HL7 International

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Micky Tripathi, PhD, MPP
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
Department of Health and Human Services
Hubert Humphrey Building, Suite 729
200 Independence Avenue SW Washington, DC 20201

Submitted electronically to:
https://www.healthit.gov/isa/ONDEC

Re: ONC's Draft United States Core Data for Interoperability (USCDI) Version 5

Dear Dr. Tripathi:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on ONC's Draft United States Core Data for Interoperability (USCDI) Version 5 and related data classes standards and elements. HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena. Our organization has more than 1,600 members from over 50 countries.

We appreciate this on-going collaborative process. HL7 applauds ONC's visionary leadership and the increasing role of USCDI in progressing and unifying health information technology use and innovation in our nation over time. HL7's feedback on the Draft USCDI v5 is detailed in our accompanying table. In addition to our leadership and Policy Advisory Committee, HL7 Work Groups contributing to these comments include Orders and Observations. Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We look forward to continuing this discussion and offer our assistance to ONC.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International

Andrew Truscott
Board of Directors, Chair
Health Level Seven International

HL7 Responses: ONC's Draft USCDI v5

HL7's comments for ONC's Draft USCDI v5 are below.

HL7 Comment Topics	HL7 Comments		Additional Commentary
Reduce Definitional Ambiguity	Regarding USCDI and the next version of the HL7 FHIR US Core and HL7 CDA C-CDA Companion Guides, some ambiguity with certain current USCDI structures and definitions create substantial challenges in identifying the appropriate updates to these implementation guides, that will also provide the specifications necessary to pass ONC's certification test and to be considered conformant to USCDI. **Below are some examples, further commentary and recommendations to highlight this point:** ▪ A number of data element definitions reference the submission that led to the inclusion of the element (e.g., Care Experience Preferences, Physical Activity). These submissions actually may contain much more information and imply a larger scope than what the definition and vocabulary may imply or intent. However, the definition does not clearly state the specific intended scope. • Depending on the discussion and context, one could consider medication administration and laboratory tests types of procedures, and therefore use a combination of data classes and related elements to adopt certain resources/entries/sections into HL7 FHIR US Core or HL7 CDA C-CDA CG for must support consideration. However,		

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	within the HL7 standards environment there is not a clear line of sight to yield that conclusion. References to very widely defined vocabulary could infer much more than what the standards would support through a procedure versus other concepts. Differences in interpretation of USCDI should be consistent, whether as expressed through a specific interoperability standard or another use of USCDI. ▪ Additionally, inclusion of reason for referral under the "Procedure" data class could be interpreted in a number of ways, including the inclusion of an order reference for the reason of procedure or on the procedure itself. The definitions are not clear about whether the focus is on the intent when ordered (of which a referral is one form, but not representative all forms of initiating a procedure) or the actual reason, that could be different than what was ordered or in cases where there is no formal order documented for that procedure. Another important question is --due to definitional ambiguity -- are we to consider the ordering of the procedure (presumably not per the definition)? Inclusion of the reason for referral with its definition may imply otherwise. • Regarding "Care Experience Preferences" it is not clear whether this indicates the preference as expressed and documented by the patient (which could yield one way of actually representing that - goals, service requests, etc.) or as expressed by		

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	the patient and as understood and documented by the provider (which could yield another way of actually representing that as observations). ▪ Introduction of "Clinical Notes" presents an ambiguity about whether a LOINC code for the notes listed (and others) represent merely the narrative or a document that includes the narrative plus further structured documentation. Consequently, a request to get representation of a particular LOINC code could be inconsistently responded to. Under this scenario, some would interpret this involving the narrative and others, the entire document (e.g., a Discharge Summary's narrative summary notes or the "full" Discharge Summary with all relevant content, or the "fuller" Discharge Summary with all the documentation for that stay). • Various current USCDI definitions do not include vocabulary references, such as "Coverage Type", while the submission portion has more clarity. Conversely in others, such as "Clinical Experience Preference", the submission portion includes much more than the definition implies. It is important that the definition, including the applicable terminology, is clear without having to review the submission and needing to understand which part applies. These ambiguities can be prevented if a more rigorous modeling approach is used. This involves either following more		

