HL7
International

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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. Rucker:

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 2021 "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 2021 "Reference Edition", we offer both general considerations and detailed suggestions regarding interoperability needs.

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) and
- Security.

Our feedback is detailed below, providing ISA section-by-section responses. As always, we encourage ONC to:
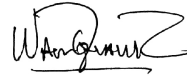- Leverage existing HL7 educational and other resources;
- Ensure ISA compatibility with other frameworks that may reference it, such as TEFCA, USCDI and ARCH; and
- Fully incorporate how specific standards are working in practice and their use affects desirable outcomes in the annual review cycle.

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

Section I

Vocabulary/Code Set/Terminology Standards and Implementation Specifications

V – Provenance
Representing Data Provenance
https://www.healthit.gov/isa/representing-data-provenance
HL7 Comments:

- HL7 recommends ONC support sustaining ongoing stewardship, validation, and maintenance of the National Library of Medicine (NLM) Value Set Authority Center (VSAC) Sensitive Condition value set. This is critical to support the implementation of standards referenced in the ISA Data Segmentation of Sensitive Information, and to support security labeling for sensitive Social Determinants of Health (SDoH) information.

  - Regarding this recommendation, HL7 offers the following background and observations:

    - o VSAC Sensitive Conditions value sets are invaluable for implementers of the Data Segmentation for Privacy (DS4P) CDA Implementation Guide (IG), which is referenced in both the ONC 2015 Meaningful Use (MU) certification and in the *21st Century Cures Act*, as well as for HL7 Version 2.9 security labeling, the FHIR DS4P, and the Cross-Paradigm US Regulatory Security Labeling IG, and the IHE IT Infrastructure Technical Framework Volume 4 - National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P).
    - o Computable DS4P is not possible without standardized value sets of sensitive conditions codes recognized under privacy policies being made available to, and used by, Security Labeling Services [SLS] parsers. The VSAC Sensitive Conditions value sets are the only open source such value sets available to DS4P implementers.
    - o The VSAC Sensitive Condition value sets were initially uploaded by the Substance Abuse and Mental Health Administration (SAMSHA), acting as the value set steward in 2016. However, no maintenance has been done since 2017.
    - o If these VSAC Sensitive Condition value sets are deprecated, then to computably segment data the industry will have to purchase proprietary sensitive value sets offered by Content Management vendors, or develop non-standard sensitive condition value sets the content of which is not reviewed or validated by the community. Neither option will support "policy interoperability" as the same information could be deemed sensitive and not disclose-able by Sender A and non-sensitive by Sender B, and therefore disclosed. In addition, Sender A's not disclosing information deemed sensitive might not be meeting the Information Blocking privacy exemption, at least in the eyes of a requester who asked both Sender A and Sender B for the same information.

- HL7 recommends that ONC evaluate the validity and level of ongoing support for the SAMHSA VSAC Sensitive Condition value sets as part of the annual ISA updates.

  - o The VSAC Sensitive Conditions value sets require updating and will need ongoing maintenance. We recommend ONC should provide funding for these standards in coordination the National Institutes of Health (NIH) or other public funding sources such as the TEFCA Recognized Coordinating Entity (RCE).
  - o There are a number of current dependencies on these VSAC Sensitive Condition value sets:
    - o FEI systems points to a number of Consent2Share (C2S) implementations: see the bottom of this page https://www.feisystems.com/solutions/behavioral-health/consent2share/.

- o The most authoritative discussion relating to the current state of C2S is in the preamble/discussion of the *21ˢᵗ Century Cures Act* ONC final rule.
- o The ONC Consent Leap Grantees are developing an open source SLS using FHIR HAPI Server for the community, which has been demonstrated in two HL7 Connect-a-thons.

Section II

Content/Structure Standard and Implementation Specifications

D – Clinical Decision Support
Provide Access to Appropriate Use Criteria:
https://www.healthit.gov/isa/provide-access-appropriate-use-criteria
HL7 Comments:
- Regarding Adoption Level, HL7 recommends the Adoption Level of Standard "HL7 CDS Hooks Services" be increased to Medium-High.
- HL7 recommends removing the Standard "HL7® FHIR® Clinical Reasoning Module, FHIR STU Release 3."

