Office of the National Coordinator for Health Information Technology

Office of Policy Update

Elise Sweeney Anthony, Executive Director, Office of Policy, ONC

January 19, 2023

Standards
Certification
Exchange
Coordination

Coordination Activities

HealthITbuzz
THE LATEST ON HEALTH IT FROM ONC

Search

Health IT Buzz > Health Equity > E Pluribus Unum

Health Equity, Interoperability, Public Health, Standards

E Pluribus Unum

Micky Tripathi and Steven Posnack | AUGUST 5, 2022

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As our nation transitions to a digital healthcare system, our stakeholders are discovering new opportunities for using health information technology to advance health care delivery, public health, and research to improve people's lives. The federal government is no exception in this regard; agencies across the Department of Health and Human Services (HHS) are beginning to leverage the data and capabilities available through electronic health records for a broad range of federal activities and programs, including product safety and surveillance, real world data and real world evidence for regulatory approvals, research, pandemic response, and social service integration, to name just a few.

https://www.healthit.gov/buzz-blog/interoperability/e-pluribus-unum

"…Secretary Becerra has put into place a department-wide management policy directing ONC to engage with HHS agencies to align and coordinate health IT-related activities in support of HHS health IT and interoperability goals."

"…ONC to establish and oversee a consistent HHS-wide approach for: 1) incorporating standard health IT requirements language in all applicable HHS funding programs, contracts, and policies; and 2) providing direct ONC assistance to HHS agencies to maximize the use of HHS-approved standards and authorities (such as Section 3004 of the Public Health Service Act) in their agency programs."

STAR HIE Program

- $5 million from the CARES Act (signed March 27, 2020), announced in two tranches:
  - September 2020: $2.5 million to support 5 HIEs in creating services that benefit public health agencies.
  - January 2021: Supplemental $2.5 million to support 17 HIEs (including 4 of the original 5 recipients) to specifically support increased data sharing between immunization information systems and HIEs.
- Objectives:
  - Build innovative health information exchange services that benefit public health agencies.
  - Improve the health information exchange services available to support communities disproportionately impacted by the COVID-19 pandemic.

STAR HIE Program

- Improved public health immunization interoperability by supporting public health agencies' ability to exchange health information during times of emergency (summarized in a May 2022 ONC Buzz Blog post)
- Supported efforts to improve vaccination data sharing between jurisdictional Immunization Information Systems and HIEs (e.g., West Virginia Health Information Network discussed in Nov. 2022 ONC Buzz Blog post)
- Earlier we heard from the Kansas Health Information Network (d/b/a KONZA), MyHealth Access Network (Oklahoma) and two of their public health partners who shared innovative health information exchange services that supported public health during the COVID-19 pandemic

The STAR HIE Program Shines

Larry Jessup; Laverne Perlie; Daisy Moossa and Terah Tessier | MAY 10, 2022

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The Strengthening t
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mation during times

STAR HIE Program Helps Unlock Powerful Public Health Data in West Virginia

Sonia Chambers; Kevin Eike; Larry Jessup and LaVerne Perlie | NOVEMBER 29, 2022

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TEFCA Update

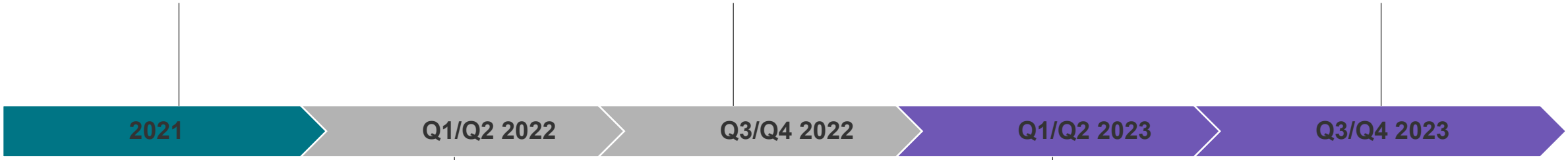
- As of January 2023, the RCE had received 6 applications from prospective QHINs
- Approved applicants will next enter the onboarding process to potentially be designated as QHINs
- RCE and ONC continue to work on Standard Operating Procedures, including for the Payment and Health Care Operations and Public Health Exchange Purposes
- The RCE plans to facilitate a connectathon-style testing event(s) as a pilot of FHIR under TEFCA in Feb-Mar 2023
- Please visit the RCE's website for resources and to sign up for announcements: RCE.SequoiaProject.org

Timeline to Operationalize TEFCA

2021
- Public engagement
- Common Agreement Work Group sessions
- RCE and ONC use feedback to finalize TEFCA

Q3/Q4 2022
- Finalize initial SOPs
- QHIN application review
- Prepare for TEFCA FHIR-based exchange pilot

Q3/Q4 2023
- Additional QHIN applications processed
- Continue onboarding of initial QHINs
- Refine Common Agreement, SOPs, and QTF, including to support FHIR-based exchange



Q1/Q2 of 2022
- Publish Common Agreement Version 1
- Publish QHIN Technical Framework (QTF) Version 1 and FHIR Roadmap
- Initiate work to enable FHIR-based exchange
- Public education and engagement

