



Executive Summary of Interim Final Rule

Background

In December of 2016, the 21st Century Cures Act was signed into law, and in March 2020, the Office of the National Coordinator for Health Information Technology (ONC) released its 21st Century Cures Final Rule ("Final Rule") in order to implement key provisions of the law. This Final Rule was set to go into effect on June 30, 2020. However, due to the coronavirus pandemic (COVID-19), the health care industry shifted focus and resources to caring for patients impacted by the virus.

Although ONC previously announced a delay of many compliance deadlines to November 2, 2020, many of the key actors did not feel ready or prepared to comply due to COVID-19. The purpose of this Interim Final Rule (IFC) letter is to outline the newly delayed compliance dates. This will allow actors to continue focusing primarily on combatting COVID-19, without the added pressure of meeting strict compliance rules. The flexibility of these dates aims to strike a balance between relieving pressure on actors and care providers, while also working to establish greater interoperability to enhance patient care in a timely manner.

Key Takeaways from the Final Rule

- The goal of this IFC is to provide flexibility in complying with the Final Rule while combating the COVID-19 pandemic
- Extensions were aligned with three distinct dates to minimize confusion:
 - April 5, 2021
 - December 31, 2022
 - December 31, 2023
- Most compliance deadlines set by the Final Rule with an original date of November 2, 2020 will be extended to the new deadline of April 5, 2021
- Notice and comment procedures and delayed effective dates have been waived for all typographical, language, or otherwise small changes
- The 30-day delayed effective date for the information blocking provisions and the Conditions and Maintenance of Certification requirements related to information blocking, communications, and assurances was waived

Attached please find a more detailed summary of the Interim Final Rule.

Detailed Summary of Interim Final Rule

Overview of Major Provisions

Extension of Compliance Dates and Timeframes

- Extensions of deadlines have been aligned around three distinct dates. The table for Applicability and Compliance Dates can be found [here](#)
- Extensions are shorter where there are fewer technological demands placed on stakeholders
- Suspended annual notice requirement in §170.403(b)(1) for year 2020. In short, this section states that if a health IT developer has already-existing contracts or agreements that contradict the requirements of the Condition of Certification (CoC), the developer must notify all affected customers, other persons, or entities that the prohibition or restriction within the contract/agreement will not be enforced.
- Finalized deadline for notice requirement in §170.403(b)(1) to be annual, beginning in CY 2021
- Most information blocking provisions are limited to the deadline extension of April 5, 2021

Information Blocking Provisions and Related Condition and Maintenance of Certification Requirements

- Granted stakeholders an additional 18 months to gain experience applying the exceptions with only the electronic health information (EHI) identified by the data elements represented in the United States Core Data for Interoperability (USCDI)
 - Encourages stakeholders to apply the exceptions to all EHI identified by the data elements represented in the USCDI during the combined period of 24 months
 - If stakeholder does not enable access, exchange, or use of data outside of the USCDI or did not appropriately apply an exception to data outside the USCDI, this error would not be considered information blocking, because data would not be considered “EHI” during time period of 24 months
- Extended date from November 2, 2020 to April 5, 2021 under the Interim Final Rule with Comment Period (IFC)
 - This date will be referred to as the “applicability date” instead of the “compliance date”

- Applicability date will likely not be extended past April 5, 2021
- Revised original compliance date of November 2, 2020 in § 171.101(b)
 - Now states that health care providers, health IT developers of certified health IT, health information exchanges, and health information networks are subject to complying with information blocking enforcement by April 5, 2021
- Extended the narrow EHI definition to just the data elements represented in the USCDI for the first 18 months after the applicability date by five months -- the extended date is now October 6, 2022
- Revised the information blocking definition to extend the period of time for which the EHI is limited to the data elements represented in the USCDI
 - For the period before October 6, 2022, at a minimum, the EHI identified for the purposes of the information blocking definition is limited to the EHI identified by the data elements represented in the USCDI standard
 - Revised and finalized the May 2, 2022 date in the Content and Manner exception (§ 171.301(a)(1) and (2))
- Extended compliance dates that required health IT developers of certified health IT to comply with the Information Blocking CoC and the Assurances CoC requirement to April 5, 2021

Certain 2015 Edition Health IT Certification of Criteria Updates

- Extended compliance deadline by which health IT developers of certified health IT would need to make technology certified to the updated criteria available to their customers from December 31, 2022 to December 31, 2023
- See table of the 2015 Edition Cures Update certification criteria with new compliance dates [here](#)

Conditions and Maintenance of Certification Requirements under the ONC Health IT Certification Program

Assurances

- The assurances condition requires a health IT developer to provide assurances to the Secretary of Health and Human Services (HHS) (“Secretary”) that it will not take any action that constitutes information blocking, except in cases of legitimate purpose(s) as specified by the Secretary
- In the Final Rule, the Assurances Condition and Maintenance of Certification requirements had an original effective date of June 30, 2020 that has since been extended to September 30, 2020
 - No public announcement has been made to extend this deadline, but no enforcement action has been taken or will be taken until April 5, 2021

- Does not intend to engage in Program enforcement for non-compliance between June 30, 2020 and April 5, 2021

Communications

- Provisions in the Final Rule permit developers to impose on communications certain types of limited prohibitions and restrictions
 - Developers are prohibited from imposing prohibitions or restrictions on protected communications
 - Under the Program, protected communications include communications required by law, made to a government agency, or made to a defined category of safety organizations
- Provisions in the Final Rule allow health IT developers certified under the Program to place limitations on certain types of communications, including screenshots and video
- ONC previously extended compliance date for the Communications CoC to September 30, 2020 -- it has not been extended further, but no enforcement action will be taken until April 5, 2021
- The notice and comment procedures of the Administrative Procedure Act ("APA") will be waived due to the COVID-19 public health emergency ("PHE")
- The delayed effective date requirements will also be waived
- Will not engage in Program enforcement for non-compliance between June 30, 2020 and April 5, 2021
- Suspending the notice that requires health IT developers to notify all affected customers, other persons, or entities that the prohibition or restriction within the contract or agreement will not be enforced for 2020 only
 - Customers must be notified annually beginning in CY 2021