Sharable Clinical Decision Support:
https://www.healthit.gov/isa/sharable-clinical-decision-support
HL7 Comments:
Regarding the Standard "HL7® Standard: Clinical Quality Language Specification, Release 1, STU4 (CQL 1.4)", HL7 recommends:
- Updating it to the latest version of the specification: "HL7(r) Standard: Clinical Quality Language Specification, Release 1, R5 (CQL 1.5)."
- Increasing Adoption Level to Medium-High.
- Updating the cost to Free.

Regarding the Standard "HL7® FHIR® Profile: Quality (QI Core), STU Release 3", HL7 recommends:
- Updating it to the latest version of the specification: "HL7(r) FHIR(r) Profile: Quality (QICore), STU 4".

Regarding the Implementation Specification "HL7® FHIR® Implementation Guide Clinical Reasoning Module, FHIR STU Release 4", HL7 recommends:
- Increasing Adoption Level to Medium.
- Adding Emerging Standard "FHIR Clinical Guidelines, STU1" http://hl7.org/fhir/uv/cpg/2019Sep/ (Balloted, Pilot, Low-Medium Adoption Level, No to Federally Required, Free and Yes to Test Tool Availability)

E – Clinical Quality Measurement and Reporting
Reporting Aggregate Quality Data to Quality Reporting Initiatives:
https://www.healthit.gov/isa/reporting-aggregate-quality-data-quality-reporting-initiatives
HL7 Comments:
- HL7 recommends removing Implementation Specification "HL7® Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture - Category III (QRDA III), STU Release 1", as it has been completely supplanted by STU Release 2.1.

- HL7 recommends adding DEQM Implementation Specification "HL7® FHIR® Implementation Guide: Data Exchange for Quality Measures STU2 for FHIR R4" (Balloted, Pilot, Low-Medium Adoption Level, No to Federally Required, Free and Yes to Test Tool Availability)

Regarding the Emerging Standard "HL7® FHIR® R4 Clinical Reasoning Module", HL7 recommends:
- Updating Type to Standard.
- Updating Adoption Level to Low-Medium.

Regarding Limitations, Dependencies and Preconditions for Considerations, HL7 recommends:
- Adding DEQM projects in the Interoperability Proving Group: https://www.healthit.gov/techlab/ipg/node/4/submission/2321
- Removing the Implementation Maturity note here, as it applied to the difference between Release 1 and Release 2.1.

Reporting Patient-level Quality Data for Quality Reporting Initiatives
https://www.healthit.gov/isa/reporting-patient-level-quality-data-quality-reporting-initiatives
HL7 Comments:
- HL7 recommends removing Implementation Specification "HL7® CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) DSTU Release 3.1 (US Realm)" as this has been supplanted by later versions.
- HL7 recommends removing Implementation Specification "HL7® CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) STU Release 4 (US Realm)" as this has been supplanted by later versions.
- Regarding Implementation Specification "HL7® CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) - Release 5.1 (US Realm)", HL7 recommends adding (with Errata) for QRDA I 5.2.

Regarding Emerging Implementation Specification "HL7® CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) STU Release 5.2 (US Realm)", HL7 recommends:
- Updating to Implementation Specification, as this has been published and is in use.
- Adding (with Errata) for QRDA I 5.2.
- Updating to Balloted Draft.
- Updating to Production.
- Updating Adoption Level to Medium-High.
- Updating Federally Required to Yes.
- Updating the cost to Free.
- Updating Testing Tool Availability to Yes.

Regarding Emerging Implementation Specification "HL7® FHIR® DaVinci Data Exchange For Quality Measures (DEQM) Implementation Guide", HL7 recommends:
- Updating to Implementation Specification.
- Updating to Balloted Draft.

- Updating Adoption Level to Low-Medium.
- Updating Federally Required to Yes.

Regarding Limitations, Dependencies and Preconditions for Considerations, HL7 recommends:
- Adding a link to testing tools available for QRDA and FHIR-based quality reporting:
  https://ecqi.healthit.gov/fhir?qt-tabs_fhir=1

  https://ecqi.healthit.gov/qrda?qt-tabs_qrda=1
- Adding a note: The Data Exchange for Quality Measures Implementation Guide is being expanded to support communication for gaps-in-care." Consider adding a category to the ISA for this use case.

