

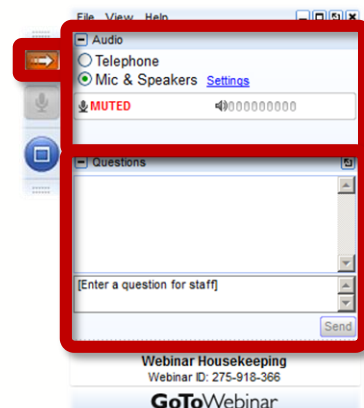


Interoperability Matters

Public Advisory Forum

7/23/2020

How To Participate Today



Your Participation

Open and close your control panel

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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

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 – Co-chair	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	Jeff Coughlin	Amit Trivedi
HITRUST Alliance	Michael Parisi	Anne Kimbol
Humana	Nancy Beavin	
ID.me	Blake Hall	Joan Rodriguez-Vogel
IHIE	Ammon Fillmore	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	Shreya Patel	Drew Murray
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	
Veterans Administration	Jeffrey Anderson, MD	Cindy Pan
WOMBA	Moti Mitteldorf	Eli Rowe

Agenda

- Welcome and Introductions
- Review of Agenda
- Information Blocking Workgroup: Phase 3 Update
- Quick Review of Timelines
- Compliance and Implementation Readiness: Discussion
- RCE Update
- Closing

Information Blocking Workgroup Phase 3

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 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)
- ✓ Public Webinar (6/11/2020)
- ✓ Meeting #15 (6/12/2020)
- ✓ Meeting #16 (7/10/2020)
- 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 plans and resources
- Review industry readiness

Focus on implementation and compliance implications of ONC Final Rule.

Quick Review of Timelines

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 170 and 171

RN 000-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 Certifications and Maintenance of Certification requirements for health information technology (Health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. The implementation of these provisions will advance interoperability and support the access, exchange, and use of electronic health information. The rule also finalizes certain modifications to the 2013 Edition Health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.

DATES: Effective date: This final rule is effective on 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 170.403, 170.404(a), 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, 202-690-7331.

SUPPLEMENTARY INFORMATION: Table of Contents

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d. Updates to the 2013 Edition Certification Criteria

2. Information Blocking

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b. Summary of Major Provisions and Modifications

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Secretary

42 CFR Parts 406, 407, 408, 422, 423, 424, 425, 426, 427, 428, and 485

45 CFR Part 156

[CMS-0115-F]

RN 000-AA79

Medicare and Medicaid Programs: Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Entities, Issuance 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 proposed rule would amend the civil monetary penalty (CMP) as provided in the Department of Health and Human Services (HHS) or Department) Office of Inspector General (OIG). To incorporate new authorities for CMP, 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: These regulations are 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 42 CFR 406.403, 407.404(a), and 45 CFR part 171 is required by November 2, 2020.

FOR FURTHER INFORMATION CONTACT: Alexander Mager, (410) 786-4437, for issues related to interoperability, CMS health IT strategy, and technical standards.

Denise St. Clair, (410) 786-4599, for issues related to APT policies and related standards.

Natalie Altshuler, (410) 786-1071, for issues related to Medicare Advantage.

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

Rebecca Zimmermann, (202) 692-4206, for issues related to Qualified Health Plans.

May Barry, (410) 786-3326, for issues related to CHIP.

Thomas Norish, (202) 322-7225, for issues related to private equity networks and trust to payer coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1003 and 1005

RN 000-AA08

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 monetary penalty (CMP) as provided in the Department of Health and Human Services (HHS) or Department) Office of Inspector General (OIG). To incorporate new authorities for CMP, 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: These regulations are 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 42 CFR 1003.403, 1005.404(a), and 45 CFR part 171 is required by November 2, 2020.

