

June 5, 2023

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Submitted electronically to:

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

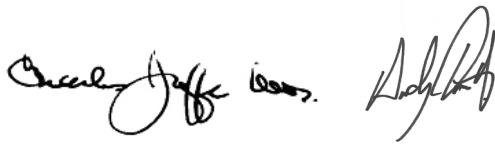
Re: ONC's Interoperability Standards Advisory (ISA)

Dear Dr. Tripathi:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on ONC's 2023 Interoperability Standards Advisory (ISA) Reference Edition. HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena.

We appreciate this on-going collaborative process. HL7's feedback on the 2023 ISA Reference Edition is detailed below and 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, Patient Empowerment and Payer/Provider Information Exchange, and Security. The HL7 Accelerator, Fast Healthcare Interoperability Resources at Scale (FAST) Taskforce also provided input. 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.

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 on the Interoperability Standards Advisory**

I. OVERARCHING COMMENTS		
	Comments	
Overarching Comments	No comment	
ONC – Comments for 2023 ISA Reference Edition		
	Comments	
Content and Structure	<p>Clinical Decision Support Sharable Clinical Decision Support https://www.healthit.gov/isa/shareable-clinical-decision-support</p>	<p>HL7 notes the HL7 FHIR 5 Clinical Reasoning Module should be added. Link should be: https://hl7.org/fhir/R5/clinicalreasoning-module.html Adoption level should be: 1</p> <p>HL7 notes the HL7 FHIR 4 Clinical Reasoning Module link at: https://hl7.org/fhir/R4B/clinicalreasoning-module.html Adoption level should be: 4</p> <p>HL7 notes that HL7 FHIR QICore 5 should be added. Link should be: http://hl7.org/fhir/us/qicore/STU5/ Adoption level should be: 1</p> <p>HL7 notes that HL7 FHIR QICore 4 should be added. Link should be: http://hl7.org/fhir/us/qicore/index.html Adoption level should be: 3</p>

<p>Content and Structure</p>	<p>Clinical Quality Measurement and Reporting Reporting Aggregate Quality Data for Quality Reporting Initiatives https://www.healthit.gov/isa/reporting-aggregate-quality-data-quality-reporting-initiatives</p>	<p>HL7 notes the Standard/Implementation Specification <u>HL7 FHIR® R4 Clinical Reasoning Module</u> Should be changed to: <u>HL7 FHIR R4 Clinical Reasoning STU Release 4</u> Link should be changed to: http://hl7.org/fhir/R4/clinicalreasoning-module.html Implementation maturity level should be changed to: Production Adoption level should be changed to: 3</p> <p>HL7 notes the Standard/Implementation Specification <u>CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2022</u> Should be changed to: <u>CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians Programs; Implementation Guide for 2023</u> Adoption level should be changed to: 4</p> <p>HL7 notes the Standard/Implementation Specification HL7 CDA R2 Implementation Guide: Quality Reporting Document Architecture Category III (QRDA III) Release 1</p> <p>Should be changed to: <u>HL7 CDA R2 Implementation Guide: Quality Reporting Document Architecture - Category III (QRDA III) STU Release 2.1</u></p> <p>HL7 notes the Standard/Implementation Specification <u>HL7 FHIR Implementation Guide: Data Exchange for Quality Measures STU2 for FHIR R4</u> Should be changed to: HL7 FHIR Implementation Guide: Data Exchange for Quality Measures for FHIR R4, STU3.1.0 Adoption level should be changed to: 3</p>
<p>Content and Structure</p>	<p>Clinical Quality Measurement and Reporting Reporting Patient-Level Quality Data for Quality Reporting Initiatives</p>	<p>HL7 notes the Standard/Implementation Specification <u>HL7 FHIR® R4 Clinical Reasoning Module</u></p>