Sharing Quality Measure Artifacts for Quality Reporting Initiatives:
https://www.healthit.gov/isa/sharing-quality-measure-artifacts-quality-reporting-initiatives
HL7 Comments:
- HL7 recommends removing the Standard "HL7® FHIR® Profile: Quality (QI Core), STU 3.2", as this has been replaced by QI Core STU4.

Regarding the Standard "HL7® CQL-based HQMF Implementation Guide STU 4 based on HQMF R1", HL7 recommends:
- Updating Adoption Level to Medium-High.
- Updating Federally Required to No.
- Updating Testing Tool Availability to Yes.

Regarding the Emerging Implementation Specification "HL7® CrossParadigm Specification: CQL Release 1 STU 4", HL7 recommends:
- Updating this to Standard.
- Updating Adoption Level to Medium-High.
- Updating Testing Tool Availability to Yes.
- Updating Federally Required to No.

Regarding the Emerging Implementation Specification "HL7® CQL-based HQMF, Release 2 DSTU 3 (based on HQMF 2.1 - US Realm", HL7 recommends:
- Updating to Implementation Specification.
- Updating to Balloted Draft.
- Updating Adoption Level to Medium-High.

Regarding the Emerging Standard "HL7® FHIR® Quality Measure IG STU 1", HL7 recommends:
- Updating to Balloted Draft.
- Updating version to STU2 for FHIR R4.
- Updating Federally Required to No.
- Updating to Production.
- Updating Adoption Level to Low-Medium.
- Updating Federally Required to No.
- Updating Testing Tool Availability to Yes.

Regarding the Emerging Standard "HL7® FHIR® profile: Quality (QI Core) STU 4.0", HL7 recommends:
- Updating to Implementation Specification.
- Updating to Production.
- Updating   Level to Low-Medium.
- Updating Federally Required to No.
- Updating Testing Tool Availability to Yes.

Regarding Emerging Implementation Specification "HL7® FHIR® Clinical Reasoning STU Release 3", HL7 recommends:
- Updating to Standard.
- Updating to Balloted Draft.
- Updating to Production.
- Updating Adoption Level to Low-Medium.
- Updating Federally Required to No.
- Updating Testing Tool Availability to Yes.

Regarding Limitations, Dependencies and Preconditions for Considerations, HL7 recommends:
- Adding an entry for CQL 1.5: Standard HL7 Cross-Paradigm Specification: CQL Release 1, R5 (CQL 1.5) [Final, Production, Medium-High Adoption Level, No to Federally Required, Free and Yes to Test Tool Availability]
  More information at: https://cql.hl7.org/.

T – Segmentation of Sensitive Information
Data Segmentation of Sensitive Information
https://www.healthit.gov/isa/data-segmentation-sensitive-information
HL7 Comments:
- HL7 notes that the reference to HL7® v2.8 - ARV Access Restrictions Segment is incorrect and incomplete.
- HL7 notes that the reference to HL7® FHIR® R4 - Security Labels should be augmented with reference to the FHIR Data Segmentation for Privacy Implementation Guide.
- HL7 recommends adoption of HL7 Privacy and Security Healthcare Classification System terminologies, which have bindings to the standards referenced in ISA Data Segmentation of Sensitive Information as security label tags. Please see these links for more information:
  Adopt HL7 Privacy and Security Classification System Terminologies
  https://confluence.hl7.org/pages/viewpage.action?pageId=97455431#ISA/SVAP2021Comments-AdoptHL7PrivacyandSecurityClassificationSystemTerminologies

- HL7 welcomes the inclusion of all four data segmentation standards, as these are aligned and enable interoperable segmentation across CDA, HL7 Version 2, FHIR, and the IHE_ITI_TF_Vol4 @ 3.1 Data Segmentation. HL7 has comments on this issue. The ISA reference to HL7® v2.8 - ARV Access Restrictions Segment is incorrect and incomplete. The reference should be to the HL7 Messaging Standard Version 2.9.