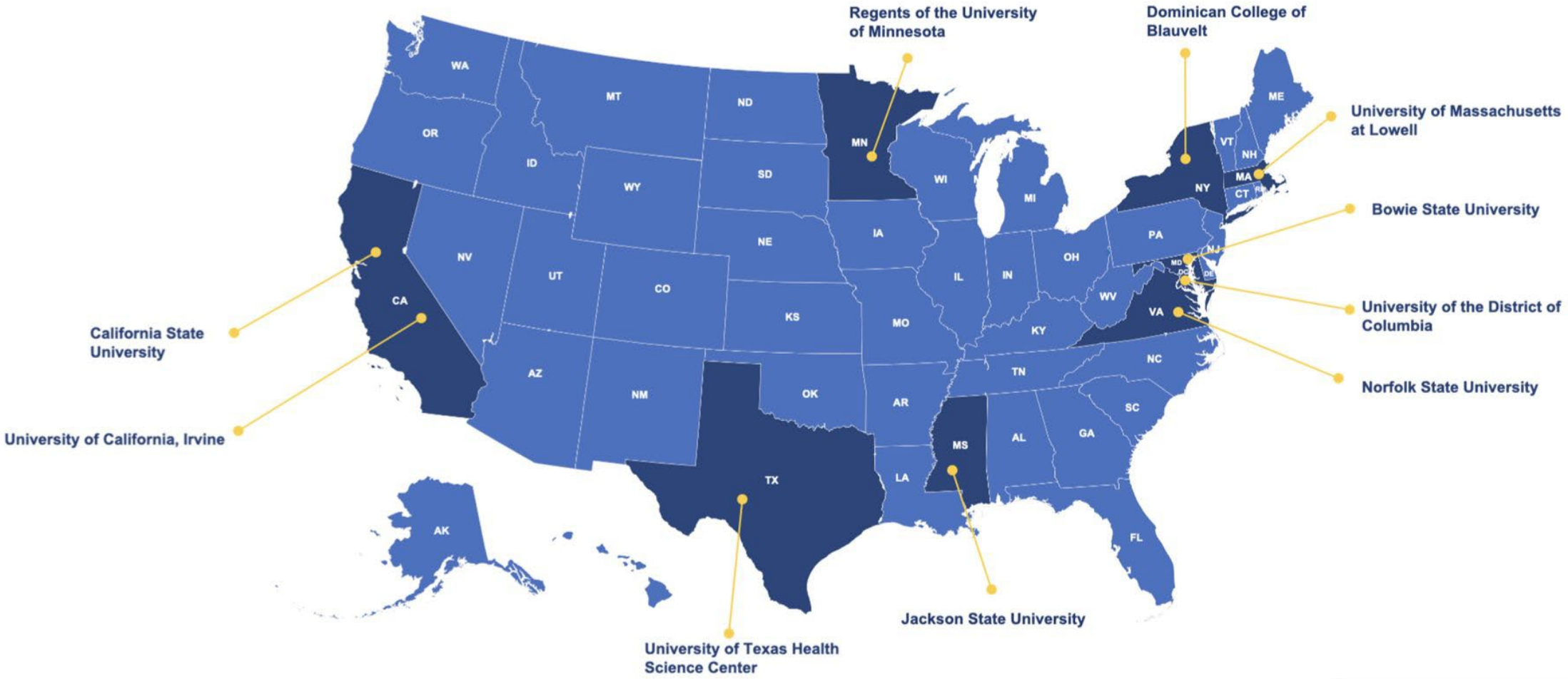
Q1/Q2 of 2023
- **Public announcement: First Approved QHIN Applicants**
- Onboarding of initial QHINs
- Additional QHIN applications processed
- Launch TEFCA FHIR-based exchange pilot

Diversifying the PHIT Workforce

- Over $75 million awarded to increase the number of public health professionals trained, with a focus on recruiting from minority serving institutions (MSIs).
- Focused on an interdisciplinary approach to data science and managing public health information.
- Building the capacity of Minority Serving Institutions (MSIs) (such as Historically Black Colleges and Universities (HBCUs), Tribal Colleges and Universities (TCUs), and Hispanic Serving Institutions (HSIs)), as well as other colleges and universities, to educate and diversify the public health workforce.
- Over four years, the PHIT Program awardees will train at least 4,000 individuals.

https://www.healthit.gov/PHIT

Public Health Informatics & Technology Workforce Development Program Recipients

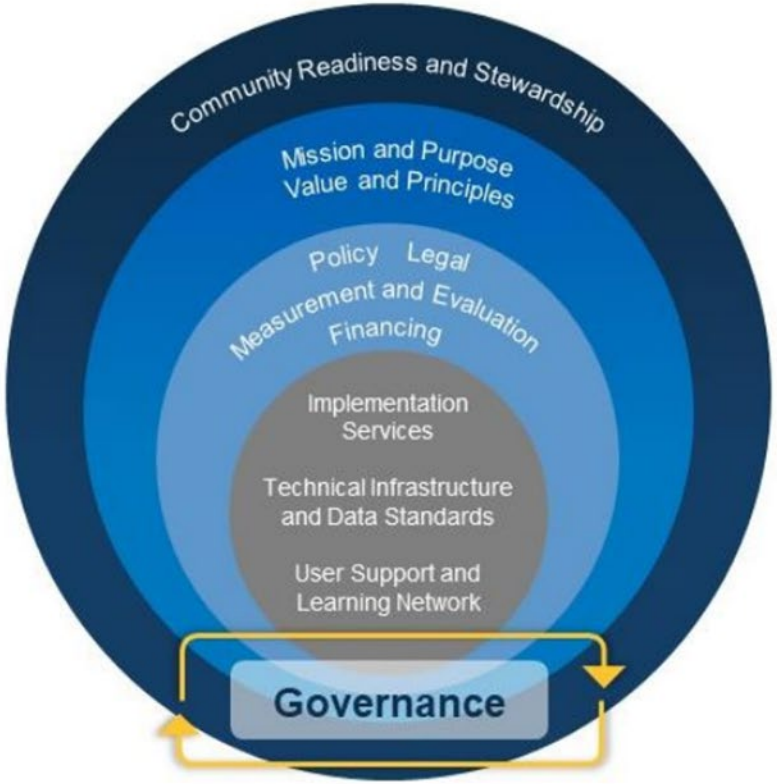


This map includes the 10 PHIT Workforce Development Program award recipients.

