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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/

Re: ONC's Interoperability Standards Advisory (ISA) Annual Update

Dear Dr. Tripathi:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on ONC's Interoperability Standards Advisory (ISA) as ONC prepares to update the ISA for the 2022 "Reference Edition". 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, including 500+ corporate members representing healthcare consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

We appreciate ONC's continued progress with each edition of the ISA and the opportunity to provide input. HL7 is pleased to see that many of its past recommendations were incorporated in the current edition. As ONC prepares to finalize the ISA for the 2022 "Reference Edition", we offer both general considerations and detailed suggestions regarding interoperability needs. Please note in our comment charts that items struck out are recommended for deletion.

In addition to our leadership and Policy Advisory Committee, HL7 Work Groups contributing to these comments include:
- Clinical Decision Support (CDS);
- Clinical Quality Information (CQI);
- Orders and Observations; and
- Patient Empowerment.

Our feedback is detailed below, providing ISA section-by-section responses. We encourage ONC to:
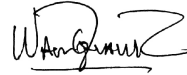- Leverage existing HL7 educational and other resources;
- Ensure ISA compatibility with other frameworks that may reference it, such as TEFCA and USCDI;
- Fully incorporate how specific standards are working in practice and their use affects desirable outcomes in the annual review cycle; and
- Choose standard terminologies and coding systems that do not require patients to pay extra to obtain code meanings.

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

Walter G. Suarez, MD, MPH
Board of Directors, Chair
Health Level Seven International

HL7 Recommendations
HL7's specific comments on ONC's ISA Annual Update are in the chart below.

Content/Structure | Clinical Decision Support | Sharable Clinical Decision Support

Changes indicated with strikethrough font

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	HL7® Standard: Clinical Quality Language Specification, Release 1, R5 (CQL 1.5)	Final	Production	●●●●○	No	Free	Yes
Standard	HL7® FHIR® Profile: Quality (QI Core), STU 4	Balloted Draft	Pilot	●●○○○	No	Free	Yes
~~Standard~~	~~HL7® Version 3 Standard: Decision Support Service, Release 2~~	~~Balloted Draft~~	~~Pilot~~	~~●○○○○~~	~~No~~	~~Free~~	~~No~~
~~Implementation Specification~~	~~HL7® Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.3, Draft Standard for Trial Use~~	~~Balloted Draft~~	~~Pilot~~	~~●●○○○~~	~~No~~	~~Free~~	~~No~~
~~Implementation Specification~~ Standard	~~HL7® FHIR® Implementation Guide Clinical Reasoning Module, FHIR STU Release 4~~ HL7® FHIR® Clinical	Balloted Draft	Pilot	●●●○○	No	Free	Yes

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
	Reasoning Module, FHIR STU Release 4						
~~Emerging Standard~~ Implementation Specification	FHIR Clinical Guidelines, STU 1	Balloted Draft	Pilot	●●○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
- See FHIR projects in the Interoperability Proving Ground. - Note that the FHIR Maturity Model and each of the levels is described on the HL7 wiki. ~~Note that the HL7 Version 3 Standard: Decision Support Service and related implementation specifications are intended to be retired once equivalent functionality is available in the CDS Hooks specification.~~	Feedback requested

Sharing Quality Measure Artifacts for Quality Reporting Initiatives

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	HL7® V3: Representation of the Health Quality Measures Format (eMeasure), DSTU Release 2.1	Final	Production	●●●●○	No	Free	Yes
Standard	HL7® CQL-based HQMF Implementation Guide STU 4 based on HQMF R1	In Development	Production	●●●●○	No	Free	Yes
~~Standard~~	~~HL7® Cross-Paradigm Specification: Clinical Quality Language (CQL), Release 1, STU 1.3~~	~~Balloted Draft~~	~~Production~~	●●●○○	~~No~~	~~Free~~	~~Yes~~
Standard	HL7® Cross-Paradigm Specification: CQL Release 1 STU 4	Balloted Draft	Production	●●●●○	No	Free	Yes
Standard	~~HL7 Cross-Paradigm Specification: CQL Release 1 R5 (CQL 1.5)~~ HL7® Standard:	Final	Production	●●●●○	No	Free	Yes

