April 14, 2023

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 United States Core Data for Interoperability Version 4

Thank you for the opportunity to provide comments on ONC's draft of the United States Core Data for Interoperability Version 4 (USCDI v4).

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 v4 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

Considerations for expanding USCDI

Combined Scope of New Elements

We support ONC's approach to prioritize new data elements that, when combined, are a "modest aggregate" lift for developers and implementers. Modest inclusions create a manageable scope for health IT developers and make it easier for them to quickly adopt updated versions of the USCDI in their products. On review, we estimate similar effort to update support from USCDI v3 to the Draft USCDI v4 when compared to the USCDI v1 to USCDI v2 transition. Elements in the following data classes are most likely to jeopardize this consistent "modest aggregate" lift due to variance in interpretation and should be clarified prior to publication: Health Status Assessments, Medications, and Goals.

Restricted Set of Values

For new data elements, we recommend defining a clear set of values to be exchanged based on industry feedback. This will reduce ambiguity in data element interpretation and promote consistent implementation across systems. For example, the Clinical Notes data class defines LOINC code Consult Note (11488-4) as the minimum applicable vocabulary standard for the Consultation Note data element.

Feedback on Specific Data Classes and Elements

Facility Information Data Class

The Facility Information concept is ambiguous and could be interpreted as the location where the patient encounter takes place or more broadly as facility or service directories. Facility Information, defined as the location where the patient encounter takes place, is a well understood concept that is widely collected and exchanged. We recommend updating the data class name to "Encounter Facility Information" and revising the definition to clarify the class captures data about the physical location where services have been, or are planned to be, provided.

Facility Identifier

Not all facilities will have a National Provider Identifier (NPI). Locally defined department or hospital identifiers are widely collected and exchanged within an organization or trading partners based on implementation-specific mappings. We recommend updating the description to include NPIs when known and locally defined identifiers when more appropriate.

Facility Type

Specifying a facility type required value set would promote consistent interpretation of this data element, but the value set in the Draft USCDI v4 submission's applicable vocabulary standard, HL7 v3 value set ServiceDeliveryLocationRoleType, should be refined before use. The values overlap in meaning and are not hierarchical. For example, the "cardiovascular diagnostics or therapeutics unit" description includes "cardiac cath lab," but "cardiac cath lab" also has its own listing in the value set. The data element description uses hospital as an example value, which is a less specific interpretation of facility that could likewise overlap with examples from the value set. We recommend working with the healthcare community to further develop consensus on the types and hierarchy of facilities to improve semantic interoperability and reduce mapping burden.

Facility Name

The data element description should be updated to define the name expected to be exchanged using this data element. We recommend referencing a known example, such as the component of PV1-3 in the HL7 v2 specification, to further clarify the intention of this data element and promote standardization.

Goals Data Class

Treatment Intervention Preference

Widely understood Treatment Intervention Preference data, like the Personal Advance Plan Document, are legislated by the states and differ, which limits discrete data exchange. Treatment Intervention Preference information is instead typically collected as a legal document that is scanned into the chart. We recommend updating the Treatment Intervention Preference description to clarify that this data can be captured as a scanned document until remaining discrete standards further mature.

Epic Systems Corporation | 1979 Milky Way Verona, WI 53593 | 608.271.9000 | www.epic.com

Care Experience Preference

Care Experience is not collected discretely nor widely exchanged today. For example, what makes a patient laugh, a preference included in the submission's applicable vocabulary standard HL7 CDA® R2 Implementation Guide: Personal Advance Care Plan (PACP), may be recorded in a note or simply brought up in a conversation. Outside of religious beliefs, the Care Experience Preference is not a well defined industry concept. Existing standards around the Care Experience Preference element are not yet mature enough for implementation in USCDI v4.

Health Status Assessments Data Class

Alcohol Use

We recommend updating the Alcohol Use data element's applicable vocabulary standard to define a set of codes, which will ensure the data is consistently exchanged. For example, the following LOINC codes could be designated as the initial set of options:

- History of Alcohol use (11331-6)
- Alcoholic Drinks per Day (74013-4)

Data for these values is widely collected and exchanged.

