)

OIG

- Proposed Rule—information blocking civil monetary penalties: 4/24/2020
- Limited enforcement discretion and delayed effective date
- Comments sought on some provisions



25642 Federal Register / Vol. 85, No. 85 / Friday, May 1, 2020 / Rules and Regulations

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 healthcare 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 final rule also finalizes certain modifications to the 2015 Edition health IT certification criteria and Program in additional part to advance interoperability, enhance health IT certification, and reduce burden and costs.

DATES:

Effective date: This final rule is effective on June 30, 2020.

Incorporation by reference: The incorporation by reference of certain publications listed in the rule was approved by the Director of the Federal Register as of June 30, 2020.

Compliance date: Compliance with 45 CFR 170.401, 170.402(a)(1), and 45 CFR part 171 is required by November 2, 2020.

FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Policy, Office of the National Coordinator for Health Information Technology, 202–690–7151.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 406, 407, 422, 423, 431, 438, 457, 482, and 485

Office of the Secretary

45 CFR Part 156

[CMS–9115–F]

RIN 0938–AT79

Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule is intended to move the health care ecosystem in the direction of interoperability, and to signal our commitment to the vision set out in the 21st Century Cures Act and Executive Order 13813 to improve the quality and accessibility of information that Americans need to make informed health care decisions, including data about health care prices and outcomes, while minimizing reporting burdens on affected health care providers and payers.

DATES: These regulations are effective on June 30, 2020.

FOR FURTHER INFORMATION CONTACT: Alexandra Mugge, (410) 786–4457, for issues related to interoperability, CMS health IT strategy, and technical standards.

Denise St. Clair, (410) 786–4599, for issues related API policies and related standards.

Natalie Albright, (410) 786–1671, for issues related to Medicare Advantage.

Laura Snyder, (410) 786–3198, for issues related to Medicaid.

Rebecca Zimmermann, (301) 492–4396, for issues related to Qualified Health Plans.

Meg Barry, (410) 786–1536, for issues related to CHIP.

Thomas Novak, (202) 322–7235, for issues related to trust exchange networks and payer to payer coordination.

Sharon Donovan, (410) 786–9187, for issues related to federal-state data exchange.

Daniel Riner, (410) 786–0237, for issues related to Physician Compare.

Ashley Hain, (410) 786–7603, for issues related to hospital public reporting.

Melissa Singer, (410) 786–0365, for issues related to provider directories.

CAPT Scott Cooper, USPHS, (410) 786–9465, for issues related to hospital and critical access hospital conditions of participation.

Russell Hendel, (410) 786–0329, for issues related to the Collection of Information or the Regulation Impact Analysis sections.

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I. Background and Summary of Provisions

In the March 4, 2019 Federal Register, we published the "Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges and Health Care Providers" proposed rule (84 FR 7610) (hereinafter referred to as the "CMS Interoperability and Patient Access proposed rule"). The proposed rule outlined our proposed policies that were intended to move the health care ecosystem in the direction of interoperability, and to signal our commitment to the vision set out in the 21st Century Cures Act and Executive Order 13813 to improve quality and accessibility of information that Americans need to make informed

Information Blocking and Enforcement Discretion: ONC

- Information Blocking Compliance 11/2/2020
  - Per May 1 Federal Register publication date
- Conditions of Certification relevant to Information Blocking
  - *Compliance*: Information blocking, APIs, assurances 11/2/2020
  - *Enforcement:* delayed for 3 months after compliance date 2/2/2021
  - *Attestation*: (Info blocking, etc.) delayed from 3/31/2021 7/30/2021

April 21, 2020. https://www.healthit.gov/curesrule/resources/enforcement-discretion. This announcement does not directly affect Part 171—Information Blocking, which is addressed in the OIG Proposed Rule also released on April 21.

