ORACLE Health

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April 14, 2025

Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Washington, DC 20416

Attn: Acting National Coordinator for Health Information Technology

RE: United States Core Data for Interoperability (USCDI) Version 6 Draft

Dear Mr. Posnack,

Oracle Health is pleased to provide feedback on the draft US Core Data for Interoperability (USCDI) standard version 6. As a leading provider of clinical and management information systems and a market leader in health information interoperability, we bring expertise and valuable insights to this subject. We appreciate the opportunity to share our knowledge and contribute to advancing the field.

As we have commented on previous USCDI versions, we continue to believe it is critical to assess the data readiness and availability of sufficiently mature standards and associated implementation guides to enable consistent adoption by all relevant HIT. This readiness includes the ability to scale at the national level without unreasonable risk for re-work when standards and implementation guides are not sufficiently mature and have insufficient adoption in operational settings.

Oracle Health supports and appreciates the hard work and dedication of you and your staff. We strongly support the ONC's drive for interoperability across healthcare stakeholders and recognize the valuable role USCDI plays in that endeavor. We are committed to working with the ONC and the industry to continue the progress in enabling interoperability.

Sincerely,

Stacy Amin
Vice President and Chief Counsel
Global Health Regulatory and Policy

Hans J. Buitendijk, M.Sc., FHL7
Senior Director, Interoperability Strategy

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General Comments

As we have commented previously in our responses since USCDI v2, we remain concerned with the ambiguity of existing and proposed USCDI data class and data element definitions and lack of mature standards for all proposed USCDI data classes and elements. We strongly urge ONC to address:

Standards Maturity

USCDI continues to require data elements with no corresponding HL7 FHIR and HL7 CDA C-CDA implementation guidance. This is problematic as:

- Updates to HL7 FHIR US Core and HL7 CDA C-CDA are untested at time of publication, thus insufficiently deployed and mature to be ready for USCDI.
- Having all USCDI being able to be part of every HL7 CDA C-CDA document, not just through HL7 FHIR-based APIs, actually increasingly leads to more documents including more than is necessary. Without explicit clarification from ONC, many EHR vendors, in an effort to avoid information blocking, will interpret USCDI v6 as written to mean that all USCDI should be included in all documents when shared. This will lead to bloated HL7 CDA C-CDA documents. For example, an increased number of Discharge Summaries will include Health Insurance Information where not needed. Including such irrelevant information creates bloated Discharge Summaries, which ultimately cut into providers' valuable time. USCDI should not drive inclusion of more data where not needed.

We recommend USCDI only includes data for which mature and widely deployed standards or implementation guides are available. This reduces use of new implementation guidance that did not have the benefit of adequate time to validate appropriateness in actual operational use and ability to scale adoption at the national level efficiently and consistently. That in turn reduces ambiguity for developers, reduce development time by focusing on what is demonstrated to work and have demonstrated value, and reduce missed expectations of providers on being able to share data predictably with others.

We also recommend emphasizing that HL7 CDA C-CDA documents should include relevant information, no more no less, particularly for encounter summaries, referral notes, and other targeted documents. While documents should be able to include most USCDI, ONC should clarify that the agency does not intend for EHR vendors to always include all available USCDI in all documents. Absent such guidance, documents will continue to be bloated, increasing the burden on both providers and vendors' HIT, which must de-duplicate and reconcile new data of interest to the provider.

Procedures

The Procedures data class continues to be interpreted more widely than appropriate due to inclusion of attributes which are not included and expanded on in other data classes, such as performance time in Laboratory and Immunization. The use of examples such as those found in medication administration leads a reader, unfamiliar with the supporting standards HL7 FHIR US Core and HL7 CDA C-CDA, to assume more data is made available than actually is.

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We recommend the USCDI use HL7 FHIR to model the data in scope and vocabulary bindings, as done in similar modeling in the UK and Australia. This would more discretely narrow the data class to exclude concepts such as lab tests and medication administrations which are modelled differently in FHIR.

