

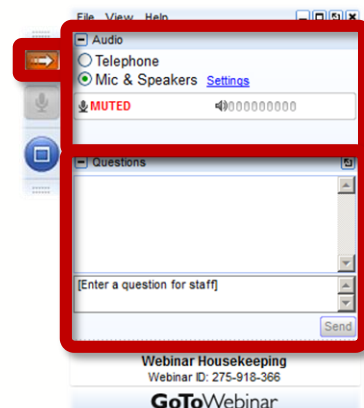


# Information Blocking Compliance and Enforcement

## Public Advisory Forum

*6/11/2020*

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[interopmatters@sequoiaproject.org](mailto:interopmatters@sequoiaproject.org)

# Meet The Sequoia Project Team



Mariann Yeager  
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# Information Blocking 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**

- Melissa Soliz, 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 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 published on April 24, 2020.

# 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 (*Spring 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**
- **Sequoia Project submitted Information Blocking Workgroup perspectives as transmitted by the Leadership Council and approved by the Sequoia Board\*\***



\*<https://oig.hhs.gov/newsroom/news-releases/2020/infoblocking.asp>,  
 \*\*<https://sequoiaproject.org/resources/public-comments/>

# 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” and identify “innocent mistakes”
  - 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
  - *Proposal*: 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 should clarify relationship of its enforcement date with ONC compliance date (11/2/2020)
- Basing enforcement on a fixed period after final rule publication, makes sense
- Given COVID-19, some on Workgroup favor CMP application/enforcement six months (vs. 60-day proposal) after publication, with initial advisory process
- OIG should finalize enforcement date 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 provisions 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
- Some on Workgroup believe that 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

# Provider Compliance and Enforcement is TBD

- **“This proposed rule does not apply to health care providers who engage in information blocking.<sup>1</sup>”**
- **“... providers that also meet the definition of a health information exchange or health information network as defined in the ONC Final Rule would be subject to information blocking CMPs.”**
- **“Once established, OIG will coordinate with, and send referrals to, the agency or agencies identified in future rulemaking by the Secretary that will apply the appropriate disincentive for health care providers that engage in information blocking, consistent with sec. 3022(b)(2)(B).”**



**“<sup>1</sup> While health care providers are not subject to information blocking CMPs, many must currently comply with separate statutes and regulations related to information blocking.”**

MACRA (2015) requires a provider to “demonstrate that it has not knowingly and willfully taken action to limit or restrict the compatibility or interoperability of Certified Electronic Health Record (EHR) Technology.”

CMS “established and codified **attestation requirements to support the prevention of information blocking, which consist of three statements** containing specific representations about a health care provider’s implementation and use of Certified EHR technology” that **do not reference “information blocking” nor its Cures/ONC definition**

The Sequoia Project letter emphasized the need for greater OIG clarity on how it will handle information blocking complaints regarding providers, especially in the absence of the forthcoming rule on provider disincentives and referrals.



# Questions



# Interoperability Matters

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