SDOH Information Exchange Learning Forum

- The Learning Forum brings together a wide range of partners to share lessons learned, promising practices, and challenges related to exchanging SDOH data.
- ONC convened a Technical Expert Panel in 2021 on SDOH information exchange to develop a set of SDOH information exchange foundational elements (see figure).
- Five sessions held in 2022 covering the foundational elements. Recordings available at http://www.healthIT.gov/SDOH-Info-Exchange-Learning-Forum

Social Determinants of Health Information Exchange Foundational Elements



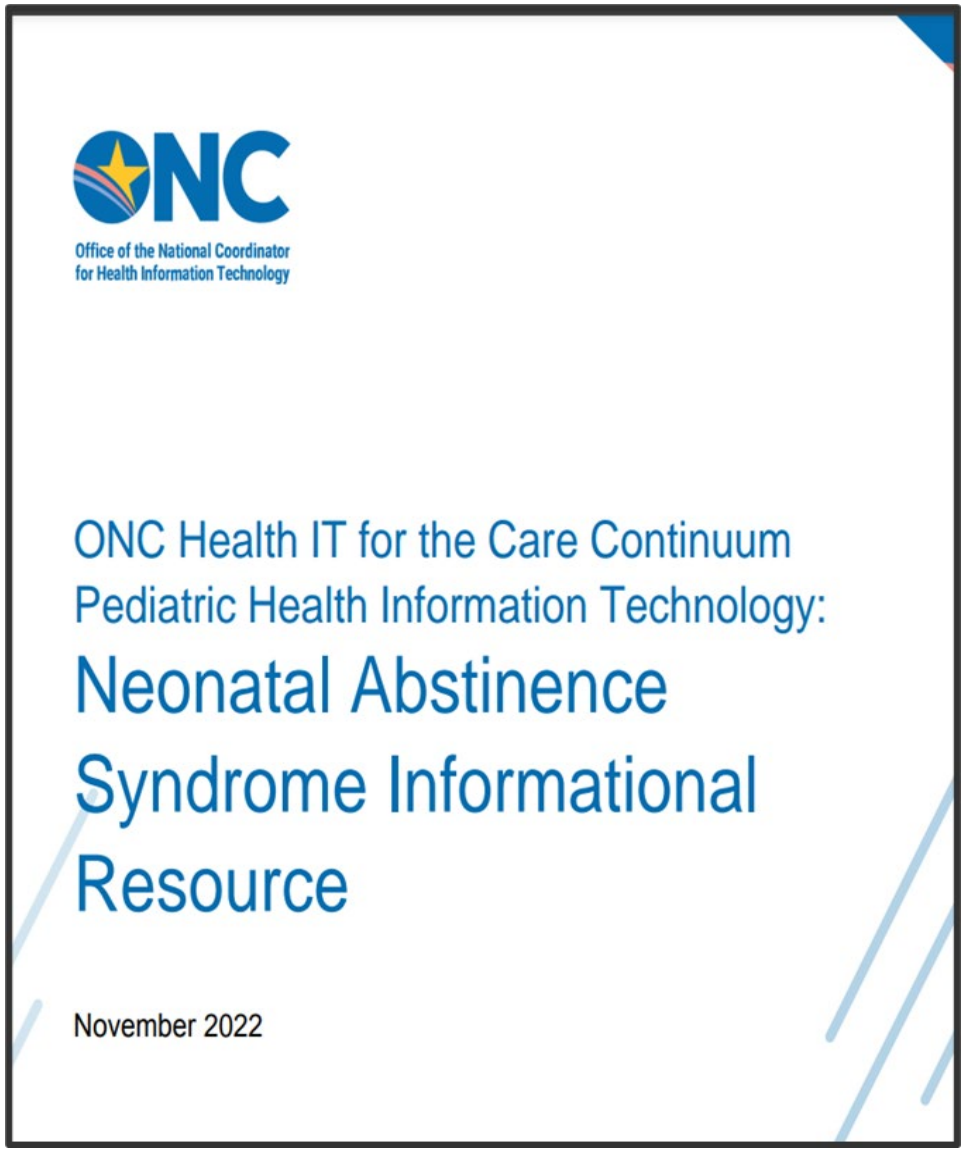
SDOH Information Exchange Learning Forum Engagement

- **2022 Learning Forum Sessions**
  - **2,422** live attendees and over **2,000** views of the recordings.
  - Topics to Date:
    - Introduction to SDOH Information Exchange and the Learning Forum
    - SDOH Information Exchange: Vision, Purpose, and Community Engagement
    - SDOH Information Exchange: Governance
    - SDOH Information Exchange: Technical Infrastructure and Interoperability
    - SDOH Information Exchange: Policy and Funding

- **What's Next?**
  - Additional Learning Forum sessions in 2023
  - Release of the SDOH Information Exchange Toolkit in early 2023

Neonatal Abstinence Syndrome Informational Resource

- **Neonatal Abstinence Syndrome Informational Resource (NAS IR)** supports pediatric care and practice settings specific to neonatal abstinence syndrome.
- Builds upon prior work, including the ONC Pediatric Health Information Technology **Informational Resources** (IR) for health IT developers and for health care providers.
- Includes information about the implementation of health IT and its use as part of delivering health care to infants experiencing withdrawal after maternal exposure to opioids and other substances during pregnancy.



