Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency

Overview of Interim Final Rule

(RIN: 0955-AA02)

On November 4, 2020, the Office of the National Coordinator for Health Information Technology (ONC) published in the *Federal Register* (85 FR 70064-70085) an interim final rule with comment period (IFC) that delays applicability and compliance dates for the information blocking provisions of the ONC Cures Act Final Rule[1] by 5 months. The IFC also delays applicability and compliance dates for certain 2015 Edition health information technology (IT) certification criteria as well as Conditions and Maintenance of Certification Start requirements under the ONC Health IT Certification Program. Additionally, ONC makes a number of technical changes to its regulations and also provides clarification on a few issues.

Generally, the effective date of the IFC is December 4, 2020; however, where the IFC revises provisions of regulations relating to information blocking[2] that previously applied as of November 2, 2020, ONC states the effective date of the IFC is November 4, 2020. **The period for public comment closes at 5 p.m. on January 4, 2021.**

ONC waives Administrative Procedures Act requirements for notice of proposed rulemaking and the 30-day delay in the effective date for this rulemaking. Citing the need for the health care system to address the challenges of the COVID-19 pandemic, ONC believes that regular notice and comment rulemaking would be impractical and contrary to the public interest. Further, requiring health care providers and IT developers to meet the November 2, 2020 information blocking deadline would create unnecessary burdens and divert time and resources from the pandemic. (ONC notes that it had previously announced enforcement discretion for provisions of the ONC Cures Act Final Rule.) As for the clarifying and technical changes in the IFC, ONC states the changes are not substantive and that even if some of those changes were substantive, failure to correct those errors on a timely basis could place unnecessary burdens on regulated parties as they attempt to comply with the ONC Cures Act Final Rule.

This overview includes tables showing the extension of compliance and applicability dates and discusses: (1) changes to the information blocking rules; (2) updates to certification criteria for the 2015 Edition of Certified Electronic Health Record Technology (CEHRT); and (3) clarification of requirements regarding Application Programming Interfaces (APIs) and refresh tokens. The IFC contains many other changes of a technical nature which are not discussed.

[1] 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (85 FR 25642) https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification

[2] The provisions of the IFC with a November 4, 2020 effective date are 45 CFR 170.401, 170.402(a)(1), and the amendments to 45 CFR part 171.

Extension of Applicability and Compliance Dates

Reacting to feedback from stakeholders that the COVID-19 public health emergency (PHE) is monopolizing their time and attention, and straining resources, which has limited their ability to prepare for the November 2, 2020 information blocking compliance date, ONC provides extensions of applicability and compliance dates for information blocking, for certain 2015 Edition health IT certification criteria, and for certain Conditions and Maintenance of Certification Start requirements under the ONC Health IT Certification Program. The extensions vary in length and are shown in Table 1 of the IFC which is reproduced below.

Table 1. Applicability and Compliance Dates.

Provision	Final Rule	Enforcement Discretion Announcement	Interim Final Rule with Comment Period
Information Blocking Overall Applicability Date – (45 CFR part 171)[3]	November 2, 2020	N/A – No Change	**April 5, 2021**
Condition of Certification (CoC) – Information Blocking – (§ 170.401)	November 2, 2020	3 months after the compliance timeframe	
CoC – Assurances – (§ 170.402(a)(1)) – Will not take any action that constitutes information blocking or actions that inhibit access, exchange, and use of electronic health information (EHI)	November 2, 2020	3 months after the compliance timeframe	
CoC – Assurances – (§ 170.402(a)(2) and (3), and (b)(1)) – Other	Effective date: June 30, 2020	Enforcement discretion expired 3 months after the effective date of the final rule	
CoC – Communications – (§ 170.403) – Communications requirements, except for § 170.403(b)(1) where we removed the notice requirement for 2020	Effective date: June 30, 2020	Enforcement discretion expired 3 months after the effective date of the final rule	
CoC – API – (§ 170.404(b)(4)) – Compliance for current API criteria	November 2, 2020	3 months after the compliance timeframe	
CoC – API – (§ 170.404(b)(3)) – Rollout of new standardized API functionality	May 2, 2022	3 months after the compliance timeframe	**December 31, 2022**