Enforcement Discretion: CMS

Current (Per Published Final Rule)

- Patient Access API (including Exchange QHPs) (*January 1, 2021*)
- Provider Directory API (*January 1, 2021*)
- Condition of Participation Admission, Discharge, and Transfer Event Notifications (S*pring 2021*)

Enforcement Discretion

- To July 1, 2021

- To July 1, 2021
- Note: In the Final Rule published May 1, 2020, CMS had moved ADT COP from 6 months (in initial display copy of the rule) to 12 months after Final Rule publication
- **All other dates remain in force**

April 21, 2020. https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index

Proposed Rule and Enforcement Discretion: OIG

OIG Proposed Rule

- Implements Cures provisions for Information Blocking CMPs
- Published April 24, 2020
- *Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules*
- **Comments due 60 days from publication–June 23, 2020**
- **Leadership Council to review draft Information Blocking Workgroup perspectives for Sequoia comments**

Federal Register / Vol. 85, No. 80 / Friday, April 24, 2020 / Proposed Rules 22979

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1003 and 1005

RIN 0936–AA09

Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the civil money penalty (CMP or penalty) rules of the Department of Health and Human Services (HHS or Department) Office of Inspector General (OIG) to: Incorporate new authorities for CMPs, assessments, and exclusions related to HHS grants, contracts, other agreements; incorporate new CMP authorities for information blocking; and increase the maximum penalties for certain CMP violations.

DATES: To ensure consideration, comments must be delivered to the address provided below by no later than 11:59 p.m. Eastern Standard Time on June 23, 2020.

ADDRESSES: In commenting, please reference file code OIG–2605–P. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission. However, you may submit comments using one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* (Attachments should be in Microsoft Word, if possible.)

2. *By regular, express, or overnight mail.* You may mail your printed or written submissions to the following address: Aaron S. Zajic, Office of Inspector General, Department of Health and Human Services. Attention: OIG–2605–P, Cohen Building, 330 Independence Avenue SW, Room 5527, Washington, DC 20201.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* You may deliver, by hand or courier, before the close of the comment period, your printed or written comments to: Aaron S. Zajic, Office of Inspector General, Department of Health and Human Services, Attention: OIG–2605–P, Cohen Building, 330 Independence Avenue SW, Room 5527, Washington, DC 20201.

Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619–0335.

Inspection of Public Comments: All comments received before the end of the comment period will be posted on *http://www.regulations.gov* for public viewing. Hard copies will also be available for public inspection at the Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW, Washington, DC 20201, Monday through Friday from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 619–0335.

FOR FURTHER INFORMATION CONTACT: Robert Penezic at (202) 205–3211, Office of Counsel to the Inspector General.

SUPPLEMENTARY INFORMATION:

I. Executive Summary:

A. Purpose and Need for Regulatory Action

This proposed rule seeks to address three issues: (1) The amendment of the Civil Monetary Penalties Law (CMPL), 42 U.S.C. 1320a–7a, by the 21st Century Cures Act (Cures Act), Public Law 114–255, sec. 5003, authorizing HHS to impose CMPs, assessments, and exclusions upon individuals and entities that engage in fraud and other misconduct related to HHS grants, contracts, and other agreements (42 U.S.C. 1320a–7a(o)–(s)); (2) the amendment of the Public Health Service Act (PHSA), 42 U.S.C. 300jj–52, by the Cures Act authorizing OIG to investigate claims of information blocking and providing the Secretary of HHS (Secretary) authority to impose CMPs for information blocking; and (3) the increase in penalty amounts in the CMPL effected by the Bipartisan Budget Act of 2018 (BBA 2018), Public Law 115–123. Each of these issues is discussed further below.

First, this proposed rule would modify 42 CFR parts 1003 and 1005 to add HHS's new authority related to fraud and other misconduct involving grants, contracts, and other agreements into the existing regulatory framework for the imposition and appeal of CMPs, assessments, and exclusions. The additions would: (1) Expressly enumerate in the regulation, HHS's grant, contract, and other agreement fraud and misconduct CMPL authority; and (2) give individuals and entities sanctioned for fraud and other misconduct related to HHS grants, contracts, and other agreements, the same procedural and appeal rights that currently exist under 42 CFR parts 1003 and 1005 for those sanctioned under the CMPL and other statutes for fraud and other misconduct related to, among other things, the Federal health care programs. We propose to codify these new authorities and their corresponding sanctions in the regulations at §§ 1003.110, 1003.130, 1003.140, 1003.700, 1003.710, 1003.720, 1003.1550, 1003.1580, and 1005.1.

