

April 15, 2021

Micky Tripathi, PhD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health IT
U.S. Department of Health and Human Services
330 C Street, SW
Washington, DC 20201

Dear Dr. Tripathi,

The Electronic Health Record (EHR) Association appreciates the opportunity to comment on the Draft United States Core Data for Interoperability (USCDI) Version 2.

The EHR Association's nearly 30 member companies serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States. Our focus is on collaborative efforts to accelerate health information and technology adoption, assist member companies with regulatory compliance, advance information exchange between interoperable systems, and improve the quality and efficiency of patient care through the use of technology.

We appreciate ONC's use of this annual update process to identify core interoperability priorities that enables predictable growth to cover the full scope of electronic health information, while not requiring large expansion projects every three to four years.

In the detailed comments that follow, we suggest inclusion of items that are already part of C-CDA and FHIR US Core. We also point out several areas of the Draft USCDI v2 that would benefit from more precise definitions, as well as clearer delineations between similar procedures, such as "diagnostic imaging" and "imaging."

Thank you for considering our input on this important document.

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Sincerely,

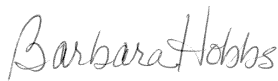


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Chair, EHR Association
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Vice Chair, EHR Association
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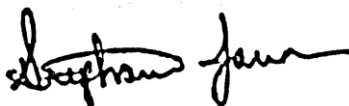
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About the HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS.

For more information, visit www.ehra.org.

Electronic Health Record Association

Comments on Draft USCDI 2

Overall

We appreciate the goal of expanding USCDI to encompass both electronic health information (as defined in 21st Century Cures Act) and other data classes that would not be considered electronic health information (for example, provider directories) but are also essential for interoperability.

As ONC works to achieve its vision for the USCDI, we encourage you to share your analysis of why certain data classes were not and might never be included in the data set. This insight would help inform stakeholders on ONC's policy goals behind its expansion of the USCDI, and support entities to provide more helpful feedback in the future. We recommend that ONC keep track of data that was considered but has been excluded from EHI, and why, along with other USCDI information on its website.

Proposed Data Concept

USCDI in Certification

As USCDI grows to encompass more electronic health information (EHI), it should be expected that some health information technology (IT) implementations, based on the purpose of the system, will not support the collection or documentation of all data classes and elements, and thus should not be expected to produce them.

For example, explanation of benefits (EOB) is a likely future candidate for USCDI, but EHRs primarily designed for clinical documentation may not capture or manage this information. A specialty-specific EHR for a geriatric clinic should not be expected to support all EHI captured by a pediatric EHR. A laboratory information system (LIS) will manage EHI in common with an EHR, but likely a subset of the EHI described by the USCDI.

We recommend establishing a method by which data classes and elements can be categorized to clearly identify the specific data classes/elements in the USCDI that each type of stakeholder and health IT system is expected to support, and thereby provide access to. A starting point might be identifying the data classes and elements pertinent to inpatient settings or ambulatory settings, and categorizing other data classes and elements relevant to administration, billing, or other purposes of use.

The name of the data set, U.S. Core Data for Interoperability, implies that it contains data relevant to interoperability, which concerns sharing of data between and among organizations using electronic systems. That may include data that is not part of the EHI definition. Examples would be data to enable cross-organization workflow integration, as well as supporting information such as directories. We suggest clarifying that such data is also appropriate to consider for future USCDI expansion. Or, if ONC intends that USCDI focus exclusively on health information, it would be helpful to clearly indicate that it is not in scope and identify how alignment on such other essential data is achieved.

Rapid Expansion of USCDI V2

Currently, the USCDI includes fewer data classes and attributes than are currently designated as either “(Shall), Must Support,” and/or with a cardinality of at least one in HL7 CDA C-CDA or HL7 FHIR, the two standards named in the 2015 Certification Edition Cures Update to implement USCDI.

We recommend that USCDI include the intersection of data classes and attributes that are identified in C-CDA and FHIR as either required (Shall), Must Support, or have a cardinality of at least one. This recommendation will raise USCDI to a level that is being widely adopted by the industry, and align everyone subject to the USCDI data scope to the same data set, rather than two different data sets. Lack of alignment will only expand the already-existing confusion around what data one can expect to have access to from any provider, whether in standard or non-standard format.

Standards Implementation Guidance Availability for USCDI V2 and Beyond

We noted some groups, including HITAC and others, are proposing data classes or elements for inclusion in USCDI v2 for which there is no current guidance to enable consistent and sufficient support using HL7 CDA C-CDA and/or HL7 FHIR US Core. Examples include Medicare Beneficiary Identifier, Diagnostic Studies, SDOH, and SOGI data. We fully support the need for these data elements. At the same time, the absence of guidance is a concern. It may lead to a rushed approach to get the guidance updated. For example, there is effectively only one HL7 ballot cycle left to gain consensus before SVAP would be published that should include all the guidance necessary to support USCDI v2. If guidance is not available, adoption of USCDI v2 will likely be delayed or implementations will vary unnecessarily, creating fewer interoperable capabilities.

We support the proposed HITAC recommendation that ONC only include data in USCDI v2 for which guidance is available. We furthermore recommend that ONC and HITAC rapidly establish a target outline of USCDI v3 and USCDI v4 that can be used by HL7 and its community to create and test the necessary guidance in advance of USCDI v3 and v4 publication. A clearer list of target data elements for USCDI versions n+1 and n+2 at or shortly following the publication of USCDI version n will facilitate efficient standards development work.

