Summary of ONC Final Rule on Information Blocking

The Office of the National Coordinator for Health IT (ONC) released its final rule on March 9, 2020, implementing provisions of the 21st Century Cures Act related to electronic health information (EHI) blocking, interoperability and the ONC Health IT Certification Program. In response to the COVID-19 pandemic, ONC released an interim final rule with comment period (IFC) on October 29, 2020, that extends the compliance dates and timeframes for providers and health IT developers to meet certain requirements related to information blocking and Conditions and Maintenance of Certification (CoC/MoC). The interim final rule moved the information blocking applicability date from November 2, 2020, to April 5, 2021.

Here are highlights of the final rule:

Definitions. The final rule includes several clarifications of terms and terminology:

- **Electronic Health Information (EHI) Definition:** ONC clarifies that before October 6, 2022, EHI for purposes of the information blocking definition is limited to the EHI identified by the data elements represented in the United States Core Data for Interoperability standard (USCDI) standard. **After October 6, 2022,** the definition of EHI means electronic protected health information (ePHI) as the term is defined for HIPAA to the extent that it would be included in a designated record set.
- **Access, Exchange and Use Definitions:** ONC clarifies the definitions of access, exchange and use in the final rule.
- **Health Information Network (HIN) and Health Information Exchange (HIE) Definitions:** ONC combines the definitions of HIN and HIE to create one functional definition that applies to both statutory terms in order to clarify the types of individuals and entities that would be covered. ONC focuses the definition's scope to be about exchange related to treatment, payment, and healthcare operations, as defined in the HIPAA Rules.
- **ONC provides definitions for:** API Information Source; Certified API Technology; API User; and Certified API Developer.

EHI Export (certification criterion and associated requirements). ONC provides specifics about the final certification criterion and scope of data that a Health IT Module must export and aligned certification criterion to the updated definition of "EHI." Developers of certified health IT whose Health IT Modules need to be certified to the EHI export criterion must do so and provide such capabilities to their customers within 36 months of the final rule's publication date.

Application Programming Interfaces (APIs). ONC finalizes the new API certification criterion; new standards and implementation specifications; and new Conditions and Maintenance of Certification Requirements. In the final rule, ONC:

- Requires the use of the HL7® FHIR® (FHIR release 4) standard along with a set of implementation specifications.
- Requires Certified APIs to implement the SMART Application Launch Framework Implementation Guides (based on the OAuth 2.0 security standard).
- Establishes the USCDI standard as the scope of patients' electronic health information that must be supported via certified API technology.
- Puts in place an app registration process to help ensure secure connections that include authentication and authorization capabilities.
- Requires health IT developers to support API-enabled services for data on a single patient and multiple patients.

- Requires API technology suppliers to publish the terms and conditions applicable to their API technology.
- Requires Certified API Developers to publish specific business and technical documentation necessary to interact with their certified API technology and make such documentation publicly accessible via a hyperlink.

Communications Condition and Maintenance of Certification – Permitted Restrictions for Intellectual Property and Visual Communications. ONC has provided additional information about sharing communications to address issues with health IT related to patient safety, usability, security and interoperability. For example, ONC noted that screenshots and videos are forms of visual communications protected under the Cures Act.

Information Blocking.

- ONC provides additional information to clarify that it would not be considered an "interference with" the access, exchange or use of EHI (and thus not "information blocking") if an information blocking "actor" engaged in practices to educate patients about the privacy and security risks posed by the apps they choose to receive their EHI.
- ONC recommends, but does not require, that the privacy policies and practices of third-party apps adhere to "market best practices."
- ONC finalized eight information blocking exceptions (there were seven in the proposed rules), including a new Content and Manner Exception. The exceptions are: Promoting Privacy Exception; Content and Manner Exception; Infeasibility Exception; Fees Exception – Profits; and Licensing Intellectual Property.
- ONC provides additional information about the compliance timeline. Healthcare providers, health IT developers of certified health IT, health information exchanges and health information networks ("actors") do not have to comply with the information blocking provision until six months after publication of the final rule. ONC and OIG are also coordinating timing of the compliance date and the start of information blocking enforcement.
- A practice that does not meet the conditions of an exception would <u>not</u> automatically constitute information blocking. Such practices would not have *guaranteed* protection from civil monetary penalties or appropriate disincentives and would be evaluated on a case-by-case basis to determine whether information blocking has occurred.