Second, Section 4004 of the Cures Act added sec. 3022 to the PHSA, 42 U.S.C. 300jj–52, which, among other provisions, provides OIG the authority to investigate claims of information blocking and authorizes the Secretary to impose CMPs against a defined set of individuals and entities that OIG determines committed information blocking. Investigating and taking enforcement action against individuals and entities that engage in information blocking is consistent with OIG's history of investigating serious misconduct that impacts HHS programs and beneficiaries. Information blocking can pose a threat to patient safety and undermine efforts by providers, payers, and others to make our health system more efficient and effective. Addressing the negative effects of information blocking is consistent with OIG's mission to protect the integrity of HHS programs, as well as the health and welfare of program beneficiaries.

We propose to implement 3022(b)(2)(C), which requires information blocking CMPs to follow the procedures of sec. 1128A of the Act. Specifically, the proposed rule would add the information blocking CMP authority to the existing regulatory framework for the imposition and appeal of CMPs, assessments, and exclusions (42 CFR parts 1003 and 1005), pursuant to the PHSA sec. 3022(b)(2)(C) (42 U.S.C. 300jj–52(b)(2)(C)). The proposed modifications would give individuals and entities subject to CMPs for information blocking the same procedural and appeal rights that currently exist under 42 CFR parts 1003 and 1005. We propose to codify this new information blocking authority at §§ 1003.1400, 1003.1410, and 1003.1420. The proposed rule also explains OIG's anticipated approach to enforcement and coordination within HHS to implement the information blocking authorities.

The Office of the National Coordinator for Health Information Technology (ONC) has finalized the

April 21, 2020. https://oig.hhs.gov/newsroom/news-releases/2020/infoblocking.asp

Proposed Regulatory Text

Subpart N—CMPs for Information Blocking

§ 1003.1400 Basis for civil money penalties.

The OIG may impose a civil money penalty against any individual or entity described in 45 CFR 171.103(b) that commits information blocking, as defined in 45 CFR part 171.

§ 1003.1410 Amount of penalties.

(a) The OIG may impose a penalty of not more than $1,000,000 per violation.

(b) For this subpart, *violation* means a practice, as defined in 45 CFR 171.102, that constitutes information

blocking, as defined in 45 CFR part 171.

§ 1003.1420 Determinations regarding the amount of penalties.

In considering the factors listed in § 1003.140, the OIG shall take into account—

(a) The nature and extent of the information blocking; and

(b) The harm resulting from such information blocking, including, where applicable--

(1) The number of patients affected;

(2) The number of providers affected; and

(3) The number of days the information blocking persisted.

CMP Applicability

- CMPs can be imposed on developers or other entities offering certified health IT, health information exchanges or networks
- Providers are not subject to CMPs unless also HIE/HIN or Developer
- Providers OIG determines are information blocking will be referred to "appropriate agency" to be subject to "applicable disincentives" (e.g., HHS OCR for HIPAA or CMS re: incentive program attestations)

OIG Investigations

- OIG has discretion on which complaints to investigate
- OIG expects to focus on cases that:
  - Caused or could cause patient harm
  - Significantly impacted a provider's ability to provide patient care
  - Persist over a long duration
  - Cause financial loss to Federal health care programs, other government or private entities
  - Actual knowledge by the Actor
- OIG will not bring enforcement actions for "innocent mistakes"
- Allegations to be evaluated per facts and circumstances unique to case

Workgroup Perspectives

- OIG sole authority to decide which allegations of information blocking it will investigate creates uncertainty for those who believe they have faced information blocking as well as Actors developing implementation and compliance plans
- Since the information blocking rule does not provide a private right of action, investigation by OIG is an essential remedy for such parties and a critical compliance issue for Actors
- OIG identifies 5 factors it will consider in initiating investigations; it should indicate whether these factors are equally weighted
  - e.g., is evidence of patient harm more likely to result in an OIG investigation than is a practice of long duration but did not result in harm?
- OIG should provide more guidance on how it will evaluate information blocking "intent
  - If possible, examples of what an Actor might do to demonstrate that it did not have the requisite intent would help Actors implement their programs to assure compliance with the information blocking requirements.