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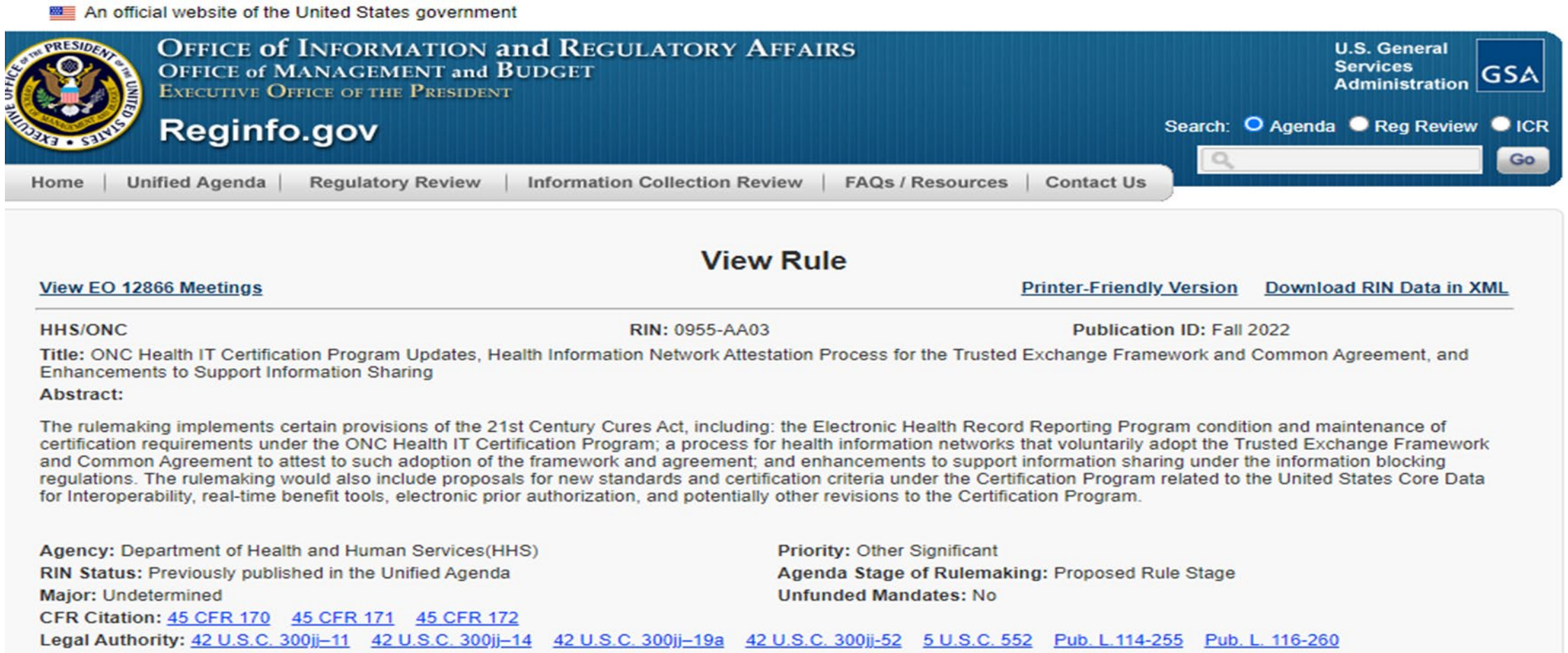

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View Rule

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HHS/ONC **RIN:** 0955-AA03 **Publication ID:** Fall 2022

Title: ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing

Abstract:

The rulemaking implements certain provisions of the 21st Century Cures Act, including: the Electronic Health Record Reporting Program condition and maintenance of certification requirements under the ONC Health IT Certification Program; a process for health information networks that voluntarily adopt the Trusted Exchange Framework and Common Agreement to attest to such adoption of the framework and agreement; and enhancements to support information sharing under the information blocking regulations. The rulemaking would also include proposals for new standards and certification criteria under the Certification Program related to the United States Core Data for Interoperability, real-time benefit tools, electronic prior authorization, and potentially other revisions to the Certification Program.

