April 29, 2022

Submitted Electronically

Micky Tripathi, PhD.
National Coordinator for Health IT
Office of the National Coordinator for Health IT
Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

Re: Draft USCDI Version 3

Dear Dr. Tripathi:

Thank you for the opportunity to provide comments on ONC's draft of the United States Core Data for Interoperability Version 3 (USCDI v3).

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 have provided some general feedback on the USCDI, as well as more detailed recommendations on areas of ambiguity in the Draft USCDI v3 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,

Danielle Friend
FHIR Research and Development
Epic

General USCDI Feedback

Expanding Scope Beyond Clinical Use Cases

The Health Insurance Information data class and its constituent data elements would expand the scope of USCDI to include concepts related to payment, which are beyond the clinical use cases that have historically been the focus of USCDI and ONC's Health IT Certification Program. EHRs might integrate with health IT that supports registration, billing, and practice management functionality, but EHRs themselves would not necessarily support the documentation and exchange of data for those purposes.

If future versions of USCDI become required in certification or other programs, expanding the focus of the USCDI to include data elements for non-clinical workflows could increase costs to users of certified health IT by requiring them to license additional modules that they otherwise might not want or need.

Applicability Across Clinical Contexts

As ONC expands the USCDI, it will need to either confirm that additional data elements are applicable across all contexts in which certified health IT is used or denote when certain data classes and elements are only applicable to specific care settings. For example, tools to document and store data elements that would be collected as part of the hospital admission and discharge process would not typically be available in certified health IT for use in ambulatory practices. Expanding the USCDI beyond the core clinical contexts and use cases will also increase the complexity of the data structures under consideration for inclusion in the USCDI, requiring additional time for the standards development community to build consensus on implementation guides to facilitate their consistent exchange and more time for their incorporation into health IT. As ONC expands the USCDI into more complex data elements, it will need to continue to closely coordinate with HL7 to ensure the USCDI's roadmap aligns with the standards development community.

Feedback on Specific Data Classes and Elements

Health Insurance Information

Coverage Status

Coverage Status is an ambiguous concept and not discretely exchanged in the C-CDA standard today. Whether a patient carries active health insurance could be derived based on other health insurance information that can be exchanged using the C-CDA standard. However, the presence or absence of coverage for a particular encounter, item, or claim would typically be documented in a billing system, not an EHR.

It is also unclear how coverage would be defined for a particular encounter, item, or service. For example, if a health plan would provide reimbursement for an item, but the patient chooses to self-pay for the item herself, is that item considered "covered"? Would the coverage status change if a claim were submitted for the item, even if she ultimately needs to pay for it out of pocket because she hasn't met her plan's deductible?

Determining which coverages are active for a patient is usually done by providing effective dates. We recommend replacing the Coverage Status data element with a Coverage Effective Dates element. Using effective dates represents which coverages a patient has available to pay for services.

If the intent is to represent which services were paid for by a given insurance, consider adding a "Covered Services" data element, which could indicate the relevant Encounters, Procedures, and other services that were paid for using the coverage. The term "Covered Services" could refer either to past services that have been paid for, or the full list of possible services a coverage could pay for. The definition should clarify which meaning is intended.

Group Number

Group Number is not discretely exchanged in the C-CDA standard today. ONC will need to work with the standards development community to enable its consistent exchange with USCDI v3.

Payer Identifier

We are not aware of any national identifiers for payers. The USCDI should specify the identifier expected to be exchanged using this data element.

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Health Status

Functional Status

Additional profiling work will need to be completed by the standards development community before this data element can be consistently exchanged using FHIR APIs.

The Functional Status data element could incorporate numerous assessments that evaluate different components of cognitive, mental, social, or other function. Some of those types of assessments and their outcomes might be better handled by other data classes and elements in the USCDI (for example, Problems or SDOH Problems/Health Concerns), especially if they drive specific clinical needs or interventions.

We recommend specifying which assessment types should be exchanged in the Functional Status data element to promote consistent implementation across systems. One example of an assessment the Functional Status data element could include in its value set is CMS' Minimum Data Set (MDS) assessment information.