Enforcement Timing: Comments Sought

- OIG will not begin enforcement until OIG CMP information blocking regulations effective
  - *Proposa*l: 60 days after Final Rule published
  - *Alternative*: 10/1/2020 or other date certain, given ONC compliance date
- Enforcement discretion: Information blocking CMPs **after** effective date
  - Conduct **before** effective date not subject to CMPs
- **OIG seeks comment on proposed approaches, including other dates certain or enforcement timing**

Workgroup Perspectives

- OIG proposal to base enforcement on fixed period (e.g., 60 days) after final rule publication, makes sense
- OIG should clarify relationship of its enforcement date with compliance date set by ONC publication date
- OIG should finalize enforcement date (i.e., period after Final Rule) considering actual and anticipated availability of increased clarity and guidance on issues re: **ONC** Final Rule
- **Enforcement should not begin without more clarity than now exists**

Regulatory & Enforcement Approach: Comments Sought

- OIG investigations of information blocking will use ONC regulatory definitions and exceptions to assess Actors' conduct and ONC Final Rule provisions are incorporated by reference in OIG's proposed rule
- CMP determination would be subject to CMP procedures and appeal process in parts 1003 and 1005
- **OIG seeks comment on proposed incorporation of information blocking regulations into 42 CFR part 1003, and proposed application of existing CMP procedures and appeal process in parts 1003 and 1005 to the information blocking CMPs**

Workgroup Perspectives

- Proposed regulatory codification of the information blocking regulations seems appropriate, as does application of existing CMP and appeals processes
- The latter will enhance compliance by organizations, attorneys, and compliance professionals already familiar with OIG CMP processes

Maximum Penalties: Comments Sought

- OIG proposes new § 1003.1410 to codify maximum OIG penalty per information blocking violation
  - Cures authorizes maximum penalty of $1,000,000 per violation and proposed regulatory language reflects this maximum
- Proposed rule would define "violation" as each "practice" that is "information blocking," using definitions in ONC Final Rule
- OIG points to ONC examples of conduct that would meet the definition of information blocking
- **OIG solicits comments on proposed regulatory language**

Workgroup Perspectives

- Proposed regulatory language is appropriate given explicit Cures provisions for maximum penalties

OIG Examples of a Single Violation

- A health care provider notifies its health IT developer of its intent to switch to another EHR system and requests a complete electronic export of its patients' EHI via the capability certified to in 45 CFR § 170.315(b)(10). The developer refuses to export any EHI without charging a fee. **The refusal to export EHI without charging this fee would constitute a single violation.**
- A health IT developer (D1) connects to a health IT developer of certified health IT (D2) using a certified API. D2 decides to disable D1's ability to exchange information using the certified API. D1 requests EHI through the API for **one patient** of a health care provider for treatment. As a result of D2 disabling D1's access to the API, D1 receives an **automated denial of the request**. **This would be considered a single violation.** [Note the focus on a refusal for a single patient by another developer.]

OIG Examples of Multiple Violations

- A developer's software license agreement with one customer prohibits the customer from disclosing to its IT contractors certain technical interoperability information (i.e. Interoperability elements), without which the customer and the IT contractors cannot access and convert EHI for use in other applications. The developer also chooses to perform maintenance on the health IT that it licenses to the customer at the most inopportune times because the customer has indicated its intention to switch its health IT to that of the developer's competitor. **For this specific circumstance, one violation would be the contractual prohibition on disclosure of certain technical interoperability information and the second violation would be performing maintenance on the health IT in a discriminatory fashion. Each violation would be subject to a separate penalty.** [Note the problematic contract provision as a violation.]
- A developer requires vetting of third-party applications before the applications can access the developer's product. The developer denies applications based on the functionality of the application. **There are multiple violations based on each instance the health IT developer vets a third-party application because each practice is separate and based on the specific functionality of each application. Each of the violations in this specific scenario would be subject to a penalty.**