Agency: Department of Health and Human Services(HHS)
RIN Status: Previously published in the Unified Agenda
Major: Undetermined
CFR Citation: 45 CFR 170 45 CFR 171 45 CFR 172
Legal Authority: 42 U.S.C. 300jj–11 42 U.S.C. 300jj–14 42 U.S.C. 300jj–19a 42 U.S.C. 300jj-52 5 U.S.C. 552 Pub. L. 114-255 Pub. L. 116-260

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule Stage
Unfunded Mandates: No

Timetable:

Action	Date	FR Cite
NPRM	12/00/2022	

https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0955-AA03

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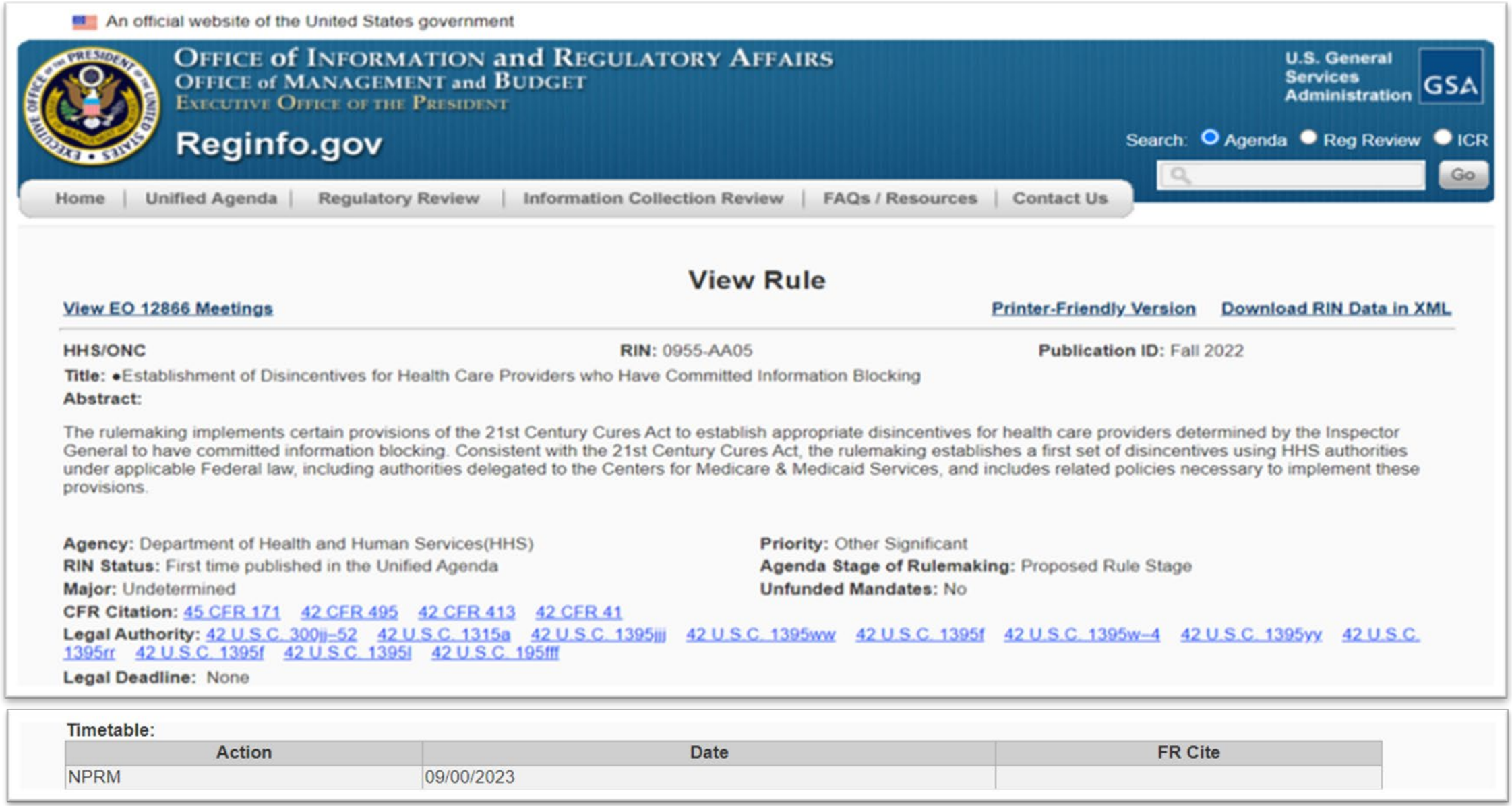

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HHS/ONC **RIN:** 0955-AA05 **Publication ID:** Fall 2022

Title: •Establishment of Disincentives for Health Care Providers who Have Committed Information Blocking

Abstract:

The rulemaking implements certain provisions of the 21st Century Cures Act to establish appropriate disincentives for health care providers determined by the Inspector General to have committed information blocking. Consistent with the 21st Century Cures Act, the rulemaking establishes a first set of disincentives using HHS authorities under applicable Federal law, including authorities delegated to the Centers for Medicare & Medicaid Services, and includes related policies necessary to implement these provisions.

Agency: Department of Health and Human Services(HHS)
RIN Status: First time published in the Unified Agenda
Major: Undetermined
Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule Stage
Unfunded Mandates: No
CFR Citation: 45 CFR 171 42 CFR 495 42 CFR 413 42 CFR 41
Legal Authority: 42 U.S.C. 300jj–52 42 U.S.C. 1315a 42 U.S.C. 1395jjj 42 U.S.C. 1395ww 42 U.S.C. 1395f 42 U.S.C. 1395w–4 42 U.S.C. 1395yy 42 U.S.C. 1395rr 42 U.S.C. 1395f 42 U.S.C. 1395l 42 U.S.C. 195fff
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2023	

https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0955-AA05

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HHS/ONC | RIN: 0955-AA06 | Publication ID: Fall 2022

Title: •Patient Engagement, Information Sharing, and Public Health Interoperability

Abstract:

The rulemaking builds on policies adopted in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification final rule (85 FR 25642) and included in the Health Information Technology: ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing proposed rule (0955-AA03). The rulemaking advances electronic health information sharing through proposals for: standards adoption; the certification of health IT to support expanded uses of application programming interfaces (APIs), such as electronic prior authorization, patient engagement, and interoperable public health exchange; and supporting patient engagement and other information sharing principles under the information blocking regulations.