FOR FURTHER INFORMATION CONTACT: Robert Pennington, (202) 201-2211, 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 Penalty 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 CMP, 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); (2) the amendment of the Public Health Service Act (PHSA), 42 U.S.C. 200101, 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 for the CMPL effected by the Bipartisan Budget Act of 2018 (BBA), Public Law 115-124. 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 grants, contracts, and other agreements with the existing regulatory framework for the imposition and appeal of CMPs, assessments, and exclusions. The additions would implement the information blocking in the regulations, HHS's intent, contract, and other agreement fraud and misconduct (CMP) authority, and OIG's new authority to impose CMPs on individuals and their corresponding entities in the regulations of 42 CFR parts 1003 and 1005 for the same prohibited and appeal rights that currently exist under 42 CFR parts 1003 and 1005 for those sanctioned under the CMP, and other entities 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 sections in the regulations of 42 CFR parts 1003, 1005, 1006, 1007, 1008, 1009, 1010, 1011, 1012, 1013, 1014, 1015, 1016, 1017, 1018, 1019, 1020, 1021, 1022, 1023, 1024, 1025, 1026, 1027, 1028, 1029, 1030, 1031, 1032, 1033, 1034, 1035, 1036, 1037, 1038, 1039, 1040, 1041, 1042, 1043, 1044, 1045, 1046, 1047, 1048, 1049, 1050, 1051, 1052, 1053, 1054, 1055, 1056, 1057, 1058, 1059, 1060, 1061, 1062, 1063, 1064, 1065, 1066, 1067, 1068, 1069, 1070, 1071, 1072, 1073, 1074, 1075, 1076, 1077, 1078, 1079, 1080, 1081, 1082, 1083, 1084, 1085, 1086, 1087, 1088, 1089, 1090, 1091, 1092, 1093, 1094, 1095, 1096, 1097, 1098, 1099, 1100, 1101, 1102, 1103, 1104, 1105, 1106, 1107, 1108, 1109, 1110, 1111, 1112, 1113, 1114, 1115, 1116, 1117, 1118, 1119, 1120, 1121, 1122, 1123, 1124, 1125, 1126, 1127, 1128, 1129, 1130, 1131, 1132, 1133, 1134, 1135, 1136, 1137, 1138, 1139, 1140, 1141, 1142, 1143, 1144, 1145, 1146, 1147, 1148, 1149, 1150, 1151, 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Information Blocking and Enforcement Discretion: ONC and OIG

- *Information Blocking* Compliance: Six months after 5/2/2020 Federal Register publication date 11/2/2020
- *Conditions of Certification* relevant to Information Blocking
 - **Compliance: Information blocking, APIs, assurances** 11/2/2020
 - *Enforcement*: delayed 3 months after compliance date 2/2/2021
 - *Attestation*: (Info blocking, etc.) delayed from 3/31/2021 7/30/2021
 - *API Certification and USCDI*: delayed 3 months from 5/2/2022 8/2/2022
- HHS OIG issued a proposed rule for developers and HIEs/HIN penalties on 4/24/2020 per ONC information blocking rules, with some enforcement discretion TBD
- Regulations for provider “disincentives” are forthcoming TBD

Compliance and Implementation Readiness

Discussion Questions

1. What are the three biggest challenges that you see for organizations trying to understand and comply with the Information Blocking Rule? This could be based on your own organization's experience or what you are observing among your peers.
2. What are the greatest needs (e.g., information, resources, ONC guidance, time) for organizations developing compliance plans and projects in response to this rule?
3. What are three types of external support that will be the most helpful to your organization to better understand Information Blocking requirements?
4. Please identify any "urban myths" or other misunderstandings that you have heard about Information Blocking? How can we best separate fact from fiction?
5. What are your thoughts on information delivery approaches?
 - Webinars
 - Formal educational courses
 - PowerPoints
 - Infographics
 - Written outlines, checklists and narrative summaries

Compliance and Implementation Resources: New Offering

- Introducing Information Blocking Compliance Public Resource Center
- Launching the Information Blocking Compliance Boot Camp and Toolkit
 - Free to Sequoia Members
- Members Only Community of Practice
- Additional offerings to follow in the future

Topic

Rules Education

Compliance Education

The Sequoia Project's Public Comments

Compliance Toolkit

Resources From Our Partners

Community of Practice

Featured Resources

Rules Education

Prepare for Nov. 2nd Compliance Deadline



CMS Rule Overview and Detailed Analysis Report

*Coming Soon



Interoperability Matters Information Blocking Workgroup Phase 1: Draft Report (PDF)



Information Blocking Guidance to the Health IT Community (PDF)



Information Blocking and Interoperability Final Rules Are Here: Now What?

*Coming Soon



Follow-Up Information Blocking and Interoperability Final Rules Webinar: Featuring Extended Q&A (PDF)

[WATCH THE WEBINAR](#)



Information Blocking Extended Q&A Report

*Coming Soon

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
- Facilitated Common Agreement Work Group (CAWG)
- Compiled MRTCs + ARTCs into a working draft CA

Stakeholder Engagement

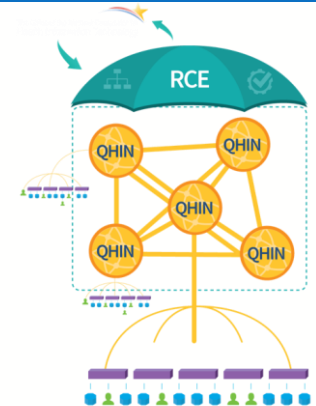
- Facilitated 30+ stakeholder feedback meetings
- Host monthly informational calls with strong stakeholder interaction
- Building understanding and value proposition for TEFCA
- Seeking input on Metrics and Operational Reporting

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 6/30
- Refinements under consideration

What's Next?

- 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
- Prepare kickoff of Year Two work



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



Questions

Interoperability Matters

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