OIG Examples of Violations: Comments Sought

- For single violation examples facts or circumstances could affect penalty amount but not likely result in determining that there were multiple violations
  - When investigating information blocking, OIG will assess facts and circumstances on a case-by-case basis, which may lead to determination of multiple violations
- In first example, **number of patients** affected by the developer's information blocking practice is factor OIG would consider for penalty amount
- For determining number of violations, the important fact would be that the developer engaged in *one practice* (charging fee to provider to export EHI for purposes of switching health IT) that meets elements of information blocking
  - Although several patients might be affected by developer's information blocking practice, the **developer only engaged in one practice** in response to the request from the provider. Therefore, the scenario in this example would be only one violation
- **ONC solicits comments, for purposes of the final rule, on the examples of a single violation and what constitutes a single violation**

OIG Examples of Violations: Comments Sought

- For the examples illustrating multiple violations, ONC notes that important facts, in determining number of violations, are the **discrete practices** that each meet the elements of information blocking definition
- In first example, the developer engages in two separate practices: (1) prohibiting disclosure of technical interoperability information and (2) performing maintenance on the health IT in a discriminatory fashion
  - Each practice would meet definition of information blocking separately and therefore, first example is a two-violation scenario
- In second example, the health IT developer vets each third-party application separately and makes a separate decision for each application.
  - For each denial of EHI access based on *discriminatory* vetting, there is a practice that meets the definition of information blocking and each denial of access would be a separate violation
- **ONC solicits comments on proposed definition of "violation"**

OIG Examples of Violations: Comments Sought

Workgroup Perspectives

- Agree makes sense to define "violation" as a "practice" per ONC Final Rule
- OIG should codify in Final Rule more specific bases for identifying single vs. multiple acts or omissions, reflecting its preamble text and finalized examples
- Appreciate OIG's statement that "[a]s with the prior examples, these examples assume that the facts meet all the elements of the information blocking definition, which includes the requisite level of statutory intent, are not required by law, and do not meet any exception established by the ONC Final Rule"
- It would be helpful if each such example in the Final Rule specifically notes that an applicable exception does not apply (e.g., the Security exception for vetting), as such examples may be used by the community in a context and format that does not include this general statement about exceptions

CMP Penalty Determination: Comments Sought

- OIG may impose CMPs of up to $1 million "per violation"
- OIG will determine CMP based on:
  - Nature and extent of information blocking
  - Harm from information blocking
  - Number of patients affected
  - Number of providers affected
  - Duration of information blocking calculated as the number of days the blocking persists
- **OIG seeks comment on additional factors**

Workgroup Perspectives

- OIG should consider as mitigating factor and basis for no or reduced CMPs, challenges Actors face from COVID-19
- Information blocking that hinders COVID-19 responses (and meets thresholds for intent, impact, lack of an applicable exception, etc.) should likely receive higher CMPs than other blocking
- Although number of patients and providers affected is a logical factor in assessing CMP levels, OIG should also take great care to avoid creating de facto incentives for information blocking against smaller entities (fewer providers and patients) as opposed to larger entities, especially as smaller entities, many of whom may be in rural or underserved areas and may have fewer resources to engage effectively with potential information blockers