Agency: Department of Health and Human Services(HHS)
Priority: Other Significant
RIN Status: First time published in the Unified Agenda
Agenda Stage of Rulemaking: Proposed Rule Stage
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 45 CFR 170 45 CFR 171
Legal Authority: 42 U.S.C. 300jj–11 42 U.S.C. 300jj–14 42 U.S.C. 300jj–19a 42 U.S.C. 300jj-52 5 U.S.C. 552 Pub. L. 114-255
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/00/2023	

https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0955-AA06

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HHS/OIG **RIN:** 0936-AA09 **Publication ID:** Fall 2022

Title: Amendments to Civil Monetary Penalty Law Regarding Grants, Contracts, and Information Blocking

Abstract:

The final regulation modifies 42 CFR 1003 and 1005 by addressing three issues. First, the 21st Century Cures Act (Cures Act) provision that authorizes the Department of Health and Human Services (HHS) to impose civil monetary penalties, assessments, and exclusions upon individuals and entities that engage in fraud and other misconduct related to HHS grants, contracts, and other agreements. Second, the Cures Act information blocking provisions that authorize the Office of Inspector General to investigate claims of information blocking and provide HHS the authority to impose CMPs for information blocking. Third, the Bipartisan Budget Act of 2018 increases in penalty amounts in the Civil Monetary Penalties Law.

Agency: Department of Health and Human Services(HHS)
RIN Status: Previously published in the Unified Agenda
Major: No
CFR Citation: 42 CFR 1003 42 CFR 1005
Legal Authority: 21st Century Cures Act Pub. L. 114-255 secs. 4004 and 5003 Bipartisan Budget Act of 2018 (BBA 2018), Pub. L. 115-123, sec. 50412
Legal Deadline: None

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule Stage
Unfunded Mandates: No

Timetable:

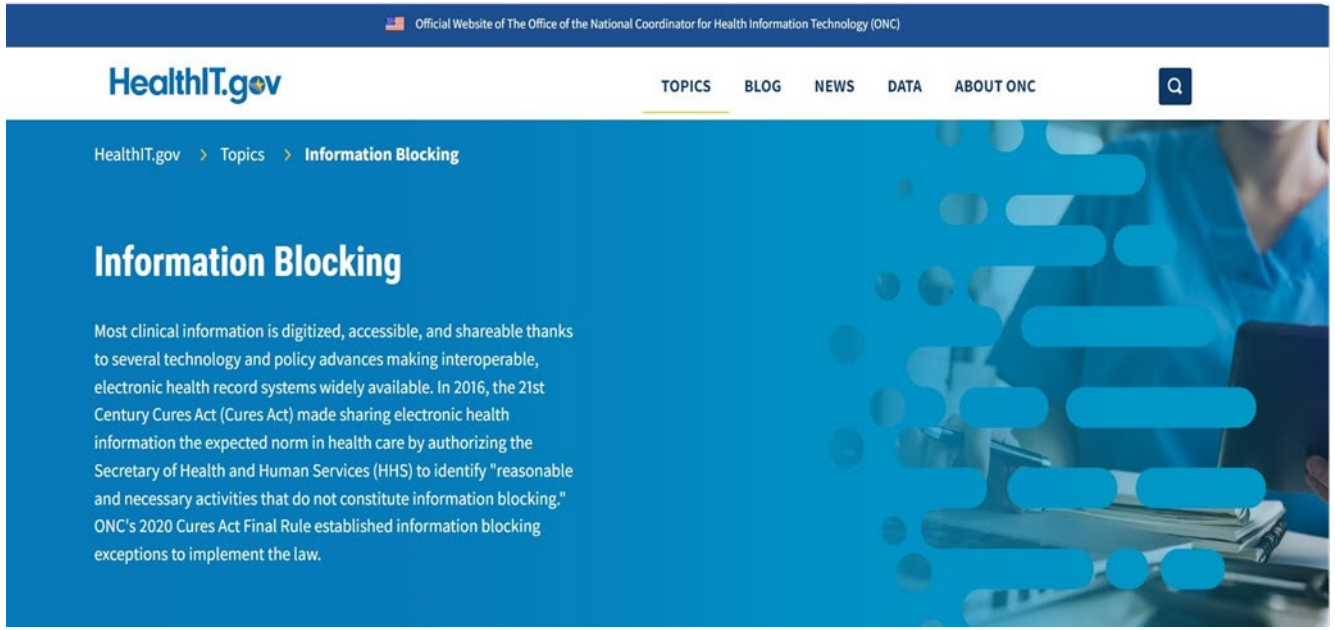
Action	Date	FR Cite
NPRM	04/24/2020	85 FR 22979
NPRM Comment Period End	06/23/2020	
Final Action	03/00/2023	

