ONC's Cures Act Final Overview

Overview

On March 9, 2020, through ONC and CMS, HHS published Final Rules that detail the regulatory and enforcement framework regulating health care stakeholders' obligations regarding interoperability, information blocking, and patient access. The ONC 21st Century Act Final Rule (Final Rule) was published in the Federal Register on May 1, 2020.

Due to the COVID-19 pandemic, ONC announced that it will be exercising enforcement discretion for many of the new certification related requirements in the Final Rule. ONC revised its compliance dates and timeframes to three (3) months after each initial compliance date or timeline identified in the Final Rule. The revised timeframes for compliance are reflected in this summary document.

ONC's 21st Century Cures Act Final Rule Details (45 CFR Part 170)

ONC's 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule implements certain provisions of Title IV of the 21st Century Cures Act to advance interoperability, addressing occurrences of information blocking, improve patient access, exchange, and use of electronic health information, and health IT certification through the following provisions and updates:

1) Changes to Information Blocking
    - Definitions of Health IT actors, Electronic Health Information (EHI), Health Information Network (HIN) and Health Information Exchange (HIE)
    - What it means to "interfere with" access, exchange, or use of EHI
    - Exceptions structure
2) Changes to ONC Health IT Certification Program
    - Electronic Health Information (EHI) Export Certification Criteria
    - FHIR Standard for Application Programming Interface (API) for patient and population Services
    - Conditions and Maintenance of Certification requirements for health IT developers
3) United States Core Data for Interoperability (USCDI)

Related Rules

- CMS Interoperability and Patient Access Final Rule Details (CMS-9115-F) - The Centers for Medicare and Medicaid Services (CMS) published Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges, and Health Care Providers, specifying new requirements for individual data access impacting health plans and providers participating in federal health care programs.
- OIG Information Blocking Rule (proposed Rule published April 24, 2020) – The Office of Inspector General (OIG) proposed a rule amending civil money penalty (CMP) regulations for information blocking. The proposed regulation would incorporate statutory changes in three areas: 1) new authorities for CMPs, assessments and exclusions related to HHS grants, contracts and other agreements; (2) new CMP authorities for information blocking; and (3) increased maximum penalties for certain violations. OIG has proposed to delay enforcement until 60 days after its rule is final.

1. Information Blocking

Any health IT developer that has a product certified through the ONC Health IT Certification Program is prohibited from information blocking and can face fines and/or the loss of their certification. This prohibition applies to all products offered by a health IT developer that has a certified product, not just to their certified products. The Cures Act provided the following clarifications.

- **EHI –** Electronic protected health information (ePHI) as the term is defined for HIPAA in 45 CFR 160.103 to the extent that it would be included in a designated record set as defined in 45 CFR 164.501 (other than psychotherapy notes as defined in 45 CFR 164.501 or information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding), regardless of whether the group of records are used or maintained by or for a covered entity as defined in 45 CFR 160.103.

  Applicable: May 1, 2022*

  *EHI for purposes of information blocking definition is limited to the EHI identified by the USCDI data elements standards adopted in the Final Rule.

- **Covered Actors –** The Cures Act defined and prohibited information blocking by covered actors, which include health care providers, health IT developers of certified products, health information exchanges (HIEs), and health information networks (HINs).
- **Exceptions Structure –** The Final Rules defines what would be considered information blocking and outlines eight exceptions of practices ***that would not constitute information blocking*** noted by the two types of exceptions below.
  - **Exceptions that involve *not fulfilling requests* to access, exchange, or use EHI:**
    1. **Preventing harm exception:** an actor engages in practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain conditions are met.
    2. **Privacy exception:** an actor does not fulfill a request to protect an individual's privacy, provided certain conditions are met.
    3. **Security exception:** an actor interferes with the access, exchange, or use of EHI to protect the security of EHI, provided certain conditions are met.
    4. **Infeasibility exception:** an actor does not fulfill a request due to the infeasibility of the request, provided certain conditions are met.
    5. **Health IT performance exception:** an actor takes reasonable and necessary measures to make health IT temporarily unavailable or to degrade the health IT's performance for the benefit of the overall performance of the health IT, provided certain conditions are met.
    6. **Exceptions that involve *procedures for fulfilling requests* to access, exchange, or use EHI: Content and manner exception:** an actor limits the content of its response to a request to access, exchange, or use EHI or the manner in which it fulfills a request to access, exchange, or use EHI, provided certain conditions are met.
    7. **Fees exception:** an actor charges fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI, provided certain conditions are met.
    8. **Licensing exception:** an actor licenses interoperability element for EHI to be accessed, exchanged, or used, provided certain conditions are met.

Applicable: November 1, 2020 (Compliance Date) – February 1, 2021 (Enforcement Discretion Date)

ONC and OIG are coordinating timing of the compliance date and the start of information blocking enforcement. Enforcement of information blocking civil monetary penalties (CMPs) in section 3022(b)(2)(A) of the PHSA will not begin until established by future notice and comment rulemaking by OIG. As a result, actors would not be subject to penalties until CMP rules are final. At a minimum, the timeframe for enforcement would not begin sooner than the compliance date of the ONC Final Rule and will depend on when the CMP rules are final. Discretion will be exercised such that conduct that occurs before that time will not be subject to information blocking CMPs.