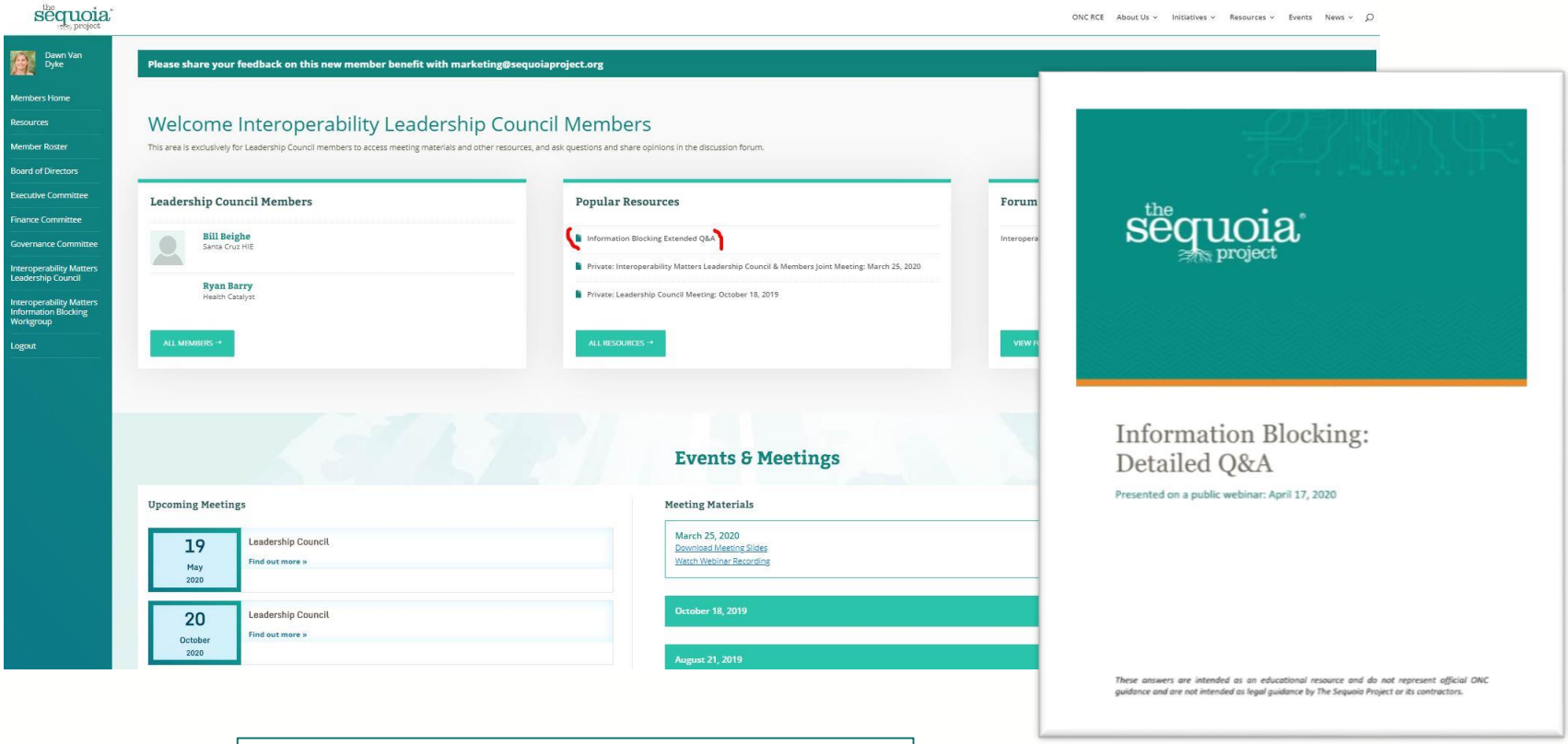
Implementation and Compliance Resources and Other Next Steps

Resources for the Community

Polling from April Public Webinar

- **82% - Compliance guides**
- **79% - Implementation tools and checklists**
- **59% - Facilitating ONC presentations and Q&A**
- 55% - Additional Sequoia Project webinars
- 36% - Opportunities for moderated industry discussion

Leadership Council-Only Resources: Extended Information Blocking Q&A and More to Come