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	closely an HL7 V3 RIM approach that is more generic with extensive ontologies to be more specific about certain subsets, or pursuing an HL7 FHIR approach with more, and more tightly scoped concepts through its resource definitions. In either case, definitions must be crisp, complete and properly mapped to the intended scope in order to ensure optimal USCDI conformance. USCDI implementation expectations can be unclear, whether through HL7 FHIR US Core, HL7 CDA C-CDA. HL7 recommends that with the emerging use and deployment of HL7 FHIR, these USCDI resources provide a better level of granularity and intent, where a specification of the intended resources in scope. There should also be clarity on the specific scope of the binding to key vocabulary and associated typing/categorization. This would provide a more solid foundation for any use of USCDI. HL7 and other SDOs as appropriate can then more accurately and predictably produce the full specifications necessary to achieve the intended interoperability scope.		
Column Heading in Laboratory Data Element Table Page 17 of PDF version of USCDI v4	**Current text: APPLICABLE VOCABULARY STANDARD(S)** Standards listed are required. If more than one is listed, at least one is required unless otherwise noted. If a cell is empty, an applicable vocabulary standard has not been identified. **Proposed text: APPLICABLE VOCABULARY STANDARD(S)**		HL7 believes that the requirement for the named standard should be maintained. Local codes should be used when no appropriate

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	Standards listed are required**, when an appropriate code exists; When no valid code exists, the local code may be the only code sent. Additional codes from equivalent code systems may also be sent, including local codes**. If more than one is listed, at least one is required unless otherwise noted. If a cell is empty, an applicable vocabulary standard has not been identified. Additionally: • HL7 recommends clarifying the terminology standard to require the code aligned to the referenced terminology whenever one exists as the primary code, but including mappings or local codes in translation with the defined gold standard terminology. • HL7 recommends adding the additional data elements [below including specimen type] as metadata linked to HL70487 and SNOMED-CT.		standard code is available, and in addition to a standard code.
Laboratory Data Element Table Page 18 of PDF version of USCDI v4 **Result Interpretation**	**Current Text:** • Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) U.S. Edition, March 2023 Release Optional: • HL7 Code System ObservationInterpretation **Proposed Text**: Remove "Optional', as the HL7 Observation Interpretation code system has been		

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	harmonized across ALL HL7 product families.		
Laboratory Data Element Table Page 18 of PDF version of USCDI v4	For all data elements, where SNOMED CT is the declared standard, HL7 recommends identifying the appropriate hierarchy for the codes. HL7 suggests the following: • Values/Results - drawn from organism, qualifier, clinical finding hierarchy; • Specimen Type - drawn from specimen hierarchy; • Result Interpretation - drawn from qualifier hierarchy; and • Specimen Source Site - drawn from body structure hierarchy (known limitation here is for artificial body structures, this may need to be extended).		
Specimen Condition Acceptability	**Current Text:** Specimen Condition Acceptability Information regarding a specimen, including the container, that does not meet a laboratory's criteria for acceptability. Examples include but are not limited to: hemolyzed, clotted, container leaking, and missing patient name. Usage note: This may include information about the contents of the container, the container, and the label. **Proposed Text:** HL7 proposes that section this be split into two elements because they are different concepts. The acceptability of the specimen may vary by test, but the condition is a characteristic of the specimen. HL7 proposed this section would read as:		

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	Specimen Condition Information regarding a specimen, its physical characteristics or the state of its container or its label. **Specimen Acceptability** Assessment by the laboratory of its acceptability for the requested test (this may be based on the condition, or other factors). Acceptability examples include but are not limited: to hemolyzed, clotted, container leaking, and missing patient name. Usage note: This may include information about the contents of the container, the container, and the label. **This may need to be documented for situations when the test is not performed or when the test is performed despite not being an ideal specimen.**		