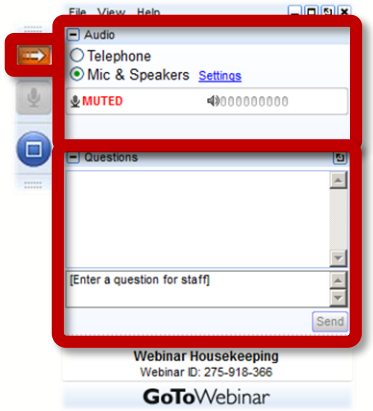
Information Blocking Compliance and Enforcement

The Sequoia Project Member Meeting

6/4/2020

How To Participate Today



Your Participation

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Note: Today's presentation is being recorded and will be provided

Problems or Questions? Contact the Sequoia Project Team at:

interopmatters@sequoiaproject.org

Meet The Sequoia Project Team

Mariann Yeager
CEO
The Sequoia Project

Steve Gravely
Founder & CEO
Gravely Group

Mark Segal
Principal
Digital Health Policy Advisors

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Sylvia Trujillo
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- 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

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- 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

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- Eric Liederman, Kaiser Permanente

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- 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

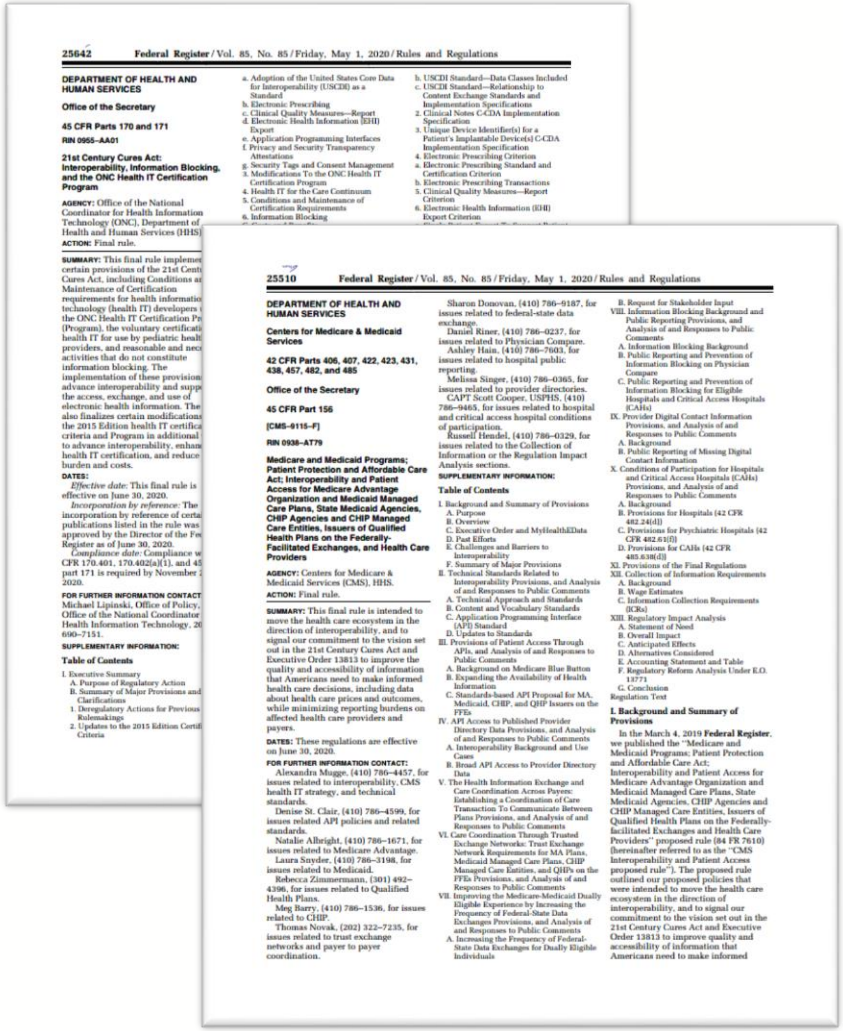
- Publication in Federal Register: 5/1/2020
- Enforcement discretion for Final Rule certification (not information blocking)

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



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

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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 (the Department) Office of Inspector General (OIG) to: Incorporate new authorities for CMPs, assessments, and exclusions related to HHS grants, contracts, and other agreements; incorporate new authorities for information blocking CMPs; and increase the maximum penalty amounts for certain CMP violations.