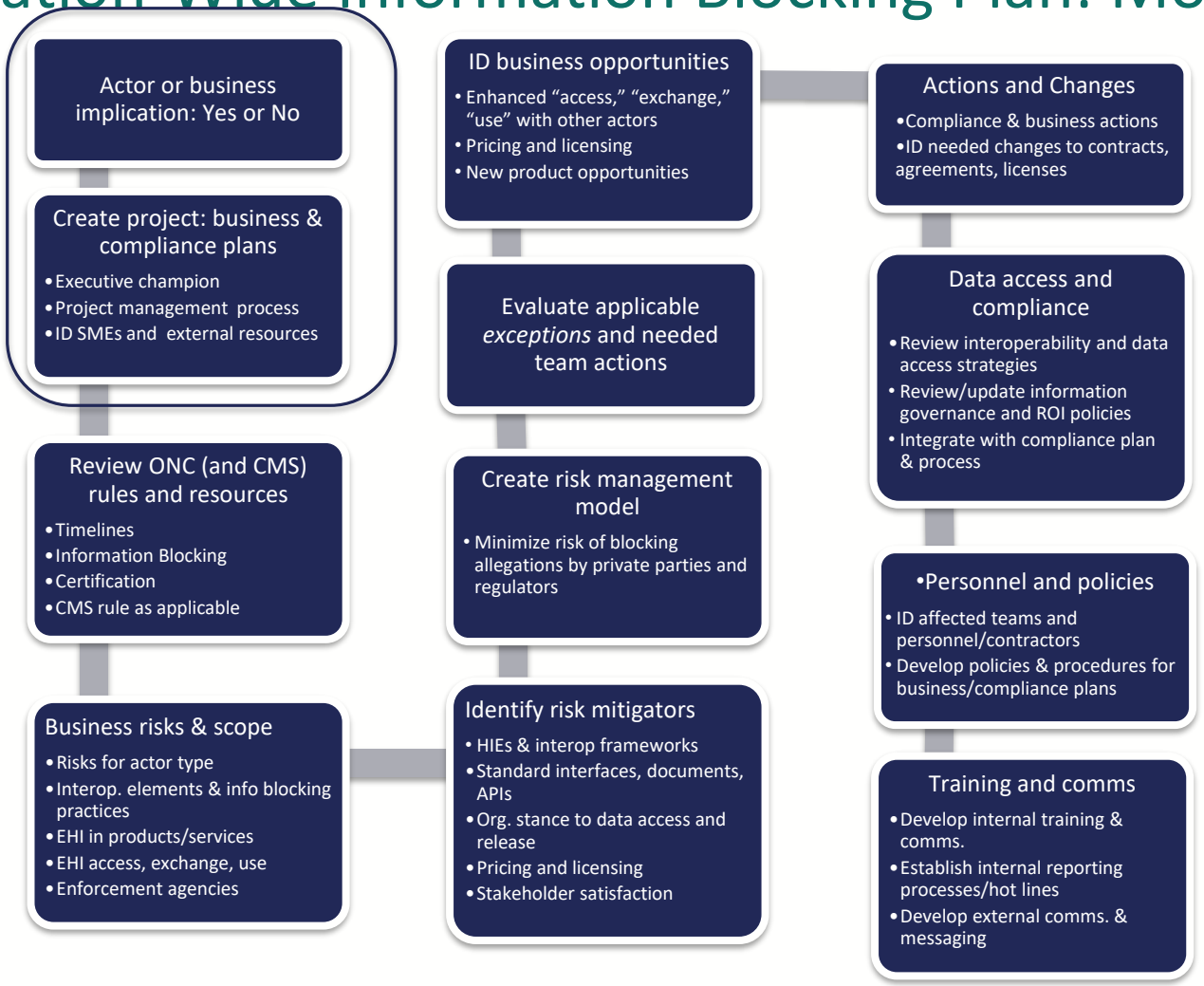


https://sequoiaproject.org/community/

Information Blocking: Implementation Planning

Sample 1 for Leadership Council Feedback

Organization-Wide Information Blocking Plan: Model



Does the ONC Information Blocking Rule Matter to My Organization?

- ❑ Is my organization an Actor under the ONC rule, and therefore subject to its requirements, and if so for which of our business units?
  - ☞ Tip: Review the definitions of the three types of Actor
  - ☞ Tip: An organization that would not otherwise be an Actor (e.g., a health plan) might have lines of business that qualify it as an Actor (e.g., an HIE/HIN or provider), at least for the applicable line(s) of business
  - ❑ Yes
    - ➢ Which lines of business? _____
  - ❑ No
    - ❑ Are you likely to have market or commercial implications from the rule, such as increased access to Electronic Health Information from Actors?
      - ❑ Yes – Go to the section on new market opportunities.
      - ❑ No - STOP

If the ONC Information Blocking Rule Matters to My Organization (1)