Provision	Final Rule	Enforcement Discretion Announcement	Interim Final Rule with Comment Period
CoC – Real World Testing – 2015 Edition health IT certification criteria with standards updates	May 2, 2022	3 months after the compliance timeframe	**December 31, 2022**
CoC – Assurances – (§ 170.402(a)(4) and (b)(2)) – EHI Export Rollout	May 1, 2023	3 months after the compliance timeframe	**December 31, 2023**
CoC – Communications – (§ 170.403(b)(1)) – Notice to all customers with which developer has contracts or agreements containing provisions that contravene Communications CoC	Annually beginning in calendar year 2020	Notice can be made until March 31, 2021, for the 2020calendar year	**Begin annual cycle 1 year later** **CY 2021**
CoC – *Initial* Attestations – (§ 170.406)	April 1-30, 2021 attestation window for attestation period running June 30,2020, through March 31, 2021	Generally remains the same except for the initial attestation, which will now be accepted through July 30, 2021	**Begin annual cycle 1 year later** **CY 2022**
CoC – Real World Testing – (§ 170.405(b)(1) and (2)) Submit ***initial*** plan and ***initial*** results submission	Plan: December 15, 2020 Results: March 15, 2022	**Initial Plan:** Initial RWT plans (i.e., 2021 RWT plans) may be submitted through March 15, 2021 **Initial Results:** Initial RWT results from the 2021 performance year may be submitted up through June 2022	**Begin annual cycle 1 year later** **Initial Plan: December 15, 2021** **Initial Results: March 15, 2023**

Updates to ONC-ACB Dates and Timeframes

In order to coordinate with extensions for certification criteria described above, ONC extends compliance dates and timeframes for the appropriate provisions applicable to the ONC-Authorized Certification Bodies (ACBs) as follows:

Section	ONC Final Rule	IFC
§170.523(p)(3)	ONC-ACBs must submit to ONC for public availability real world testing plans by December 15 of each calendar year and results by March 15 of the subsequent calendar year	Initial plans due to ONC by December 15, 2021, and initial results by March 15, 2023.
§170.550(m)(2) and (3)	An ONC-ACB may only issue a certification to a Health IT Module and permit continued certified status for §§170.315(b)(6) and (g)(8) until May 1, 2023, and May 2, 2022, respectively.	An ONC-ACB may only issue a certification to a Health IT Module and permit continued certified status for §§170.315(b)(6) and (g)(8) until December 31, 2023, and December 31, 2022, respectively

Deadline for Transition from CCDS to USCDI

Under the ONC Cures Act Final Rule, criteria being updated from the Common Clinical Data Set (CCDS) to the USCDI, a transition from the CCDS to the USCDI must occur no later than 24 months after the publication date of the final rule. During that 24-month period, the CCDS remains permissible for certified Health IT Modules until they modules are updated to the USCDI. Under the IFC, the CCDS may remain applicable for certified Health IT Modules up to December 31, 2022, when such modules are updated to the USCDI.

Information Blocking

1. Extension

ONC arrived at the 5-month extension period for information blocking (from November 2, 2020 to April 5, 2021) by balancing what it describes as the critical goal of ensuring patients have access to their electronic health information (EHI) when and where they need it against the burden on providers and IT developers as they confront challenges relating to COVID-19. It distinguishes the information blocking provisions from the 2015 Edition Cures Update certification criteria (which receives a longer extension period) by noting that the information blocking rules do not explicitly require the purchase or update of certified health IT. ONC does not envision further extensions for the information blocking provisions.

In the IFC, ONC refers to the April 5, 2021 date as the applicability date; previously, it was referred to as the compliance date. ONC makes conforming changes to other parts of the information blocking regulation that are triggered by the original November 2, 2020 compliance date. Specifically, for the first 18 months after the applicability date, the information blocking

rules apply only with respect to data elements represented in the USCDI; thus, ONC clarifies that the end of the 1-month period is now October 6, 2022. After that date, the information blocking rules apply with respect to all EHI.

ONC also updates requirements for health IT developers to comply with Conditions of Certification requirements under §§170.401 and 170.402 relating to information blocking to apply beginning April 5, 2021.

2. Technical Changes

ONC also makes a number of technical language or cross-reference changes to the information blocking regulation. As noted above, ONC now refers to April 5, 2021 as the applicability date in lieu of the earlier reference to a compliance date; therefore, ONC changes the regulation text at §171.101(b) to state that actors "are subject to" the information blocking regulation rather than actors "must comply with" the regulations.

In its definition of information blocking codified in the ONC Cures Act Final Rule, the agency determined that the terms "interfere with" and "interference" included prevent and materially discourage; however, the final rule included in several places references to "prevent" or "materially discourage". ONC removes those terms from §§171.103(a)(2) and (a)(3) and 171.203(e)(2). ONC also changes references to health IT developer in the definition of information blocking to "health IT developer of certified health IT" to avoid ambiguity.

In the Content and Manner Exception, ONC intended to consistently refer to an actor "fulfilling a request" in the regulation text; however, in §§171.301(b)(1)(ii)(A), the phrase "fulfilling a response" is used. ONC corrects this error.

In the Licensing Exception, ONC corrects an erroneous cross-reference in the regulation text at §§171.303(b)(2)(i)—a reference to paragraph (b)(3) is substituted for the erroneous reference to paragraph (c)(3).