DATES: To ensure consideration, comments must be delivered to the address provided below by 5:00 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 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, 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

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

the sequoia project

June 3, 2020

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

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

Dear Mr. Zajic:

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 Penalties (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 corporate home for several independently governed health IT interoperability initiatives, including the eHealth Exchange health information network and the Carequality interoperability framework. The eHealth 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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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" an 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
  - *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 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.[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."

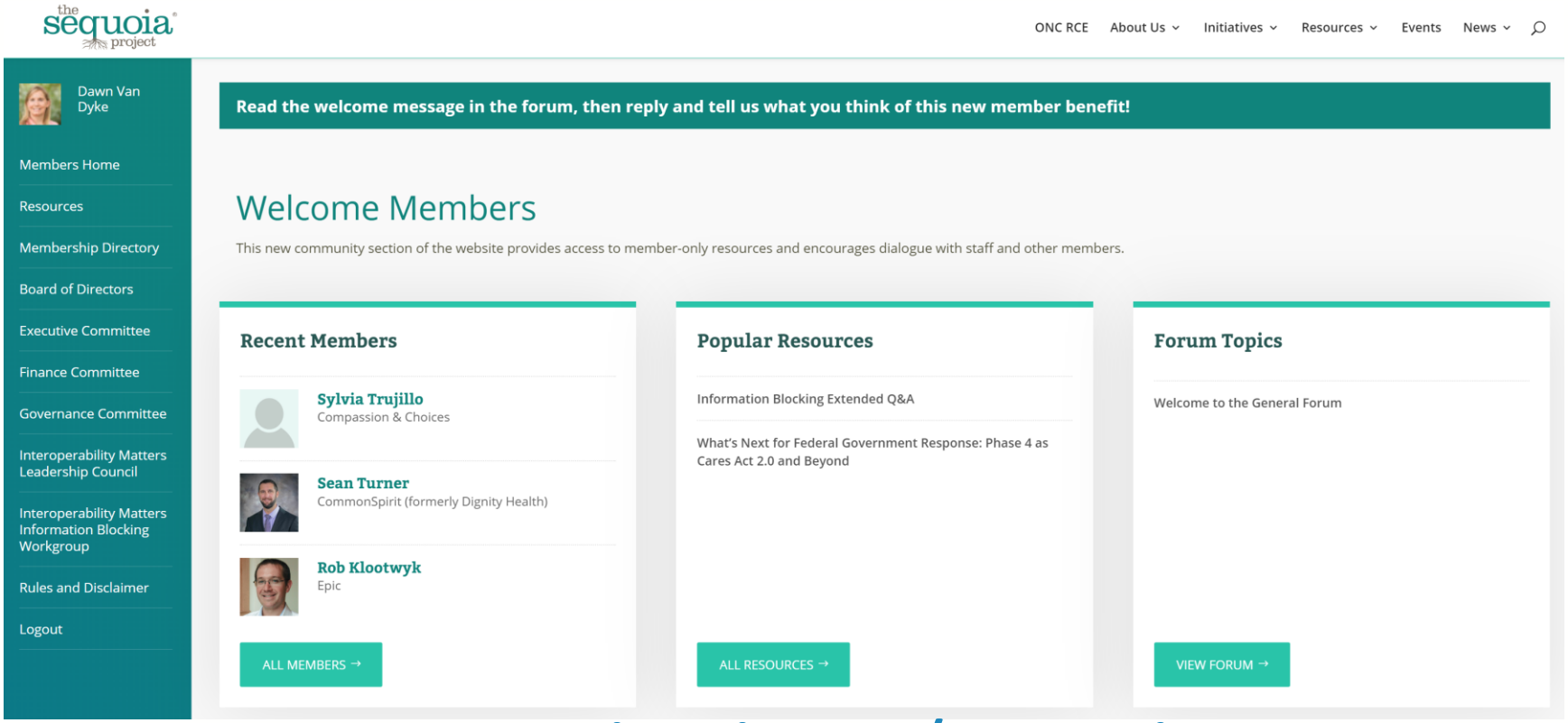
CMS "established and codified **attestation requirements to support the prevention of information blocking, which consist of three statements** containing specific representations about a health care provider's implementation and use of Certified EHR technology" that **do not reference "information blocking" 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.

Federal Register / Vol. 85, No. 80 / Friday, April 24, 2020 / Proposed Rules **22981**

New Online Community for Members!

Features Include Access to Member-Only Resources; the new Member Directory, Message Forums for Discussion, and more



www.sequoiaproject.org/community

Questions

Interoperability Matters

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