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
	Clinical Quality Language Specification, Release 1, R5 (CQL 1.5)						
Implementation Specification	HL7® CQL-based HQMF, Release 2 DSTU 3 (based on HQMF 2.1 - US Realm	Balloted Draft	Production	●●●●○	No	Free	Yes
Implementation Specification	HL7® FHIR® profile: Quality (QI Core) STU 4.0	Balloted Draft	Production	●●○○○	No	Free	Yes
Standard	HL7® FHIR® Clinical Reasoning STU Release 3	Balloted Draft	Production	●●○○○	No	Free	Yes
~~Emerging Implementation Specification~~ Implementation Specification	HL7® FHIR® Quality Measure IG STU 2 for FHIR R4	Balloted Draft	Production	●●○○○	No	Free	Yes
~~Emerging Implementation Specification~~ Standard	HL7® FHIR® Clinical Reasoning STU Release 4	Balloted Draft	Pilot	~~Feedback Requested~~ ●●○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• QI Core Profiles are used to express the data involved in a sharable measure and depend on US Core profiles. • Note that the maturity level of FHIR resources may vary. The FHIR Maturity Model and each of the levels is described on the HL7 wiki. • See FHIR projects in the Interoperability Proving Ground.	• Feedback requested

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability

Providing Patient-specific Assessments and Recommendations Based on Patient Data for Clinical Decision Support

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	HL7® Version 3 Standard: Decision Support Service, Release 2.	Balloted Draft	Pilot	●○○○○	No	Free	No
Standard	HL7® Implementation Guide: Decision Support Service, Release 1.1, US Realm, DraftStandard for Trial Use	Balloted Draft	Pilot	●○○○○	No	Free	No
Standard	HL7® FHIR® Profile: Quality Improvement Core (QI Core), Release 1, STU 3	Balloted Draft	Pilot	●●○○○	No	Free	No
Standard	HL7® Cross-Paradigm Specification: Clinical Quality Language, Release 1, STU 4(1.4)	Balloted Draft	Pilot	●●●○○	No	Free	Yes
Implementation Specification Standard	HL7® Standard: Clinical Quality Language Specification, Release 1 STU4	Final	Pilot	●●●○○	No	Free	Yes

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
	HL7® Standard: Clinical Quality Language Specification, Release 1, R5 (CQL 1.5)						
Standard	HL7® CDS Hooks Services, Version 1.0 STU	Balloted Draft	Production	●●●○○	No	Free	Yes

Additional HL7 Responses to ONC's ISA
HL7 has the following additional comments:

- HL7 recommends including the HL7 CDA R2 Implementation Guide: Dental Data Exchange, Release 1, STU 1 - US Realm https://www.hl7.org/implement/standards/product_brief.cfm?product_id=579 for Referrals involving a Dental Provider

- HL7 recommends adding the WEDI Attachments Collaboration Project under Administrative Transactions to Support Clinical Care -> Health Care Attachments to Support Claims, Referrals, and Authorizations - https://www.healthit.gov/isa/health-care-attachments-support-claims-referrals-and-authorizations. More information at: https://www.wedi.org/

- HL7 recommends removing the CDA IG Additional CDA R2 Templates - Clinical Documents for Payers - Set 1, Release 1.1 from under Administrative Transactions to Support Clinical Care -> Health Care Attachments to Support Claims, Referrals, and Authorizations - https://www.healthit.gov/isa/health-care-attachments-support-claims-referrals-and-authorizations

- HL7 recommends under Laboratory> Support the Transmission of a Laboratory's Directory of Services to Providers Health IT or EHR System> Emerging Implementation Specification > HL7 FHIR Order Catalog Implementation Guide/Laboratory Services 0.1.1 – STU Ballot - https://www.healthit.gov/isa/support-transmission-a-laboratorys-directory-services-providers-health-it-or-ehr-system
  - Removing the current ballot hyperlink and updating the hyperlink to an IG at: http://hl7.org/fhir/uv/order-catalog/2020Sep/index.html
  This reflects the latest eDOS guidance published earlier in 2021.

- HL7 recommends an Adoption Level of One under Laboratory> Support the Transmission of a Laboratory's Directory of Services to Providers Health IT or EHR System> Emerging Implementation Specification

>HL7 Version 2.5.1 Implementation Guide: Standards & Interoperability (S & I) Framework Laboratory Test Compendium Framework (eDOS) Release 2, STU Release 3.1 (US Realm). **-** https://www.healthit.gov/isa/support-transmission-a-laboratorys-directory-services-providers-health-it-or-ehr-system

- HL7 recommends an Adoption Level of One under Laboratory> Support the Transmission of a Laboratory's Directory of Services to Providers Health IT or EHR System> Emerging Implementation Specification > HL7 Version 2.5.1 Implementation Guide: Standards & Interoperability (S & I) Framework Laboratory Test Compendium Framework (eDOS) Ask at Order Entry (AOE) Release 2, STU Release 3.1 (US Realm). **-** https://www.healthit.gov/isa/support-transmission-a-laboratorys-directory-services-providers-health-it-or-ehr-system