2. ONC Health IT Certification Program

The Final Rule updates requirements for developers that participate in the ONC Health IT Certification Program, including the addition of provisions related to the ability of a health IT user to communicate regarding certain aspects of their health IT.

- **Electronic Health Information (EHI) Export Certification Criteria** – Focuses on the ability to export the electronic health information stored in and by certified health IT to support patient EHI access requests as well as to support a health care provider interests in exporting an entire patient population to transition to another health IT system. The new EHI export criterion include:
    - **Single Patient EHI Export ((§170.315(b)(10)(i)):** The single patient export functionality includes the capability for a user to execute a single patient export and must be able to be limited at least one of two ways: (1) to a specific set of identified users, and (2) as a system administrative function. A user must be able to execute the single patient EHI export capability at any time the user chooses and without subsequent developer assistance to operate regardless of whether the developer is operating the export for a healthcare provider or a healthcare provider is maintaining and operating the technology in their own production environment.
    - **Patient Population EHI Export ((§170.315(b)(10)(ii)):** The patient population EHI export functionality supports patient data transitions in instances of healthcare providers switching health IT systems. Certified health IT developers are required to provide reasonable cooperation and assistance to other persons, such as customers, users, and third-party developers, to ensure the capability is deployed in a way that enables the successful migration of patient
    - **Standard/Format:** The certification criterion does not require a specific standard format to be used. The export files, for both the single patient and the patient population EHI export functionalities, must be electronic, in a computable format, and include the publicly accessible, up-to-date hyperlink of the export's format, which allows any person to directly access the information without any preconditions or additional
    - **Stored Data:** "Stored" data applies to all EHI and is agnostic as to whether the EHI is stored in or by the certified health IT module or in or by any of the other "non-certified" capabilities of the health IT product of which the certified health IT module is a part.
    - **Image Data:** For conformance, any images, imaging information, and image elements that fall within the scope of EHI for this certification criterion will need to be exported unless links to images/imaging data (and not the images themselves, which may remain in a PACS) are the only EHI stored in or by the product to which this certification criterion applies in which case only the links would need to be part of the
    - **Timeframe:** Neither type of export will require the Health IT Module to support a specific or user-defined timeframe range or time limit to demonstrate
    - **"Direct-to-patient" Functionality:** This certification criterion does not require "direct-to-patient" functionality to demonstrate conformance.

Applicable: May 1, 2023 (Compliance Date) – August 1, 2023 (Enforcement Discretion Date)

- **FHIR Standard for Application Programming Interface (API) for patient and population Services** – The Final Rule requires the use of the HL7® Fast Healthcare Interoperability Resources (FHIR®) Release 4 standard and several implementation specifications. The United States Core Data for Interoperability standard (USCDI) is the scope of patients' electronic health information that must be supported via certified API technology. Two types of API-enabled services are required:
    1. services for which a single patient's data is the focus, and
    2. services for which multiple patients' data are the focus. new provisions for certified health IT developers who now will be required to establish a secure, standards-based API for use by providers and to support a patient's access to core data in their electronic health record.

  Applicable with current API criteria: November 1, 2020 (Compliance Date) – February 1, 2021 (Enforcement Discretion Date)

  Applicable for new standardized API functionality: May 1, 2022 (Compliance Date) – August 1, 2022 (Enforcement Discretion Date)

- **Conditions and Maintenance of Certification requirements for health IT developers** – The Cures Act established seven Conditions of Certification, and most have an accompanying Maintenance of Certification Requirement:
    1. Information Blocking
    2. Assurances
    3. Communications
    4. Application Programming Interfaces (APIs)
    5. Real World Testing
    6. Attestations
    7. (Future) EHR Reporting Criteria Submission

  Applicable dates: Compliance dates range from 6 months to 36 months for each Condition. Please refer to the Enforcement Discretion Dates and Timeframes for details.

3. United States Core Data for Interoperability (USCDI)

The Final Rule sets a new baseline for interoperability and replaces the Common Clinical Data Set (CCDS). The USCDI establishes a minimum set of data classes to improve the flow of EHI and helps ensure that the information can be effectively understood when it is received. Over time, it will be updated to expand the baseline set of interoperable data available nationwide.

- Clinical Notes (New)
- Discharge Summary Note
- History & Physical
- Progress Note
- Consultation Note
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedures Note
- Provenance (New)
- Author time stamp
- Author organization
- Allergies and Intolerances (New)
- Substance (Drug Class)
- Reaction
- Patient Demographics (Expanded)
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address
- Vital Signs (Expanded to include pediatrics)
- Head Occipital-frontal circumference percentile (Birth to 36 Months)
- Weight-for-length percentile (Birth to 36 Months)
- BMI percentile (2-20 Years of Age)