Fees. With respect to certified API technology, ONC establishes criteria for allowable fees, guidelines for the fees Certified API Developers would be permitted to charge, and to whom those fees could be charged. Certified API Developers are permitted to charge fees to API Information Sources for the development, deployment and upgrade of their certified API technology, and towards recovering API usage costs (if applicable). Certified API Developers are also permitted to charge API users for value-added services related to certified API technology, so long as such services are not necessary to efficiently and effectively develop and deploy production-ready software that interacts with certified API technology. ONC includes regulatory text that actors may charge fees, including fees that result in a reasonable profit margin, for accessing, exchanging or using EHI.

Conditions and Maintenance of Certification for Health IT Developers and Their Certified Health IT Modules. ONC identifies Conditions of Certification with accompanying Maintenance of Certification Requirements including: information blocking; (health IT developer) assurances about information blocking; communications; APIs; real-world testing; attestations; and future EHR reporting criteria for submission.

U.S. Core Data for Interoperability (USCD). ONC adopts the United States Core Data for Interoperability (USCDI v1) as a standard. Use of the USCDI standard is required as part of the new API certification criterion, "standardized API for patient and population services." The USCDI Version 1 is available at https://www.healthit.gov/uscdi. In order to better align with the standards such as HL7® Fast

Healthcare Interoperability Resources (FHIR®) and Consolidated Clinical Document Architecture®, the USCDI has defined a new data class named "Allergies and Intolerances" and moved the concept of "medication allergies" into this data class. ONC will follow a predictable, transparent and collaborative process to expand the USCDI, including providing stakeholders the opportunity to comment on the USCDI's expansion. ONC will be launching a public website to solicit recommendations from the public for changes and additions to the USCDI.

Interim Final Rule Extension of Compliance Dates and Timeline

April 5, 2021	December 31, 2022	Calendar Year Extension
- Information blocking provisions (45 CFR Part 171) - Information Blocking CoC/MoC requirements (§ 170.401) - Assurances CoC/MoC requirements (§ 170.402, except for § 170.402(b)(2) as it relates to § 170.315(b)(10)) - API CoC/MoC requirement (§ 170.404(b)(4)) - compliance for current API criteria - Communications CoC/MoC requirements (§ 170.403) (except for § 170.403(b)(1) – where ONC removed the notice requirement for 2020)	2015 Edition health IT certification criteria updates (except for § 170.315(b)(10) – EHI export, which is extended until December 31, 2023) - New standardized API functionality (§ 170.315(g)(10))	- Submission of initial attestations (§ 170.406) - Submission of initial plans and results of real-world testing (§ 170.405(b)(1) and (2))

The IFC also:

- Made changes to the program by updating standards and clarifying regulatory text for specific certification criteria.
- Made technical corrections and clarifications.

Resources from ONC

- [ONC interim final rule](#) extending compliance dates and timeframes
- [ONC final rule website](#)
- [ONC final rule](#)
- ONC fact sheets:
  - [2015 Edition Cures Update Overview](#)
  - [Standards-based API Certification Criterion](#)
  - [The ONC Cures Act Final Rule](#)
  - [Changes and Clarifications from the Proposed Rule to the Final Rule](#)
  - [Information Blocking Exceptions](#)
  - [Information Blocking Actors](#)
  - [United States Core Data for Interoperability](#)
  - [APIs Conditions and Maintenance of Certification](#)
  - [Highlighted Regulatory Dates](#)