https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0936-AA09

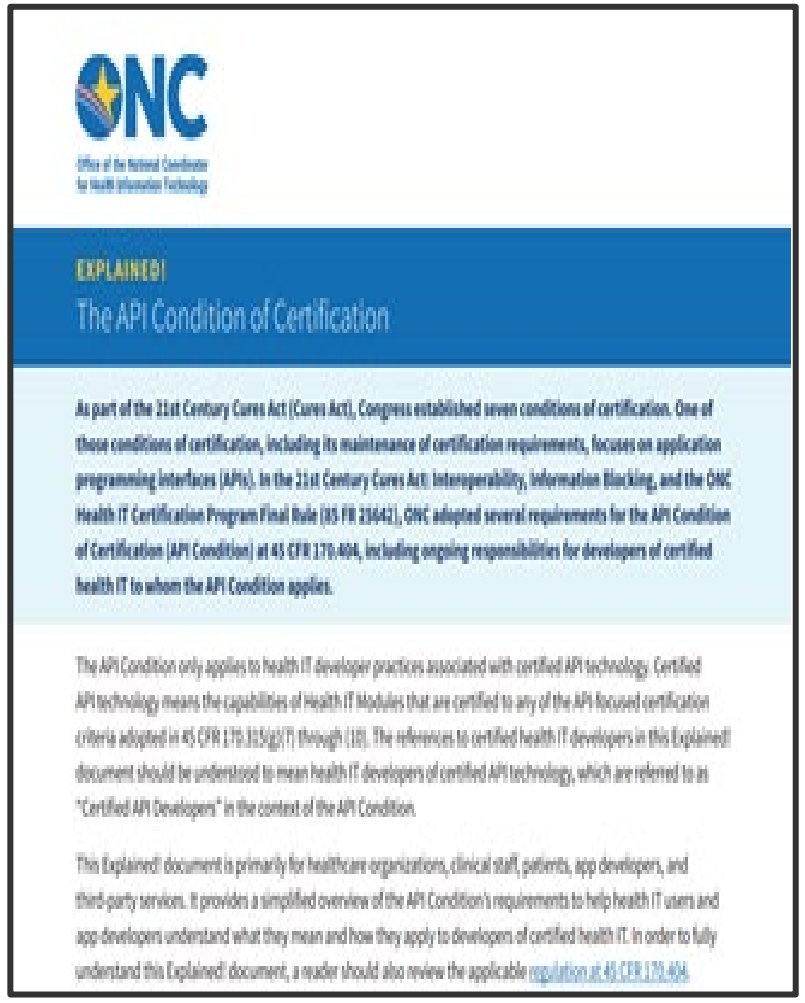
Where Can You Find More Information?

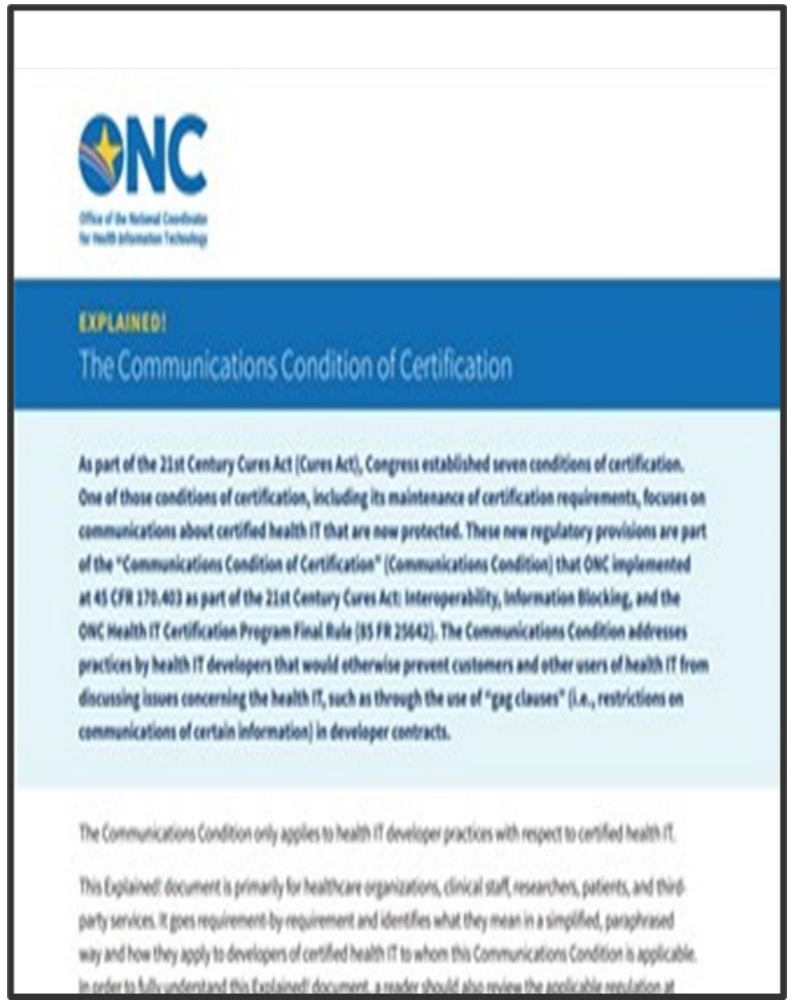
Education & Outreach Resources

- https://www.healthit.gov/topic/information-blocking
- Frequently Asked Questions (FAQs)
- Fact Sheets
- Technical Assistance and Guides
- Webinars and Other Presentations
- Health IT Buzz Blog
- Report Information Blocking Portal: healthit.gov/report-info-blocking
- Health IT Feedback and Inquiry Portal
- Information Blocking Portal Process
- Understanding Electronic Health Information (EHI) Fact Sheet
- ONC Speaker Request Form https://www.healthit.gov/speaker-request-form