Care Team Members

We note that the provider name and provider identifier are already represented in FHIR and C-CDA. We support their addition in USCDI v2.

We recommend that more guidance be given in regards to the care team member name: specifically, that not all name elements may be required, depending on context and user, e.g., some clinicians prefer to withhold their last names from patients out of concern for their safety and privacy. Additionally, not every care team member has an identifier such as an NPI, including clinicians. Even when an NPI is present, sharing it may not always be appropriate. We suggest clarification in the USCDI introduction that data classes and attributes included in USCDI may, in some cases, not be appropriate to be shared for privacy and security reasons, in accordance with the applicable information blocking exceptions.

Diagnostic Imaging

The newly proposed Diagnostic Imaging data class contains attributes for both Diagnostic Imaging Narrative and Diagnostic Imaging Report. However, a Diagnostic Imaging Report already regularly contains narrative/free text notes, in addition to further encoded, qualitative, and/or quantitative data. We suggest removal of Diagnostic Imaging Narrative as a separate attribute, and including it as part of the definition of a Diagnostic Imaging Report. We recommend ONC work with HL7 to provide that clarification in the C-CDA and FHIR US Core implementation guides.

The definition of Diagnostic Imaging Order is unclear, as the provided definition indicates a request, while the Rationale for Separate Consideration compares it to a Procedure data class. If Diagnostic Imaging Order is truly intended to be a request, FHIR US Core would not have an ability to support that, because ServiceRequest is not included, and it would be a major change for the implementation guide to accommodate. If this attribute is meant to be a special form of a performed procedure that requires particular data, or to ensure that kind of procedure is covered, then the name should be changed.

We suggest adding more information to the definition of diagnostic images/imaging, especially to draw the distinction from more general images/imaging. We consider diagnostic imaging to be images taken to establish a diagnosis (e.g., a chest x-ray to determine pneumonia), while other imaging is used to support findings (e.g., a picture of a wound to track healing progress). We suggest that this data class be focused on diagnostic imaging as defined here.

Laboratory

We support moving the Laboratory Report Narrative from Clinical Notes to the Laboratory data class. This reduces ambiguity in differentiating between a clinical note and a Laboratory Report. In line with our suggestion to include narrative notes as part of the Diagnostic Imaging Report, we also suggest the attribute names be Laboratory Report and Pathology Report, following the same description of the report: comprising elements of narrative, encoded, qualitative, and quantitative content.

Encounter

We appreciate the inclusion of Encounter, considering it provides context to many of the other USCDI data, and because it is currently included in C-CDA and FHIR US Core. We also note the opportunity to align with quality measures that are based on encounters.

While the appropriate vocabulary standards are listed for Encounter Diagnosis, only potential vocabulary standards are listed for Encounter Type. We recommend inclusion of at least CPT and SNOMED as currently supported by C-CDA and FHIR US Core.

While some health IT would always have a procedure in the context of an encounter, it is possible that other health IT would have procedures outside of an encounter context. USCDI should not mandate either approach, but should accommodate either.

It is unclear what scope of reasons and diagnoses are expected to be included in the Encounter Diagnosis proposal. The term “reasons” creates confusion, as those are typically free text, while the proposal suggests including coded diagnoses only. We recommend separation of these two concepts and inclusion of both the Encounter Reason, following the definitions used in HL7 CDA C-CDA and HL7 FHIR US Core, as well as Encounter Diagnosis.

We also recommend more clarity in defining which diagnoses should be included as an Encounter Diagnosis. The proposal specifically references discharge diagnosis, but it is not clear what other diagnoses would be in scope. The term “primary diagnosis” may be the admission diagnosis, considering the reference to the primary reason of the encounter and the interest in coded diagnosis, or it could be the primary billing diagnosis. However, the main focus of the proposal appears to be on diagnoses used in quality measures without any reference to billing diagnosis. We suggest clarifying that any clinically relevant diagnosis documented in relation to the encounter is considered in scope, e.g., admission, visit, or discharge diagnosis.

Problem

The proposal suggests inclusion of Date of Diagnosis, indicating that it reflects “the date a patient first had the diagnosis.” This is very similar to the definition in Level 2 for Date of Onset, which states “the date on which the signs/symptoms/pathology of the diagnosis began.” During a HITAC USCDI Taskforce discussion it was clarified that the intent of the Date of Diagnosis was meant to be the date the clinician diagnosed the patient. We support that clarification and suggest reflecting that intent in both the name – by changing it to Date Diagnosed – as well as the definition. We note that the supporting standards, HL7 CDA C-CDA and HL7 FHIR R4 (thus HL7 FHIR US Core), does not include an attribute that would specifically capture this concept. The closest is the recorded date, which may not always be the same, although for documentation purposes it may be appropriate, because it can be more easily captured as part of the documentation process. We suggest the definition reflect that this is the date the diagnosis was recorded.

We recommend adding Date of Onset as defined in the Level 2 proposal, as there is sufficient adoption for inclusion at this time.

We note that the definition of Problems and Health Concerns overlap; the definition of Problems seems to include Health Concerns as well. We suggest clarifying the difference using the definition from the supporting HL7 CDA C-CDA and HL7 FHIR standards.