

September 30, 2022

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Submitted electronically to:

<https://www.healthit.gov/isa/ONDEC>

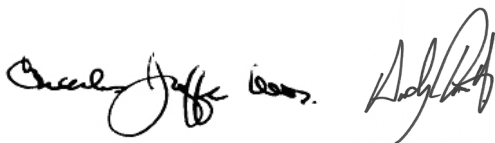
Re: ONC's Draft United States Core Data for Interoperability (USCDI) Version 4

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 4 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's feedback on the Draft USCDI v4 is detailed in our accompanying table. In addition to our leadership and Policy Advisory Committee, HL7 Work Groups contributing to these comments include Clinical Decision Support, Clinical Quality Information and Learning Health Systems. 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
HL7 International

Andrew Truscott
Board of Directors, Chair
HL7 International

Health Level Seven International (HL7) Response and Input

Comments for United States Core Data for Interoperability (USCDI) Standard (Draft Version 4)

I. OVERARCHING COMMENTS		
	Comments	
Overarching Comments	No comment	
ONC – Comments for United States Core Data Interoperability (draft v4)		
Data Class	Data Element(s)	Comments
Allergies and Intolerance (Level 2)	<p>Substance (Non-Medication): This describes allergens that affect clinical care which are not specifically a drug class or medication (i.e. other data elements within the Allergies and Intolerances data class). https://www.healthit.gov/isa/taxonomy/term/1436/level-2</p> <p>Substance (Food): Common food substances and allergens that can cause harmful or undesirable physiological responses when exposed to the substance or the substance is consumed. https://www.healthit.gov/isa/taxonomy/term/1441/level-2</p>	<p>HL7 notes the area of non-medication allergy requires broad stakeholder and expert guidance. We recommend some method be identified to resolve terminology and capture issues, perhaps with a common agreed-upon value set for broad use.</p> <p>Additionally, HL7 emphasizes that non-medication substances (food and non-medication) have a significant effect on clinical care and that specific items are important to determining exclusions and different pathways, with respect to providing clinical decision support and measuring clinical quality performance. The information is also applicable to specific clinical trial criteria and will support Clinical Decision Support (CDS), electronic clinical quality measures (eCQMs), digital quality measures (dQMs), clinical research and clinical trial participant identification.</p>
Care Team Member (USCDI v3)	<p>Care Team Member Role: Responsibility of an individual within the care team. (e.g., primary care physician, caregiver)</p>	<p>HL7 notes that the inclusion of "ongoing care provision" in the updated Care Team Member Role use case description will critically reinforce continuity of care. HL7 supports this addition and</p>

	<p>https://www.healthit.gov/isa/taxonomy/term/1301/uscdi-v3</p>	<p>emphasizes its necessity to prevent disjointed health services and resulting care gaps.</p> <p>HL7 proposes an update and modification of the use case as follows:</p> <p>Updated Use Case Reference: Collection of data related to a provider of health care or related services is associated with attribution and documentation of care, quality of care and safety reporting, financial information, consultation and referral, and discovery of services that may be needed for future care <i>as well as ongoing care provision</i>.</p> <p>Documentation of provider information can be performed automatically or require manual intervention to associate it with a past, current or future episode of care <i>as well as ongoing care provision</i>.</p>
<p>Care Team Member (Level 2)</p>	<p>Provider NPI: https://www.healthit.gov/isa/taxonomy/term/1356/level-2</p> <p>Provider DEA: https://www.healthit.gov/isa/taxonomy/term/1361/level-2</p>	<p>The current Care Team Member data element definition is “Information on a person who participates or is expected to participate in the care of a patient.”</p> <p>HL7 notes that the use of the phrase "a person" -- to indicate only people as Care Team Members -- defines a narrow scope for what is needed in care coordination and care provision. HL7 suggests and supports including the organization and organization NPI data elements. HL7 also supports an updated Care Team Member data element definition of “Information <i>on a person or an entity</i> who participates or is expected to participate in the care of a patient.”</p> <p>HL7 additionally notes that the care team should be defined by “all of those involved in the care of an individual patient” and that documentation should include comprehensive roles on that care team such as: family and community members, community services and healthcare professionals who are outside the traditional (hospital and clinic) healthcare facilities and that therefore do not exist in EHR representations of care teams.</p>

		<p>Given the importance of care team members, HL7 also recommends adding this concept to the Interoperability Standards Advisory (ISA) which can be referenced at: https://www.healthit.gov/isa/isa-document-table-contents</p>
<p>Provenance (Level 2)</p>	<p>Author: https://www.healthit.gov/isa/taxonomy/term/1171/level-2</p>	<p>HL7 observes that while USCDI Version 3 continues to include AuthorTimeStamp and AuthorOrganization, the Provenance author data element is essential for understanding the true originator of a message and, more specifically, the data element referenced in any given message. HL7 emphasizes that to determine the validity and reliability of any given data element in a message is foundational, especially with elements originating elsewhere and that are shared along with other data elements in a message.</p> <p>HL7 emphasizes more detailed provenance such as this, is a requirement for data curation in research and to assure aggregate analysis correctly interprets information used to extrapolate information for population health. For example, a functional status or mental health assessment, or an SDOH assessment has different value and reliability if directly completed by a patient versus completion by a practitioner who is informed by the patient. Until such provenance can be assured, the ability to interpret data and aggregate it appropriately will remain challenging.</p>