Application Programming Interfaces ("API")

- Will exercise enforcement for health IT developers to comply with API CoC requirements starting on April 5, 2021
- Extends the compliance timeline for the rollout of the new standardized API functionality to December 31, 2022
 - Dates in the definition of 2015 Edition Base EHR will be revised to be consistent with this extension

Real-World Testing

- The Cures Act added a new Condition and Maintenance of Certification requirement that health IT developers must successfully test the real-world use of health IT interoperability in the type(s) of setting(s) in which such technology would be marketed

- Extended compliance dates for updating the 2015 Edition Cures Update criteria to December 31, 2022
- Extended compliance dates for submitting initial real-world testing plans to December 15, 2021 and initial real-world testing results to March 15, 2023

Attestations

- Extended annual cycle for attestations by one year to calendar year 2022
 - The first attestation window will continue to cover an irregular time period, from the effective date of the final rule through the extended date of March 31, 2022
 - A regular six-month period will commence with the next attestation window

Updates to ONC-Authorized Certification Bodies (ACBs) Dates and Timeframes

- ONC-ACBs must submit initial plans to ONC by December 15, 2021 and initial results by March 15, 2023
- Finalized that ONC-ACB may only issue a certification to a Health IT Module and permit continued certified status for data export and application access until December 31, 2023 and December 31, 2022, respectively
- Finalized that a transition from the Common Clinical Data Set (CCDS) to the USCDI must occur no later than 24 months after the Final Rule publication date
 - CCDS may remain applicable up to December 31, 2022

Corrections and Clarifications to the ONC Cures Act Final Rule

- Corrected errors found in the Federal Register document from May 1, 2020
 - Will waive the notice and comment requirements of the APA
- Areas in the Final Rule that were corrected include the following:
 - General applicability and applicability of standards and implementation
 - Updated the language to say “health information technology” instead of “Health IT Modules”
 - Standards for health information technology to protect EHI created, maintained, and exchanged
 - Record actions related to EHI, audit log status, and encryption of end-user devices
 - Referred to auditable events and tamper-resistance standard as “ASTEM E1247-18” and corrected it to “ASTM E1247-18”
 - Updated the requirements to align with the new numbering sequence of the updated standard

- Corrected the policies that referred to the previous ASTM standard with the policies that refers to the updated ASTM E1247-18 standard
 - Removed the requirement for Health IT Modules to support 7.1.3 Duration of Access in the ASTM E2147-18 standard
 - The 7.1.3 Duration of Access requirement will not be in the scope for certification or testing
 - Synchronized clocks
 - Removed reference to RFC 1305 in § 170.210(g)
- Applicability of certification criteria for health information technology
 - Removed the 2014 Edition from the CFR in the ONC Final Rule
 - Finalized removal of terms and definitions specific to the 2014 Edition including the “2014 Edition Base EHR,” “2014 Edition EHR certification criteria” and “Complete EHR, 2014 Edition” definitions
- Electronic Prescribing
 - Changed the transaction “RxFillIndicator” to “RxFillIndicatorChange”
- Clinical Quality Measures – Report Criterion
 - Corrected compliance timeline (found in Table 1 –2015 Edition Cures Update of the Final Rule) for the “clinical quality measures – report” criterion to December 31, 2022
- CMS Quality Reporting Document Architecture Implementation Guides
 - Adopted the standards for CMS clinical quality measure reporting in the CMS Implementation Guide (§ 170.205(h)(3) and § 170.205(k)(3)) to the latest CMS Quality Reporting Document Architecture (“QRDA”) standards
 - Adopted the 2020 CMS QRDA category I for inpatient measures and category III for ambulatory measures
- Multi-factor Authentication
 - Changed wording from “identify” to “identity” in the regulatory text related to the multifactor authentication
- Transmission to Public Health Agencies – Electronic Case Reporting
 - Revised regulation text to correct the certification requirements for “electronic case reporting” criterion to eliminate a significant burden from developers
- Conditions and Maintenance of Certification Requirements for Health IT Developers
 - Application Programming Interfaces – Clarification for Native Applications and Refresh Tokens
 - Proposes to make the use of “refresh tokens” mandatory with a minimum refresh token life of three months
 - Proposed to make use of refresh tokens mandatory for those that have a minimum refresh token life of three months

- Specified that Health IT Modules' authorization servers must issue a refresh token to native (phone) applications that are capable of storing a client secret
 - Finalized revisions to the Final Rule to clarify language regarding native applications (i.e. phone apps) and refresh tokens
- Principles of Proper Conduct for ONC-Authorized Certification Bodies (ACBs)
 - Removed various policies in the regulatory text to reduce administrative burden on health IT developers and the ONC-ACBs
- Information Blocking Definition and Security Exception
 - Finalized revisions to clarify the definition of information blocking in the Final Rule
 - Finalized policy to use the term “health IT developer of certified health IT” as the actor to whom the information blocking rule would apply
 - Information blocking rule only applies to developers of certified health IT, not all health IT developers
- Content and Manner Exception
 - Clarified that when an actor fulfills a request in any manner requested, any fees charged by actor for fulfilling the request are not required to satisfy the Fees Exception clause
 - Finalized small errors in language choice to create consistency in the Final Rule