Interoperability and Information Blocking in Transition

The Office of the National Coordinator for Health Information Technology (ONC) final rules on healthcare interoperability and "information blocking" present complex clinical, operational and security challenges. Hospitals, health IT vendors and other stakeholder organizations will need to strategize around how to maximize the benefit from these policies while also balancing continued investment in and commitment to technical infrastructure.

Title IV of the 21st Century Cures Act (Cures Act) was "designed, [in part] to advance interoperability; support the access, exchange, and use of electronic health information (EHI); and address occurrences of information blocking."[1] The Cures Act definition of interoperability calls for "'all electronically accessible health information' to be accessed, exchanged and used 'without special effort on the part of the user'."[2]
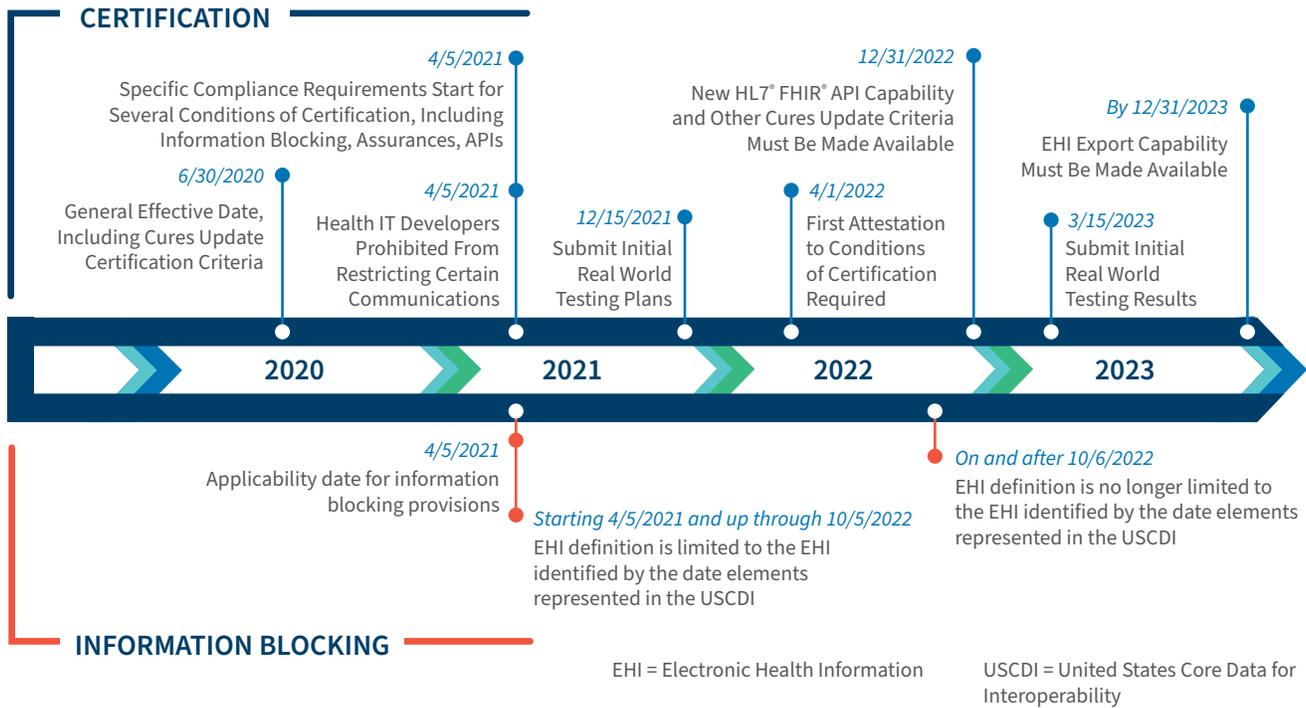
---

1 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program. 85 Fed. Reg. 25642, 25643 (May 1, 2020). https://www.federalregister.gov/d/2020-07419

2 21st Century Cures Act and interoperability in health care: Where are we now? Cerner https://www.cerner.com/perspectives/21st-century-cures-act-and-interoperability-in-health-care-where-are-we-now

EXPERTS WITH IMPACT™

FTI CONSULTING™

Information blocking, according to 45 CFR 171.10 effective November 4, 2020 of the Federal Register, "means a practice that is likely to interfere with access, exchange, or use of electronic health information; and if conducted by a health IT developer of certified health IT, health information network or health information exchange, such developer, network of exchange knows, or should know, that such practice is likely to interfere with access, exchange or use of electronic health information; and if conducted by a healthcare provider, such provider knows that such practice is unreasonable and is likely to interfere with access, exchange or use of electronic health information."

The Centers for Medicare & Medicaid Services and The Office of the National Coordinator for Health Information Technology (ONC) rules are final. The Office of the Inspector General rule on enforcement is expected later this year.