Substance Use

The patient's reported use of drugs could be interpreted as reported by the physician, patient, or via direct methods like drug concentration in body fluids and the reported use could vary or conflict based on source. We recommend updating the data element to specify the data source should be physician report.

The element description includes "other substances used for non-medical purposes or in excess of a valid prescription," which is not a well defined concept or widely collected. Further, a drug could be reported with varying levels of specificity or more accurately be a mixture of drugs. A value set of potential substances should be included to facilitate consistent interpretation. We are not aware of a commonly adopted value set representing Substance Use as described. ONC should work with other government stakeholders to identify or construct a value set to facilitate consistent implementation and exchange of the data element.

Physical Activity

Although Epic recognizes the potential positive impact of incorporating data on physical activity as a new area of focus, additional work is needed before Physical Activity data can be consistently exchanged. We recognize and are supportive of the work being done by the Physical Activity Alliance on the HL7 FHIR® Physical Activity Implementation Guide to define collection of this vital sign. However, the existing standards are not yet mature enough for implementation in USCDI v4. Physical activity data about the days per week the patient engaged in physical activity specifically is a well understood industry concept and could be included if limiting Physical Activity to this scope. In that case, we recommend updating the applicable vocabulary standard to the following LOINC codes:

- How many days per week did you engage in moderate to strenuous physical activity in the last 30 days (89555-7)
- On those days that you engage in moderate to strenuous exercise, how many minutes, on average, do you exercise (68516-4)

Laboratory Data Class

Specimen Source Site and Specimen Identifier

For clinic or bedside specimen collection, specimen source and identifier information will likely be available in EHRs. However, when specimens are collected at the lab, EHRs often won't have this information. ONC should consider whether the communication of specimen information should be a responsibility of Lab Information Systems in addition to EHR systems when making updates to certification criteria that may reference USCDI v4.

Medications Data Class

Medication Adherence

We expect there will be challenges with expectations of communicating Medication Adherence, which can be defined and measured in many ways. Some examples include patient self-report or report to a healthcare professional, direct

measurement of drug concentration in body fluids, Electronic Medication Packaging (EMP) devices, or Medication Possession Ratio (MPR).

Healthcare organizations using EHRs may have limited access to data needed to accurately measure Medication Adherence depending on how the data element is interpreted. For example, direct measurement relies on data from labs, EMP devices on data from the device, and MPR on data from pharmacy claims and dispense information.

We recommend limiting the scope of Medication Adherence to data collected in the EHR, which corresponds to the example values in the existing description, "taking as directed," "taking not as directed," and "not taking."

Procedures Data Class

Time of Procedure

Time of Procedure may not always be accurately represented as a single time and/or date. For example, a procedure may start and stop multiple times resulting in several ranges necessary to accurately reflect the time of procedure. We recommend updating the description to include ranges of time and/or dates.

Vital Signs Data Class

Average Blood Pressure

The term "average blood pressure" could denote a general average like per encounter, specific measurements like 24 Ambulatory Blood Pressure Monitoring (ABPM) or Self-Measured Blood Pressure Monitoring (SMBP), or a value related to the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7) measure. Depending on the intended average, including timestamps in the existing Systolic and Diastolic Blood Pressure elements in the Vital Signs data class could prevent duplicative elements. The data element name and description should be updated to clarify which meaning is intended, for example update the name to "24 Ambulatory Blood Pressure Monitoring (ABPM)." If the intent is to exchange ABPM or SMBP, we recommend specifying a discrete LOINC code as part of the defined applicable vocabulary standard.

Patient Summary and Plan Data Class

The Patient Summary and Plan data class is ambiguous, which is not alleviated by the proposed change in data class name. 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 a Patient Summary and Plan for a patient, like the assessment portion of a clinical note, are redundant given existing USCDI data classes and elements. We recommend clarifying the intended meaning of this data class and avoiding conceptual overlap with existing data classes or elements.

Epic Systems Corporation | 1979 Milky Way Verona, WI 53593 | 608.271.9000 | www.epic.com