Certification Criteria and Standards for the 2015 Cures Update Edition of CEHRT

1. Criteria

The IFC specifics changes to multiple certification criteria. However, nearly all of the changes are technical in nature, as ONC uses the IFC as an opportunity to correct typographical errors, conform cross-references with their respective regulations, and ensure consistency between proposed and final rules as well as between the preamble discussions and matching regulatory text. For example, a 2014 Edition term "EHR Module" was used and is changed in the IFC to the 2015 Edition term "Health IT Module" to reflect the removal of the 2014 Edition and all of its associated provisions from ONC's Health IT Certification Program. One potentially impactful error expanded the certification requirements for "Transmission to Public Health Agencies – Electronic Case Reporting" by unintentionally including material not proposed via rulemaking and thereby creating new, significant burden for developers. This error is corrected in the IFC by revisions to §§170.315(f)(5) and 170.405(b)(3).

2. Standards

ONC's health IT certification program incorporates standards for use with certain certification criteria. Nearly always the most recent version of a standard available prior to rulemaking that has support from the health IT standards community is adopted. ONC uses the IFC to replace finalized standards for which updates are available; for example, the HL7 ® FHIR US Core Implementation Guide STU3 Release 3.1.0 (US Core IG 3.1.0) is updated to US Core IG 3.1.1. In one instance ONC inadvertently finalized use of USCDI v1 in which material not proposed via rulemaking was included. Stakeholders objected and ONC concurred; ONC quickly made corrections by publishing the USCDI v1 July 2020 Errata.[3] ONC uses the IFC to incorporate by reference the July 2020 Errata version.

3. Compliance Dates

ONC delays the compliance date for health IT developers to transition to the updated standards in the 2015 Edition Cures Update certification criteria. See Table 2 of the IFC (85 *FR* 70070).

APIs – Clarification of Native Applications and Refresh Tokens

ONC reports that since publication of the final rule it has received requests from stakeholders to clarify how certain requirements regarding refresh tokens apply to native applications. ONC describes native applications as "clients installed and executed on the device used by the resource owner (i.e., desktop application, native mobile application.)[4]"

The issue involves the final rule requirement that Health IT Modules must issue refresh tokens (valid for a period of no less than three months) to applications "capable of storing a client secret." Stakeholders are concerned that a strict reading of the final rule could exclude native applications that use additional technology that make them capable of storing a client secret, or native applications that can securely handle a refresh token without needing a client secret. ONC discusses technologies that native applications can use to secure a refresh token, client secret, or both. Without clarification, it believes that health IT developer support for native applications would vary widely. ONC agrees that such variation could greatly affect the types of applications supported by certified API technology as compliance timelines come into effect in the next two years.

New regulatory text is added at §171.315(g)(10(v)(A)(*l*)(*iii*) and related changes made to clarify that Health IT Modules must issue refresh tokens (valid for a period of no less than three months) to native applications that are capable of securing a refresh token. ONC notes that under the final rule, health IT developers must publish the methods by which their Health IT Modules support the secure issuance of an initial fresh token to native applications, and attestations by app

[3] https://www.healthit.gov/isa/sites/isa/files/2020-07/USCDI-Version-1-July-2020-Errata-Final.pdf

[4] See Internet Engineering Task Force: https://tools.ietf.org/html/rfc6749#section-9. A Google search identified this definition for non-engineers: "Native apps are developed specifically for a particular mobile device and are installed directly onto the device itself. Users download the app via app stores such as Apple App Store, Google Play store, etc. Native apps are built for specific mobile operating system such as Apple iOS or Android OS."

developers to health IT developers regarding the ability of their applications to secure a fresh token, client secret, or both must be treated in a good faith manner. Further, ONC emphasizes that health IT developers can determine the methods they use to support interactions with native applications, and clarifies that they are not required to support all methods that third-party application developers may seek to use. ONC encourages the industry to coalesce around a single set of requirements across all health IT developers.

ONC cites discussion from the ONC Cures Act proposed rule (84 FR 7481) to demonstrate that the decision to make the issuance of refresh tokens mandatory was aimed at enabling persistent access by patient-used applications. That is, ONC believes that patients should not have to frequently re-authenticate and re-authorize while using their preferred application. Therefore, ONC believes the changes regarding native applications and refresh tokens in this IFC are consistent with the policies that it proposed and that the public commented on during the rulemaking that led to the final rule.

Regulatory Impact

ONC states that because the provisions of the IFC are limited (i.e., date extensions, standards updates, and regulatory clarifications and corrections), its regulatory impact analysis did not identify any new quantifiable costs or benefits. It notes that there are likely unquantifiable costs and benefits of the IFC, such as possible temporary changes in labor and other supply chain costs/shortages due to the pandemic. ONC seeks comment on whether stakeholders incurred costs in trying to meet the compliance dates imposed under the ONC Cures Act Final Rule and whether the COVID-19 PHE may have an impact on costs of complying with 45 parts 170 and 171 in the future (taking into account the new IFC compliance and applicability dates).