  HL7 notes the reference should include all of the segments that support security labeling for DS4P, which include:
  - o FHS - File Header Segment
  - o BHS - Batch Header Segment
  - o MSH - Message Header Segment
  - o ARV - Access Restriction Value Segment

  Additionally, the reference to an ARV segment needs context. An ARV segment never occurs on its own, and is always, at a minimum, included in an MSH, and often the MSH may be included in a BHS, and the BHS could be included in an FHS.
  HL7 notes, the ARV Segment acts as a manifest of a security label applicable throughout segments and fields included in an MSH. There may be 0...* ARV Segments, each conveying a distinct Security Label with references to specific segments or fields to which they apply when not applicable to the entire MSH. (i.e. an ARV Segment can support either header and granular segmentation). The containing MSH security label fields are the "high water mark" for all the contained ARVs. Any containing BHS security label fields are the "high water mark" for all the contained MSH. Any containing FHS security label fields are the "high water mark" for all the contained BHS. The diagram of examples where all enveloping HL7 v2 container segments are used can be accessed at:
  https://confluence.hl7.org/display/SEC/Cross+Paradigm+US+Regulatory+Security+Label+IG+for+CUI%2C+Part+2%2C+and+7332+Structure?preview=/66936255/66937079/v2%20Security%20Labeling%20Structure.pdf

- HL7 recommends that the ISA Reference to FHIR Security Labels should be augmented with reference to the HL7 FHIR DS4P IG.

  While HL7 supports the ISA reference to the FHIR Security Labels R4, we note that the FHIR Security Labels Module, as part of the FHIR Core, does not include implementation guidance on the use of the security labels in the context of DS4P. For this reason, HL7 is developing the FHIR Data Segmentation for Privacy - STU 1 Ballot (FHIR DS4P), which is an evolving specification explaining how to construct security labels conformant with the HL7 Privacy and Security Healthcare Classification System (HCS).
  It includes the HCS Security Labeling value sets with which U.S. and other realms can construct consensus and interoperable security labels representing the policies applicable to domain specific policies.
  In future ISA comments, HL7 plans to recommend including the Cross-Paradigm US Regulatory Security Labeling IG, which will propose consensus security labels to represent priority national and exemplar state privacy policies governing certain health information. This IG will include the FHIR US Regulatory Security Labeling IG, which is a profile on the FHIR DS4P IG that is also under development. Examples of how security labels for the same policy can be generated for HL7 Version 2, CDA, and FHIR are shown at Cross Paradigm US Regulatory Security Label IG for CUI, Part 2, and 7332 Structure.
- HL7 notes that ISA references to Data Segmentation of Sensitive Information standards need to be complemented with ISA references to the HCS terminologies to which these standards are bound.

Standards and Implementation Specifications for Services and Exchange

B – Clinical Decision Support Services
Providing Patient-Specific Assessments and Recommendations Based on Patient Data for Clinical Decision Support:
https://www.healthit.gov/isa/providing-patient-specific-assessments-and-recommendations-based-patient-data-clinical-decision
HL7 Comments:
Regarding the Standards "HL7® CrossParadigm Specification: Clinical Quality Language, Release 1, STU 2" and "HL7® CrossParadigm Specification: Clinical Quality Language, Release 1, STU 3", HL7 recommends:

- Removing previous versions, as they have been supplanted by CQL 1.4/1.5 for this purpose.

Regarding the Implementation Specification "HL7® Standard: Clinical Quality Language Specification, Release 1 STU4", HL7 recommends:

- Updating version to R5 (CQL 1.5) and updating link to: http://cql.hl7.org.
- Updating Standards Process Maturity of CQL to Final.
- Updating Implementation Maturity to Pilot; multiple organizations are piloting the use of CQL for this purpose.
- Updating Adoption Level to Medium.
- Updating Testing Tool Availability to Yes.

Regarding the Emerging Implementation Specification "HL7® CDS Hooks Services", HL7 recommends

- Updating to Standard, as CDS Hooks has been published since April of 2019.
- Updating version to 1.0.
- Updating Adoption Level to Medium-High.

Retrieval of Contextually Relevant, Patient-Specific Knowledge Resources from Within Clinical Information Systems to Answer Clinical Questions Raised by Patients in the Course of Care
https://www.healthit.gov/isa/retrieval-contextually-relevant-patient-specific-knowledge-resources-within-clinical-information
HL7 Comments:

- Regarding Implementation Specification "HL7® FHIR® Implementation Guide Clinical Reasoning Module, FHIR STU Release 4", HL7 recommends updating the version to FHIR R4.