- Step one is to **create an organizational "information blocking" project or initiative**. If your organization **is an Actor** (in whole or in part) this project will likely be more elaborate, with a compliance focus. If it is **not an Actor**, it will likely focus on commercial, product, and technical issues. _____
- This **project** should drive development of an **integrated set of business plans** appropriate to the focus and scale of your organization (e.g., product, engineering, marketing, commercial, legal, HR/training, communications, etc.)._____
  _____
- If your organization is an Actor, you will also need to develop and implement a Compliance Plan, which should complement and integrate with the business plans.
- Before or after project creation, you will want to designate an overall senior **executive project owner**/champion to ensure that this project receives needed resources, influence and accountability_____

If the ONC Information Blocking Rule Matters to My Organization (2)

- ❑ Once the **project** is established, best practice is to establish a project management process (e.g., PMO) accountable to the **executive project owner**_____
  - ❑ You may want to create **sub-projects**_____
- ❑ Depending on your size and structure, you will also want to designate **business unit project owners**_____
- ❑ To support this project, you will want to Identify/designate/train **internal subject matter experts** (SMEs) and project champions and influencers_____
  - ☞ Tip: You may need to identify and mitigate staff misalignments between a HIPAA-driven focus on *information protection* and Cures focus on *information sharing.* This process may require cultural/professional reorientation and change management to navigate the shift from a HIPAA focus to one that strikes a HIPAA/Information Blocking balance.
- ❑ You will also want to identify needed external resources (e.g., legal, compliance, policy, training) _____
- ❑ Finally, you will want to identify and engage with external industry resources (e.g., associations, interoperability initiatives, experts, colleagues)_____

Interoperability Matters Updates

Data Quality and Usability Work Group

- Prioritized by Leadership Council in August 2019
- Approved by the Sequoia board in September 2019 as budgeted 2020 project
- Coordinated timeframe with similarly chartered Carequality-CommonWell Data Content Work Group
- Targeted launch for Interoperability Matters in Fall 2020
- Identified Co-Chairs
  - Dr. David Camitta, Common Spirit
  - Dr. Bill Gregg, HCA
- Next Steps:
  - Develop work group charter
  - Develop work plan
  - Launch in coordination with conclusion of existing Content Work Group

RCE Update

ONC TEFCA RCE Progress

Common Agreement

- Completed ONC-RCE contract language review sessions
- Completed research for about 6-7 MRTC policy topics
- Drafted and reviewed ARTCs with ONC
- Launched Common Agreement Work Group (CAWG)
- Compiling MRTCs + ARTCs into a single agreement for CAWG review

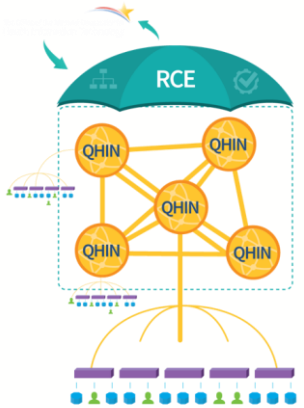
Stakeholder Engagement

- Launched stakeholder engagement in November ‘19
- Stakeholder feedback meetings well attended
- Started monthly informational calls in April, with strong stakeholder interaction
- Building understanding and value proposition for TEFCA

QHIN Technical Framework

- Public input informed the QTF
- Defined scope (document-based queries and message delivery, with FHIR v4 as road map)
- Draft QTF v2 submitted to ONC 3/30
- Review sessions under way

What's Next?



- RCE will facilitate the CAWG process
- RCE will host monthly informational calls
- RCE will host a public call regarding the ARTCs
- RCE will submit drafts to ONC
  - Common Agreement Draft Version 1 for Public Comment – Combined contract terms (MRTCs / ARTCs)
  - QHIN Technical Framework (QTF) – Draft 2
- ONC will post the QTF Draft 2 and Common Agreement Draft Version 1 for public comment
- Public comments will inform next iteration of the Common Agreement and QTF

Get involved: https://rce.sequoiaproject.org/contact/

Leadership Council Meetings: 2020

Leadership Council Meeting Dates: 2020

Date	Time
July 21, 2020	2:30-3:30pm ET
September 15, 2020	2:30-3:30pm ET
October 20, 2020	2:30-4:00pm ET
December 15, 2020	2:30-3:30pm ET

Interoperability Matters

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