Disability Status

Additional profiling work will need to be completed by the standards development community before this data element can be consistently exchanged using FHIR APIs.

Disability Status could encompass a broad range of health conditions that are acute or chronic in nature, and the definition of whether a person is considered disabled could vary by context. For example, a broken leg could be considered a temporary disability from a healthcare provider's perspective that requires accommodation of a wheelchair or crutches. In the benefits determination context, however, a broken leg might not qualify as a disability.

We recommend specifying a set of assessments, observations, or conditions that should be exchanged within the Disability Status data element. This will help distinguish it from the Problems data class and provide recipients of the information with the context necessary to understand the sending entity's definition of disability.

Mental Function

Additional profiling work will need to be completed by the standards development community before this data element can be consistently exchanged using FHIR APIs.

We recommend specifying a set of assessments that could be used to evaluate Mental Function including alertness, orientation, comprehension, concentration, and immediate memory, especially in transitions of care. Identifying a specific set of assessments for this data element will facilitate consistent implementation and interpretation of the information. Because many jurisdictions restrict the ability of healthcare organizations to disclose related to mental function, it could take longer for health IT and provider organizations to be ready to exchange this information once the USCDI v3 is finalized, compared to other data elements.

Patient Demographics

Date of Death

Date of Death is not discretely exchanged using the C-CDA standard today. ONC will need to work with the standards development community to enable its consistent exchange with USCDI v3.

Tribal Affiliation

We are not aware of a commonly adopted value set to denote Tribal Affiliation. ONC should work with other government stakeholders to identify or construct a value set to facilitate consistent implementation and exchange of the data element. It is also not discretely exchanged using the C-CDA standard today. ONC will need to work with the standards development community to enable its consistent exchange with USCDI v3.

Related Person's Name

Related Person's Name is not discretely exchanged using the C-CDA standard today. ONC will need to work with the standards development community to enable its consistent exchange with USCDI v3. ONC should also clarify the distinction between the definition for this data element and the Care Team Member data element.

Related Person's Relationship

Related Person's Relationship is not discretely exchanged using the C-CDA standard today. ONC will need to work with the standards development community to enable its consistent exchange with USCDI v3. ONC should also clarify the distinction between the definition for this data element and the Care Team Member data element.

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Occupation

This data element is not discretely exchanged using the C-CDA standard today. ONC will need to work with the standards development community to enable its consistent exchange with USCDI v3.

Although the value set associated with this data element is extensive, its granularity will create usability challenges and make interoperability more burdensome. For example, the value set distinguishes between different kinds of card dealers, different pressman, and different types of computer programmers based on the programming language. This will add burden to registration staff or clinicians when documenting this information. It will also increase the burden on IT departments to complete mappings to ensure the data element can be consistently exchanged and interpreted.

We recommend working with the value set steward to either simplify the value set or make it hierarchical. The data element should also allow extensibility in the value set so that occupation data can be shared even if a coded value does not yet exist.

Occupation Industry

This data element is not discretely exchanged using the C-CDA standard today. ONC will need to work with the standards development community to enable its consistent exchange with USCDI v3.

Although the value set associated with this data element is extensive, its granularity will create usability challenges and make interoperability more burdensome. This will add burden to registration staff or clinicians when documenting this information. It will also increase the burden on IT departments to complete mappings to ensure the data element can be consistently exchanged and interpreted.

We recommend working with the value set steward to either simplify the value set or make it hierarchical. The data element should also allow extensibility in the value set so that occupation industry data can be shared even if a coded value does not yet exist.

Procedures

Reason for Referral

Within the C-CDA standard, Reason for Referral would better be accommodated in its own Referral data class. Patients can be referred to other providers or entities for purposes other than a particular procedure.

Clinical Notes

Discharge Summary Note

The Discharge Summary Note data element definition refers to the inclusion of a sub-data element for “location” that is ambiguous. Location could refer to the hospital location from which the patient was discharged, or it could refer to the location to which the patient was discharged from an inpatient facility. We recommend specifying that it is the location to which the patient was discharged, and specifying a value set of options (e.g., home, hospice, skilled nursing facility, etc.).

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