ONC RULE TIMELINE

CERTIFICATION

4/5/2021
Specific Compliance Requirements Start for Several Conditions of Certification, Including Information Blocking, Assurances, APIs

6/30/2020
General Effective Date, Including Cures Update Certification Criteria

4/5/2021
Health IT Developers Prohibited From Restricting Certain Communications

12/15/2021
Submit Initial Real World Testing Plans

12/31/2022
New HL7® FHIR® API Capability and Other Cures Update Criteria Must Be Made Available

4/1/2022
First Attestation to Conditions of Certification Required

By 12/31/2023
EHI Export Capability Must Be Made Available

3/15/2023
Submit Initial Real World Testing Results

2020   2021   2022   2023

4/5/2021
Applicability date for information blocking provisions

Starting 4/5/2021 and up through 10/5/2022
EHI definition is limited to the EHI identified by the date elements represented in the USCDI

On and after 10/6/2022
EHI definition is no longer limited to the EHI identified by the date elements represented in the USCDI

INFORMATION BLOCKING

EHI = Electronic Health Information

USCDI = United States Core Data for Interoperability

Source: https://www.healthit.gov/curesrule/overview/oncs-cures-act-final-rule-highlighted-regulatory-dates

FTI CONSULTING™

Healthcare Interoperability

Healthcare interoperability would allow for the exchange of information across the continuum of care among end-users, i.e., providers and patients. Improved outcomes, process-of-care efficiencies and less duplication of effort would result. Despite the potential benefits, hospitals lack the electronic health record infrastructure necessary to integrate health information without a substantial manual effort.[3] More specifically, barriers to interoperability include inconsistent technical specifications, a lack of standardized terminology, limited capacity (if any) to integrate data from third-party sources (e.g., wearables), disparate user interfaces, and divergent privacy, security and trust standards.[4,5,]

As part of the ONC's final rule, the United States Core Data for Interoperability (USCDI) establishes "a set of data classes and constituent data elements required to support interoperability nationwide."[6] In addition, expectations for data sharing include open application programming interfaces (APIs).[7]

Information Blocking

Policies enforcing the elimination of information blocking will be essential to facilitate interoperability. This will be balanced by Section 4004 of the 21st Century Cures Act authorizing the Secretary of HHS to identify reasonable and necessary activities that do not constitute information blocking, i.e., exceptions to the rule.

INFORMATION BLOCKING EXCEPTIONS

PREVENTING HARM EXCEPTION

PRIVACY EXCEPTION

SECURITY EXCEPTION

EXCEPTIONS THAT INVOLVE not fulfilling requests to accesss, exchange, or use EHI

INFEASIBILITY EXCEPTION

HEALTH IT PERFORMANCE EXCEPTION

8 EXCEPTIONS TO THE **INFORMATION BLOCKING PROVISION**

LICENSING EXCEPTION

FEES EXCEPTION

CONTENT AND MANNER EXCEPTION

EXCEPTIONS THAT INVOLVE procedures for fulfilling requests to accesss, exchange, or use EHI

Source: https://www.healthit.gov/curesrule/final-rule-policy/information-blocking

---

[3] Powell, K. & Alexander, G. (Summer, 2019). "Mitigating Barriers to Interoperability in Health Care." Online Journal of Nursing Informatics (OJNI), 23(2). Available at https://www.himss.org/resources/mitigating-barriers-interoperability-health-care 5Ibid.

[4] Soule, Dan. "The Biggest Barriers to Healthcare Interoperability." Health Catalyst; April 22, 2020. https://www.healthcatalyst.com/insights/healthcare-interoperability-barriers-solutions/

[5] Cohen, Jessica K. "6 barriers to healthcare interoperability, according to ONC." Becker's Health IT; January 11, 2019 https://www.beckershospitalreview.com/ehrs/6-barriers-to-healthcare-interoperability-according-to-onc.html

[6] 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program: Adoption of the United States Core Data For Interoperability (USCDI) as a Standard. 85 Fed.Reg. 25642, 25644 (May 1, 2020). https://www.federalregister.gov/d/2020-07419/p-15

[7] The Office of the National Coordinator for Health Information Technology. 2018 Report to Congress: Annual Update on the Adoption of a Nationwide System for the Electronic Use and Exchange of Health Information, p.6. https://www.healthit.gov/sites/default/files/page/2018-12/2018-HITECH-report-to-congress.pdf

FTI CONSULTING™

Bottom Line:

Title IV of the 21st Century Cures Act poses several fundamental questions to providers:

People/Patients

— Do our caregivers and members of the healthcare workforce understand their role in providing patients access to their health information? What are the relevant institutional policies and procedures?

— Do our patients understand their rights to access, exchange and use their health information? What is the patient's health information experience at our institution?

Process/Workflow

— Have we reviewed our Release of Information workflow? What are our policies on release of health information? Do our IT solutions have configuration points that impact when and under what conditions information is made available to patients?

Risk

— Have we done enough to mitigate our risk (compliance, financial)? Do our written polices (clinical and administrative) align with the regulations?

— Have we worked with our vendor partners to ensure that our technology solutions meet the standards?

The views expressed herein are those of the author(s) and not necessarily the views of FTI Consulting, Inc., its management, its subsidiaries, its affiliates, or its other professionals.

FTI Consulting, Inc., including its subsidiaries and affiliates, is a consulting firm and is not a certified public accounting firm or a law firm.

MARK SUGRUE, MSN, RN-BC
Managing Director
+1 617.697.6658
mark.sugrue@fticonsulting.com

DAVID GRUBER, MD
Managing Director
+1 917.214.8318
david.gruber2@fticonsulting.com

FTI Consulting is an independent global business advisory firm dedicated to helping organizations manage change, mitigate risk and resolve disputes: financial, legal, operational, political & regulatory, reputational and transactional. FTI Consulting professionals, located in all major business centers throughout the world, work closely with clients to anticipate, illuminate and overcome complex business challenges and opportunities. ©2020 FTI Consulting, Inc. All rights reserved. **www.fticonsulting.com**