Facility Information

USCDI v5 started to include Facility Information as a standalone data class without any references to the data classes and context where this is considered relevant. Facility and location information is relevant in many different contexts, but is most relevant where an encounter occurred. USCDI effectively creates an expectation that facility information is captured on all other data classes, that HL7 CDA C-CDA and HL7 FHIR US Core do not support.

HL7 FHIR US Core and C-CDA scoped this to the Encounter generally and identified the data classes that reference Encounter, enabling one to infer the location through that reference. When the Encounter location is not applicable, then they should (not shall) provide the location within the resource itself using the attribute or may use the event-location extension to encourage consistent placement of the location:

- US Core DiagnosticReport Profile for Laboratory Results Reporting
- US Core Immunization Profile
- US Core MedicationDispense Profile
- US Core Observation Clinical Result Profile
- US Core Procedure Profile
- US Core ServiceRequest Profile

We suggest the USCDI should be updated to reflect this targeted scope and is adjusted as that is expanded over time.

Workflow Context

USCDI defines data classes very broadly allowing for interpretations that are not only about being able to view/access the data (e.g., presence of an order), but could be interpreted to initiate/manage the workflow (e.g., the placement of an order, the reporting of the result in response to the order, etc.).

We suggest including an introductory statement to USCDI that the current purpose in the context of certification is for viewing/accessing USCDI data only. The statement should convey that data classes should not be used to manage the placement, fulfillment, or performance of procedure orders; rather, they should be used to view documented orders or performed procedures.

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Vocabulary

References to vocabulary are mostly to the overall code system to be used, not to the specific branches that are applicable. For some (e.g., Clinical Notes) there are references to very specific individual LOINC codes, and not having a more targeted middle ground set is causing challenges where they could be very helpful. For example, what are "all Clinical Tests" to be considered?

The HITAC provided a recommended starting set of specific LOINC-coded tests in their USCDI v3 recommendations (see Appendix B) but this was never formally adopted. What is truly the scope of Procedures? Which SDOH assessment tools are recognized widely enough to be supported (not necessarily documented, but viewable when received)? The lack of specific cited tools has caused significant confusion for both HIT developers and health care providers and misses an opportunity for further standardization of data exchange across care settings.

Overall, we suggest that vocabulary is more specifically bound in USCDI and accordingly proposed to enable appropriateness of scope.

Document vs. Note

USCDI v1 started to combine the concept of a structured document and narrative summary note by using the same LOINC code for either (e.g., the same LOINC code used for the C-CDA Document Type Discharge Summary and for the Discharge Summary narrative note). This action is now clearly showing the anticipated challenges that we raised in our USCDI v5 response letter dated April 15, 2024, as it is not possible to query for either, in their own right, where relevant. It also highlights grouping or categorization of related/like LOINC codes is relevant as well so that one can query for all related documentation, or just notes (e.g., all discharge summary related notes and documents or just the narrative discharge notes). We suggest the ONC work with Regenstrief to identify specific LOINC codes to distinguish narrative summaries from structured documents, as well as appropriate categories of documentation, and adjust USCDI accordingly.

Specimen

USCDI v4 introduced "Specimen Condition Acceptability" with a definition of "Information regarding a specimen, including the container, that does not meet a laboratory's criteria for acceptability." In FHIR US Core, this is supported using Specimen.condition, but the definitions are not aligned. Prior feedback to USCDI v4 and v5 has been that USCDI should use the same or similar definition where "Specimen Condition Acceptability" represents the conditions relevant to determine the acceptability of a specimen for a specific test. The actual acceptance of a specimen, considering its condition and the requirements of that test, may not be the same as the requirements of another test using that specimen, and should be captured on the test in terms of reasons for not being able to or not having performed a test due to the specimen's condition. These two concepts need to be kept separate. We recommend the definition of "Specimen Condition Acceptability" be changed to state "Information regarding a specimen's condition, including the container, that is used to determine a laboratory's criteria for acceptability."

