

Information Blocking Compliance and Enforcement Public Advisory Forum 6/11/2020



How To Participate Today





Problems or Questions? Contact the Sequoia Project Team at:

interopmatters@sequoiaproject.org



Meet The Sequoia Project Team



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Mark Segal Principal Digital Health Policy Advisors



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



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 due: 6/23/2020





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**

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

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)

DEPARTMENT OF HEALTH AND

Office of Inspector General

42 CFR Parts 1003 and 1005

Grants, Contracts, and Other

Inspector General's Civil Mc AGENCY: Office of Inspector ((OIG), HHS.

SUMMARY: This proposed rule amend the civil money penal penalty) rules of the Departm Health and Human Services

Department) Office of Inspec (OIG) to: Incorporate new as

CMPs assessments and excl

related to HHS grants, contra

agreements; incorporate new authorities for information b

and increase the maximum t certain CMP violations.

DATES: To ensure considerat comments must be delivered address provided below by r

11:59 p.m. Eastern Standard

reference file code OIG-2605

Because of staff and resource limitations, we cannot accept by facsimile (fax) transmis

However, you may submit co

using one of three ways (no

1. Electronically. You may

electronically through the Fe eRulemaking Portal at http://

www.regulations.gov. (Attack should be in Microsoft Word

2. By regular, express, or o mail. You may mail your prin

written submissions to the fo

address: Aaron S. Zajic, Offic

Inspector General, Departme and Human Services, Attenti

2605-P, Cohen Building, 33

Independence Avenue SW. 8 Washington, DC 20201.

Please allow sufficient tir

comments to be received before close of the comment period.

3. By hand or courier. You

deliver, by hand or courier,

close of the comment period,

printed or written comments S. Zajic, Office of Inspector G

Department of Health and Hu

Services, Attention: OIG-266

June 23, 2020. ADDRESSES: In commenting

Agreements: Fraud and Abuse; Information Blocking; Office of

HUMAN SERVICES

RIN 0936-AA09

Inspection of Public Comments: All comments received before the end of the

sanctioned for fraud and othe misconduct related to HHS grants, contracts, and other agreeme same procedural and appeal rights tha 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

June 3, 2020

Agron S Zaiic 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

Re: Proposed Rule on Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking: Office of Inspector General's Civil Money Penalty Rules RIN 0936-AA09

Submitted electronically at http://www.regulations.gov

The Sequoia Project is pleased to submit these comments on the Proposed Rule on Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's (OIG) Civil Money Penalty Rules. Our comments focus on the amendment by the 21st. Century Cures Act (Cures Act) of the Public Health Service Act (PHSA), 42 U.S.C. 300jj-5, authorizing the OIG to investigate claims of information blocking and providing the Secretary (Secretary) of Health and Human Services (HHS) authority to impose Civil Monetary Penaltie (CMPs) for information blocking.

The Sequoia Project is a non-profit, 501(c)(3) public-private collaborative that advances the interoperability of electronic health information for the public good. The Sequoia Project previously served as a comorate home for several independently governed health IT interoperability initiatives, including the eHealth Exchange health information network and the Carequality interoperability framework. The effealth Exchange and Carequality now operate under their own non-profit organizations. The Sequoia Project currently supports the RSNA Image Share Validation Program, the Patient Unified Lookup System for Emergencies (PULSE), and the Interoperability Matters Cooperative. Lastly, we are honored to have been selected by the Office of the National Coordinator for Health IT (ONC) to be the Recognized Coordinating Entity (RCE) for the Trusted Exchange Framework and Common Agreement (TEFCA).

These comments reflect our experience supporting large-scale, nationwide health information sharing, including active work with several federal government agencies. Through these efforts, we serve as an experienced, transparent and neutral convener of public and private sector stakeholders to address and resolve practical challenges to interoperability. Our deep experience implementing national-level health IT interoperability, including our track record

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*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

- 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

- 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

- 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

- 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

- 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
- Patthough 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.¹"
- "... 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)."

"1 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.

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Questions





Interoperability Matters

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