April 15, 2021

Submitted Electronically

Micky Tripathi, Ph.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

Re: Draft United States Core Data for Interoperability Version 2

Dear Dr. Tripathi:

Thank you for the opportunity to provide comments on ONC's draft of the United States Core Data for Interoperability Version 2 (USCDI v2).

As a leading developer of interoperable health information technology, we support ONC's goal of aligning the industry's efforts and thoughtfully adopting standards to improve health information exchange. We believe that ONC's Draft USCDI v2 effectively balances key factors like prioritization by provider organizations, the maturity of available standards for representation and exchange, and maintaining a reasonable development and implementation effort for an annual update.

We have provided some general feedback on the USCDI, as well as more detailed recommendations on areas of ambiguity in the Draft USCDI v2 that should be resolved before it is published and adopted by the industry.

We would be happy to answer any questions you might have on our feedback and to continue to work with ONC and Standards Development Organizations to improve standards-based data exchange in healthcare.

Thank you for your consideration.

Sincerely,

Dave Fuhrmann
Senior Vice President, Research and Development

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General Comments on the USCDI

Scope of Annual Changes

Considerations for Expanding the USCDI

We support ONC's approach of making thoughtful and measured expansions as it developed the Draft USCDI v2. Measured annual updates to the data classes and elements included in the USCDI create a more manageable scope for health IT developers. This makes it easier for them to adopt updated versions of the USCDI in their products quickly. It also focuses industry efforts on data classes and elements with mature standards and clear use cases.

Selection of Appropriate Data Classes and Elements

We support the data classes and elements added in the Draft USCDI v2 as natural additions to the existing data set of USCDI v1. The new data class and elements for Encounter Information, Problems, Diagnostic Imaging, and Care Team Members are well understood concepts in the industry and have mature specifications for standardized representation and exchange via common exchange mechanisms like FHIR and CDA.

USCDI and Certification

The proposed USCDI v2 data classes and elements seem reasonable for inclusion in all certified health information technology. As ONC further expands USCDI, some data classes and elements might not be applicable in all contexts. For example, a future version of the USCDI might include a Discharge Disposition data element, but that data element is not typically used outside of the inpatient context.

ONC should determine the best way to accommodate data elements that are specific to a particular context of care or use in certification and other regulatory programs that reference the USCDI. It should be indicated within the USCDI when certain data classes and elements are only applicable to specific settings. That will provide flexibility for developers to focus on adopting the data classes and elements from new versions of the USCDI that are applicable to the context in which their certified product is used.

USCDI and Non-EHI

Future versions of the USCDI might recognize the need to include data elements that are not patient identifiable but are needed for interoperability. ONC should consider how to handle those data elements in the USCDI. Provider directory information (including, for example, Direct addresses) is considered "core data for interoperability" by many industry stakeholders. However, because the data in a provider directory is not patient identifiable or health information, it does not fit well in the current structure of the USCDI.

If future versions of USCDI recognize non-health information as core interoperability data classes, ONC should consider how to designate those classes or elements in a way that does not imply that such data is associated with a patient's records, exchanged as part of a patient's records, or required for patient disclosure.

Areas of Expansion for Future Versions of the USCDI

Many industry stakeholders, including Epic, recognize the immense potential that the consistent exchange of Social Determinants of Health Data (SDOH) has to reduce health disparities and provide holistic care to patients. A future version of the USCDI (i.e., USCDI v3 or beyond) should include SDOH data classes. Existing standards for SDOH data are not mature enough for implementation at scale with USCDI v2. To accelerate the readiness of standards for SDOH data exchange, ONC should work with the provider community to identify the assessments

most commonly used to evaluate a patient's SDOH so that Standards Development Organizations can prioritize the creation of Implementation Guides to represent and exchange them.

Provenance of Additional Data Classes and Elements

Provenance information will not be applicable or valuable for all additional data classes and elements in future versions of the USCDI. For example, it is often difficult to assign an Author Organization and Author Time Stamp to patient and provider demographics data. For other data classes (for example, vitals), provenance metadata provides little value to the clinician receiving the data. We recommend that ONC specify the data elements for which provenance information should be exchanged as they are added to the USCDI, and require it only when there is a clear use case.

Process for Expanding the USCDI

ONC's current approach to developing new versions of the USCDI builds consensus amongst industry stakeholders on the data classes and elements that should be prioritized for exchange. The standards development community often needs to clarify or update implementation guides before those data classes and elements are ready for exchange at scale via the FHIR and CDA standards. Industry stakeholders might be hesitant to adopt the new version of the USCDI until updated Implementation Guides are available. For example, some stakeholders have suggested including the Medicare Beneficiary Identifier in a future version of the USCDI. However, FHIR US Core Implementation Guides do not yet include coverage information such as a subscriber ID, which is how the Medicare Beneficiary Identifier would be handled in the standard.