	<p>https://www.healthit.gov/isa/reporting-patient-level-quality-data-quality-reporting-initiatives</p>	<p>Should be changed to: <u>HL7 FHIR R4 Clinical Reasoning STU Release 4</u> Link should be changed to: http://hl7.org/fhir/R4/clinicalreasoning-module.html Adoption level should be changed to: 3</p> <p>HL7 notes the Standard/Implementation Specification <u>CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2022</u> Adoption level should be changed to: 4</p> <p>HL7 notes the Standard/Implementation Specification <u>HL7 CDA R2 Implementation Guide: Quality Reporting Document Architecture - Category III (QRDA III) STU Release 2.1</u> Link should be changed to: <u>HL7 CDA R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) - US Realm</u></p> <p>HL7 notes the Standards/Implementation Specifications <u>CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2023</u> Link should be changed to: <u>CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2024</u></p> <p>HL7 notes the Standards/Implementation Specifications <u>HL7 FHIR Implementation Guide: Data Exchange for Quality Measures, STU3.1.0</u> Adoption level should be changed to: 3</p>
<p>Content and Structure</p>	<p>Clinical Quality Measurement and Reporting Sharing Quality Measure Artifacts for Quality Reporting Initiatives https://www.healthit.gov/isa/sharing-quality-measure-artifacts-quality-reporting-initiatives</p>	<p>HL7 notes the Standard/Implementation Specification <u>HL7® V3: Representation of the Health Quality Measures Format (eMeasure), DSTU Release 2.1</u> Should be changed to: HL7® V3 Standard: Representation of the Health Quality Measures Format</p>

		<p><u>(eMeasure), Release 1</u> HL7 notes the Standard/Implementation Specification HL7 Standard: <u>Clinical Quality Language Specification, Release 1, R5 (CQL 1.5)</u> Link should be changed to: http://cql.hl7.org/</p> <p>HL7 notes the Standard/Implementation Specification <u>HL7 FHIR® Clinical Reasoning STU Release 3</u> Implementation maturity level should be changed to: Pilot Adoption level should be changed to: 1</p> <p>HL7 notes the Standard/Implementation Specification <u>HL7 CQL-based HQMF Implementation Guide STU 4.1 based on HQMF R1</u> Type should be changed to: Implementation Specification Standards process maturity should be changed to: Balloted Draft</p> <p>HL7 notes the Standard/Implementation Specification <u>HL7 FHIR Clinical Reasoning STU Release 4</u> Link should be changed to: http://hl7.org/fhir/R4/clinicalreasoning-module.html Standards process maturity should be changed to: Balloted Draft Implementation maturity level should be changed to: Production Adoption level should be changed to: 3 Test tool availability: Yes</p> <p>HL7 notes the Standard/Implementation Specification <u>HL7 FHIR profile: Quality (QI Core) STU 4.0</u> Should be changed to: <u>HL7 FHIR profile: Quality (QI Core) STU 4.1.1</u> Adoption level should be changed to: 3</p> <p>HL7 notes the Standard/Implementation Specification HL7 FHIR profile: Quality (QI Core) STU 5.0.0 Should be added with the following related information: Balloted Draft, Pilot, Adoption level of 1, note federally required, Free and Yes to test tool availability Link at: https://build.fhir.org/ig/HL7/fhir-qi-core/</p>
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<p>Services and Exchange</p>	<p>Clinical Decision Support Services Providing Patient-Specific Assessments and Recommendations Based on Patient Data for Clinical Support https://www.healthit.gov/isa/providing-patient-specific-assessments-and-recommendations-based-patient-data-clinical-decision</p>	<p>HL7 notes the HL7 CDS Hooks Version 2 should be added. Link should be: https://cds-hooks.hl7.org/2.0/ HL7 notes to remove the Clinical Quality Language Release 1 STU 4 (1.4). Link is at: http://cql.hl7.org/STU4/</p> <p>HL7 notes to update the HL7 Clinical Quality Language Specification, Release 1 Mixed Normative/Trial-Use (CQL 1.5). Link is at: http://cql.hl7.org/N1/ Adoption level should be: 4</p> <p>HL7 notes to remove the HL7 Quality Improvement Core (QI-Core) Implementation Guide US-Core Version 3.1 and add the QI-Core IG US-Core Version 4.1 Link is at: http://hl7.org/fhir/us/qicore/index.html</p> <p>Adoption level should be: 3</p>
<p>Allergies and Intolerance (Level 2)</p>	<p>Substance (Non-Medication): https://www.healthit.gov/isa/taxonomy/term/1436/level-2</p> <p>Substance (Food): 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>

<p>Care Team Member (USCDI v3)</p>	<p>Care Team Member Role: https://www.healthit.gov/isa/taxonomy/term/1301/uscdi-v3</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 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 Health Care Providers, Family Members and Other Caregivers in 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 also essential for understanding the true originator of a message and, more specifically, the data element referenced in any given message. It therefore should be added for understanding. 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>