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USCDI v6 Proposed and Updated Data Classes and Elements

We provide the following feedback on the specific changes proposed to USCDI.

Facility Address [Facility Information]

We support inclusion of this data element in the USCDI v6, with a further refinement to the specific address type to be used – e.g., billing address vs. physical location. A clear definition is needed to ensure consistency and appropriate use across all implementations of this element. This includes understanding what data elements are relevant in the context of other data classes where facility information is relevant, as indicated in our General Comments.

Unique Device Identifier (UDI) [Medical Devices]

While we support greater interoperability of medical device data, we find this proposal for non-implantable devices too broad in its current form. We are concerned about the scope of medical devices, what data would be included and the potential amount of manual entry needed to meet this requirement.

For example, laboratory information systems (LIS) do not include UDI as a part of the current workflow. We strongly urge ONC to work with the FDA and CMS to focus first on enabling LIS systems to capture the device identifier, then advance both the ability of EHR systems to receive and forward such information, followed by an expansion to address the full UDI with both the device and production identifiers as defined by the FDA.

We believe more work is necessary to support data transactions between systems before implementing a specific data element that would be required for certification. We recommend focusing on other more implementable and usable capabilities until such a time that workflow challenges would not necessitate manual data entry by the end user and a broader adoption by the sourcing systems and instruments.

Portable Medical Order [Orders]

The proposal included examples such as POLST (Portable Medical Order for Life-Sustaining Treatment), MOLST (Medical Orders for Life-Sustaining Treatment) and out-of-hospital DNR (do-not-resuscitate). We note that the current CDA-based POLST implementation guide is still too immature for adoption in this context as it has not been updated to address the gaps that the FHIR–based guide includes. However, the FHIR-based guide has not been balloted nor published, thus not ready for adoption.

We suggest a more limited scope that aligns with the Advance Directive Interoperability (ADI), where the provider authors the PMO document which is indicated by its location, content, type, and verification status. The document could include structured or unstructured data, whether a person has one or more portable medical order documents, and the type of the PMO. Specifically, we recommend ONC define PMO Orders as follows:

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Definition: Information about a provider authored portable medical order document indicating its location, content, type, and verification status.

Usage note: May include structured or unstructured data, whether a person has one or more portable medical order documents, the type of portable medical order, the location of the document, and whether it has been verified. Such documents may be used should a person be unable to communicate during an emergency or health crisis to a treating provider their preferences for CPR and/or life-sustaining treatment interventions, and often also include goals of care.

Examples include but are not limited to an indication that a POLST, MOLST, DNR or similar document is on file, a reference to the location of the portable medical order document, and the validating provider.

We believe this approach is more feasible and allows for future expansion as standards mature.

Care Plan [Patient Summary and Plan]

We also generally agree with the inclusion of Care Plan data with additional clarification on the scope of data required. Care Plans can vary widely based on the care setting and care plan type, where not all care plans will include all elements defined. We support expansion of the patient summary and care plan data, but inclusion of every proposed element does not represent real-world workflows. Therefore, we suggest defining Care Plan data as it is applicable to the care setting.

We also suggest addressing data elements of the "Care Plan" which overlap with or differ from the "Assessment and Plan of Treatment" data class, ensuring alignment and limiting redundancy. For example, further clarifying "prioritized problems" which, in its current form, could refer to the Problem List, Health Concerns, or other care plan elements.

Date of Onset [Problems]

We support the inclusion of this element.

Family Health History [Problems]

We support the inclusion of this data element and suggest using SNOMED or ICD for this element. The Applicable standards indicate LOINC but do not list ICD-10 and should be corrected.

We also suggest that a codified representation of the familial relationship of the individual to the patient (e.g., mother, father, etc.) should be part of the data element to promote standardization and reduce complexity.

Performance Time [Procedure]

We support an update to Performance Time and also suggest, in the same context of our general comment on Procedures, that ONC includes relevant times in the specific data

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classes which are already in place. For Laboratory this would include consideration of date/times such as specimen collection date/time, test result date/time, and reporting date/time.