As ONC continues to refine its process for expanding the data classes and elements included in the USCDI, it could consider adopting the following process to maximize stakeholder input and industry preparedness for adoption:

1. Build consensus within the healthcare and health IT community on the set of data classes and elements that should be prioritized for the next version of the USCDI. ONC could identify which data classes and elements should be prioritized based on feedback from healthcare providers and the maturity of standards for exchange.
2. Solicit industry feedback and recommendations on updates required to implement workflows to consistently capture the data, as well as whether and how existing Implementation Guides need to be updated to facilitate consistent handling and interpretation by health IT systems.
3. Work with Standards Development Organizations to publish consistent updates to relevant Implementation Guides for both FHIR and CDA.
4. Finalize the new version of the USCDI as ready for adoption by the industry when the above steps are complete, a US Core profile is created, and the resources have an implementation maturity of at least two.

Feedback on Specific Changes in the Draft USCDI v2

Problems Data Class

Date of Diagnosis and Date of Resolution

Feedback from our users suggests that many problems have imprecise starting and resolution dates: for example, a patient may recall that their problem started in 'Summer 2017,' but cannot provide an exact date. This concept is sometimes referred to as "fuzzy dates." If this data element is incorporated in USCDI, it will be important to clarify how health IT developers and providers should understand dates when exchanged between systems. If a receiving system learns that a patient last had a cancer screening due every three years in 2018, for

example, should the receiving system's clinical decision support treat the patient as due for another screening at the start of 2021? At the end? At some point in the middle?

ONC should also clarify whether the data element is intended to capture the date the problem was observed by the patient, the date it was recorded in the patient's record, or both based on guidance from US Core Implementation Guides for FHIR and CDA and input from the standards development community.

Care Team Members Data Class

Provider Name

This data element is redundant with the existing Care Team Members data element. We recommend removing it.

Provider Identifier

Not all staff or entities listed in the patient records as part of the Care Team would have an NPI or other unique cross-organizational provider identifier.

Defining the data provenance for the Provider Identifier data element would be challenging and provide limited value to recipients. It is unclear what Author Organization would be associated with a provider identifier (some options might include the creator of the identifier, for example, CMS' NPPES system, or the healthcare organization that added the provider to the patient's care team). Similar challenges would apply when assigning an Author Time Stamp to the Provider Identifier data element. Moreover, understanding the provenance metadata for provider demographic data offers little value to clinicians when exchanged. We recommend not requiring data provenance to be exchanged with this data element.

Encounter Information Data Class

Encounter Type

The HL7 value set for Encounter Type referenced by the Draft USCDI v2 classifies encounters at different levels of granularity without a clear hierarchy within the list, making it too broad to be used consistently when exchanged. For example, the same patient encounter might be a telemedicine consult (448337001), outside of normal hours (18546400), and for acute pain (421946003) simultaneously.

We recommend specifying a restricted set of values for Encounter Type as the data element is rolled out in USCDI v2. For example, the following SNOMED terms could be designated as the initial set of options:

- Patient Encounter Procedure (308335008);
- Hospital Admission (32485007); and
- Emergency Department Patient Visit (4525004).

The USCDI should also align its definition of Encounter Type with the way CPT codes are used to identify encounters in quality reporting.

Diagnostic Imaging Data Class

Diagnostic Imaging Report

We recommend that the USCDI v2 specify that the following components should be included when exchanging the Diagnostic Imaging Report data element:

- Diagnostic Imaging Procedure Code
- Human Readable Procedure Name
- Date Ordered

- Date Performed
- Date Resulted
- Modality
- Anatomy That Was Imaged (free text)
- Diagnostic Imaging Narrative

ONC should also work with Standards Development Organizations to update specifications for consistent implementation across health IT developers in the FHIR and CDA standards, and specify a code set for Modality.

Diagnostic Imaging Narrative

Many actors consider the Diagnostic Imaging Narrative a component of the Diagnostic Imaging Report. USCDI v2 should include the Diagnostic Imaging Narrative as a component of the broader Diagnostic Imaging Report data element.

Clinical Notes Data Class

Removal of the Laboratory Report Narrative, Pathology Report Narrative, and Diagnostic Imaging Narrative Data Elements from Clinical Notes

We agree that these data elements fit more naturally into the data classes to which they are assigned in the Draft USCDI v2, which align more closely with how they are handled in the FHIR and CDA standards.

Assessment and Plan of Treatment Data Class

It is unclear how the Assessment and Plan of Treatment data class is intended to be used; an applicable standard is not referenced for the data class within the USCDI. While some have interpreted the data class as aligning with the FHIR US Core CarePlan resource profile, that does not align with how the data class would be represented in the CDA standard. Further, data elements that some stakeholders would consider to be part of an Assessment and Plan of Treatment for a patient are redundant with other USCDI data classes and elements.

ONC should clarify in the USCDI v2 what constituent data elements are expected to be exchanged as part of the Assessment and Plan of Treatment data class, and the applicable standards that should be used to represent those data elements.

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