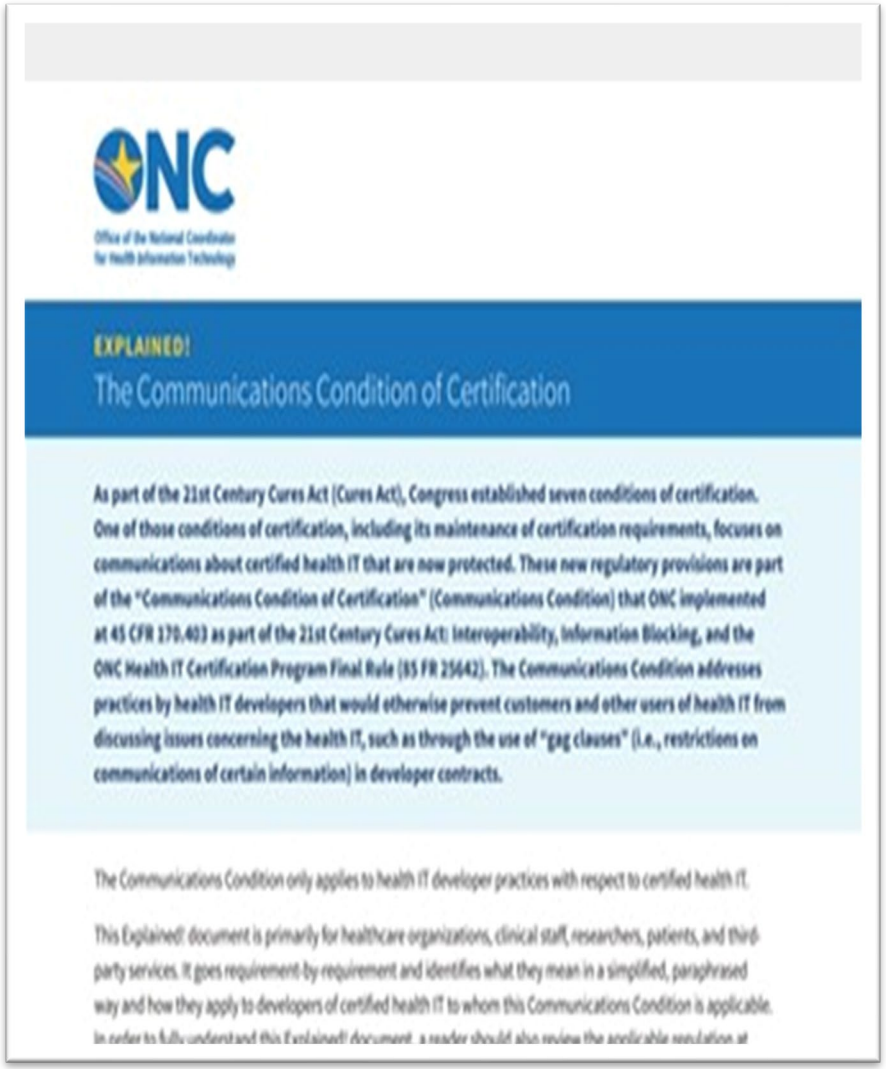
What's New in Educational Resources?





https://www.healthit.gov/buzz-blog/healthit-certification/not-so-hidden-gems-in-the-21st-century-cures-act-final-rule-get-to-know-the-conditions-of-certification

What's New in Educational Resources?



EXPLAINED!

The Communications Condition of Certification

As part of the 21st Century Cures Act (Cures Act), Congress established seven conditions of certification. One of those conditions of certification, including its maintenance of certification requirements, focuses on communications about certified health IT that are now protected. These new regulatory provisions are part of the "Communications Condition of Certification" (Communications Condition) that ONC implemented at 45 CFR 170.403 as part of the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (85 FR 25642). The Communications Condition addresses practices by health IT developers that would otherwise prevent customers and other users of health IT from discussing issues concerning the health IT, such as through the use of "gag clauses" (i.e., restrictions on communications of certain information) in developer contracts.

The Communications Condition only applies to health IT developer practices with respect to certified health IT.

This Explained! document is primarily for healthcare organizations, clinical staff, researchers, patients, and third-party services. It goes requirement-by-requirement and identifies what they mean in a simplified, paraphrased way and how they apply to developers of certified health IT to whom this Communications Condition is applicable.

The Communications Condition of Certification

Maintenance of Certification Requirements (Cont.)

The rule says... as a maintenance of certification requirement, developers of certified health IT cannot establish, renew, or enforce contracts violating this Communications Condition, and they must amend existing contracts violating this Communications Condition whenever those contracts are next modified for other reasons or renewed.

This means... that as of June 30, 2020, any new contracts you enter into with a developer of certified health IT must not have prohibited terms or provisions preventing you from communicating about the developer's health IT, including gag clauses. Further, if your current contract has such provisions, they must be removed whenever the developer renews or makes changes to the contract after June 30, 2020. To note, ONC exercised enforcement discretion for non-compliance with these requirements from June 30, 2020 until April 5, 2021 (85 FR 70064, 70071-72).

https://www.healthit.gov/sites/default/files/page/2022-12/Communications_Condition_of_Cert_Fact-sheet_508.pdf

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