

## HTI-2 Proposed Rule Overview

### Overview

Since the passage of the 21st Century Cures Act (Cures Act), the health IT and health care industry has made significant strides towards data interoperability throughout health care. The Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule builds on this foundation through new proposals that enable better and more equitable patient care through systemic improvements in the access, exchange, and use of data.

The new HTI-2 Proposed Rule includes new and revised standards and certification criteria in the ONC Health IT Certification Program. These revisions include an update to the United States Core Data for Interoperability (USCDI) v4, as well as standards and criterion related to e-prescribing and public health exchange.

The proposed rule also expands the certification and use of API technology based on HL7's Fast Healthcare Interoperability Resources (FHIR®) standard for additional uses cases across the health care sector. Specifically in the following areas:

- Electronic Prior Authorization
- Access to Billing and Payment Transactions
- Public Health Exchange

Additionally, the proposed rule includes proposals for new and revised exceptions under the information blocking regulations as well as revisions to the criterion for encrypt authentication credentials, new criteria for “administrative” APIs, and a new criterion for a standardized FHIR®-based API for public health reporting

### Key proposals in HTI-2 Proposed Rule

To support an effective transition from the current state to a FHIR-enabled interoperable health IT ecosystem, the proposed rule includes updates for existing health IT standards and for existing certification criteria in the Program including public health reporting criteria.

#### A New Baseline Version of USCDI

The USCDI standard is a baseline set of data that can be commonly exchanged across care settings for a wide range of uses and is a required part of certain certification criteria in the Program.

**ONC proposes to update the USCDI standard in § 170.213 by adding USCDI v4 and by establishing an expiration date of January 1, 2028 for USCDI v3 for purposes of the Program.**

### Key Proposals:

- A New Baseline Version of USCDI
- Minimum Standards Code Set Updates
- Bulk Data Enhancements
- Electronic Prior Authorization
- Information Blocking
- TEFCA™
- New and Revised Standards and Certification Criteria Proposal

The adoption of USCDI v4 would update the USCDI standard to include new data elements, including under the health status assessment and laboratory data classes among others, as discussed in section III.B.1. of the proposed rule. Expanding the data elements included in USCDI would increase the amount and type of data available to be used and exchanged through certified health IT. ONC's proposed standards updates for public health and USCDI v4 would make available more information that reflects the patient's understanding and involvement in their own care, including their treatment goals and preferences, physical activity and substance use, and a more complete look at how they take their medications. This could help address disparities in health outcomes for all patients, including those who may be marginalized and underrepresented. This could also support data users' abilities to identify, assess, and analyze gaps in care, which could in turn be used to inform and address the quality of healthcare through interventions and strategies. This could lead to better patient care, experiences, and health outcomes.

### **Minimum Standards Code Set Updates**

In the 2015 Edition Final Rule, we established a policy of adopting newer versions of "minimum standards" code sets that update frequently (80 FR 62612). Adopting newer versions of these code sets enables improved interoperability and implementation of health IT with minimal additional burden (77 FR 54170). If adopted, newer versions of these minimum standards code sets would serve as the baseline for certification, and developers of certified health IT would be able to use newer versions of these adopted standards on a voluntary basis. Because these code sets are updated frequently, ONC will consider whether it may be more appropriate to adopt a version of a minimum standards code set issued after publication of this proposed rule, but before publication of a final rule.

### **Bulk Data Enhancements**

ONC proposes to adopt the HL7 FHIR Bulk Data Access v2.0.0: STU 2 implementation specification (Bulk v2 IG) and require server support for the group export operation and a query parameter for performance improvement. ONC believes this will better support application developers interacting with § 170.315(g)(10)-certified Health IT Modules in exporting complete sets of FHIR resources, as constrained by the US Core IG and USCDI, for pre-defined cohorts of patients. This would raise the floor from the current Bulk v1 IG requirements for certification, where ONC requires support for the group export operation and not any of the optional query parameters in the IG. ONC believes that these new certification requirements, based on additional implementer clarifications included in the Bulk v2 IG, will provide meaningful improvements in the performance of Bulk APIs.

### **Electronic Prior Authorization**

The proposed rule would support the Department of Health and Human Services agency-wide approach to electronic prior authorization that meets the Department's interoperability and burden reduction goals, such as reducing documentation requirements associated with completing prior authorization requests for payers. This ensures that patients receive the care they need in a timely manner, lower administrative cost, and reduce complexity on providers and patients. This proposed rule would also update certification criteria and standards updates that would facilitate electronic prior authorization using certified health IT to ensure that health care providers are able to interact with these APIs using certified health IT, and to support the required actions under the proposed electronic prior authorization measure.

## Information Blocking

The proposed rule would update two existing exceptions and establish two new exceptions. These proposals respond to patient, provider, and other communities' concerns about patient privacy, care access, EHI sharing preferences, and a balance of certainty and flexibility for actors as they seek to optimize interoperability and sharing of EHI.

- Proposed new Protecting Care Access Exception would, under specified conditions, cover actors' limiting EHI sharing in order to reduce a risk of potentially exposing patients, providers, or persons who facilitate care to legal action based on the mere fact that they sought, obtained, provided, or facilitated lawful reproductive health care. The Protecting Care Access Exception would also apply where an actor limits sharing of a patient's EHI potentially related to reproductive health care in order to protect that patient from potential exposure to legal action.
- Proposed new Requestor Preferences Exception would provide actors a framework under which they can be confident they will not be committing information blocking if they agree to a requestor's ask for restrictions on when, under what conditions, and how much EHI is made available to that requestor.
- Revisions to existing exceptions would: expand application of the existing Privacy Exception to further support more actors' practices protecting the privacy of patients' health information; and update the existing Infeasibility Exception to offer actors more clarity and more flexibility under certain conditions. Other proposals would also enhance clarity around the codified definitions of certain terms for information blocking purposes.

## TEFCA

ONC proposes to add a new part, part 172, to title 45 of the Code of Federal Regulations to implement certain provisions related to the Trusted Exchange Framework and Common Agreement (TEFCA™). These provisions will establish the qualifications necessary for an entity to receive and maintain Designation as a Qualified Health Information Network (QHIN) capable of trusted exchange pursuant to TEFCA™. The proposals also cover the procedures governing QHIN Onboarding and Designation, suspension, termination, and administrative appeals to ONC. ONC proposes to adopt these provisions in regulation to support the reliability, privacy, security, and trust within TEFCA™, which will support the ultimate success of TEFCA™.

## New and Revised Standards and Certification Criteria Proposals

HTI-2 proposes a number of updates to standards and certification criteria in the ONC Health IT Certification Program. Included in the proposed rule are support or updates for Diagnostic Imaging Hyperlinks, Real-time Tools/Pharmacy interoperability, Public Health Data Exchange, Modular and Foundational API capabilities, Patient, Provider and Payer API capabilities, Multi-factor Authentication, Computerized Provider Order Entry—Laboratory, and Revised criterion for encrypt authentication credentials.



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