Health Level Seven® International
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October 1, 2018

Don Rucker, MD
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: http://www.regulations.gov

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 2019 "Reference Edition". HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related interoperability standards, including the rapidly evolving Fast Healthcare Interoperability Resources (HL7® FHIR®), the Consolidated Clinical Document Architecture (C-CDA®), and the widely used V2 messaging standards. HL7 has more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms. As the global authority on interoperability in healthcare, HL7 is a critical leader and driver in the standards arena. The products of our organization provide the underpinnings for connected, patient-centered health care and an information highway for precision medicine.

We appreciate ONC's continued progress with each edition of the ISA and the opportunity to provide input the 2018 ISA. HL7 was pleased to see that many of its past recommendations were incorporated. As ONC prepares to finalize the ISA for the 2019 "Reference Edition", we offer both general considerations and responses to questions ONC specifically raised, as well as detailed suggestions on previously documented and new interoperability needs.

Once again, the HL7 Work Groups have submitted substantive feedback on questions posed by ONC. Work Groups contributing substantively to these comments include:

- Clinical Decision Support (CDS);
- Clinical Quality Information (CQI);
- Mobile Health;
- Orders and Observations (OO);

- Public Health (PH); and
- Security.

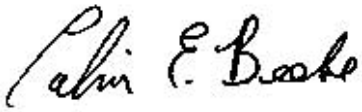
Our feedback is detailed below, with Appendix 1 answering ONC's four specific questions and Appendix 2, our detailed ISA section responses. Our comments also highlight important high-level points such as:

- The proper use and citation of HL7® FHIR®;
- Opportunities for improvements in ISA usability and navigation;
- ISA compatibility with other frameworks that may reference it, such as the forthcoming TEFCA; and
- Leveraging existing HL7 educational and other resources.

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



Calvin Beebe
Board of Directors, Chair
Health Level Seven International

Appendix 1: HL7 Answers to ONC Questions
Responses to ONC Questions

18-1. In what ways has the ISA been useful for you/your organization as a resource? ONC seeks to better understand how the ISA is being used, by whom, and the type of support it may be providing for implementers and policy-makers.

General

Needed Survey/Focus Groups on ISA Use - HL7 strongly supports ONC's intention to better understand how the ISA is being used. As we have mentioned in our prior comments, the ISA is a very helpful inventory for a complex health care environment but it is challenging to gauge how people are using the ISA and what support it is providing. HL7 recommends that, in addition to this request for comments, ONC use a structured survey and/or series of focus groups to gather feedback about how the ISA is being used, by whom, and the type of support it may be providing for implementers and policy-makers.

ISA, TEF and TEFCA - Regarding the ISA and the support that it may be providing for implementers and policy-makers, as HL7 indicated in its comments on the draft ONC Trusted Exchange Framework (TEF), references to the ISA (notably in Principle 1.A.) in that document and its successors should be adjusted to reflect the status and intent of the ISA as indicated by ONC. Specifically, that the ISA is informational only to be used as a reference of available, potential standards, not a normative set of standards that must be adhered to by all Health IT or TEFCA participants. Likewise, in the Introduction to the updated ISA, ONC should take into account the intended role of the ISA in the ONC Trusted Exchange Framework and Common Agreement (TEFCA) and similar documents. Fundamentally, references to the ISA in the TEFCA should reflect its status as informative and non-prescriptive. The ISA was not designed for the purpose of incorporation by reference into a trusted exchange framework or a legal Common Agreement. For example, the ISA includes standards with a range of maturity levels and in some cases multiple standards for a given use case. In the "Federally Required" column of the ISA, we suggest that ONC provide a hyperlink to the applicable programs(s) where such requirements exist. Without that further context, the status of "Federally Required" could be misleading to some users of the ISA.

HL7 Specific

HL7® FHIR® - HL7 and its related standards, implementation resources and other tools are mentioned throughout the ISA. We emphasize three important points in relation to this usage:

- Wherever HL7 FHIR® is mentioned in the ISA, we request that it be correctly cited by including both "HL7" and its proper indication as our registered trademark. It should always be cited as HL7® FHIR®.
- To enable the guidance set out in the ISA to be effectively implemented, the relevant HL7® FHIR® or HL7® CDA® standards, implementation guides, and HL7® FHIR® resources need to be specified more precisely in many places. We provide some examples of such more precise use in these appendices and HL7 would be happy to work with ONC to achieve this.
- In general, it is important that the distinction between HL7 primary standards and their implementation guides/specifications are understood and called out appropriately. In general, the HL7® FHIR® implementation specifications are more relevant than the underlying HL7® FHIR® standard. For example, in Section II-B: Care Plan, references in the "Emerging Standard" and "Emerging Implementation Specification" section could be improved by a focus on the implementation specification. In this section and others like it, the preference should be to focus on the relevant implementation specification, as was done with "View, Download, and Transmit Data from EHR".

As a specific example, in Section II-B: Care Plan, references to "Emerging Standard" and "Emerging Implementation Specification" could be improved by more informed referencing of the relevant HL7 materials in relation to the Common Clinical Data Set (CCDS) Care Plan data. These data are profiled in both Argonaut R1 and US Core R1 and, more specifically, the Care Plan profile within that specification. These can be found at: http://hl7.org/fhir/us/core/history.html and http://hl7.org/fhir/us/core/2018Jan/StructureDefinition-us-core-careplan.html. Where a use case needs to focus on the Care Plan data set, a reference to the profile in either or both of these implementation guides is appropriate and sufficient. On the other hand, where there is a need to specify a more complete representation of a Care Plan, a reference to the higher level HL7® FHIR® resource specification would also be appropriate, as a detailed implementation guide has not yet been published for that resource.

We also note robust discussion in the standards community on the appropriateness and maturity of the Argonaut and HL7® FHIR® US Core specifications for some of the CCDS Care Plan data elements. This example underscores the need for a clearer specification of the interoperability needs for particular use cases beyond the use of a section heading, if the ISA is to give more meaningful guidance on the appropriateness and maturity. The HL7 Patient Care Work Group is willing to assist in providing advice to assist in achieving these outcomes.

HL7's Prior ISA Input - HL7 has provided detailed input in response to prior ONC ISA calls for comments on the ISA. We highlight below some of our past key recommendations that have yet be included in the ISA and for which we continue to advocate.

- **CDS Hooks -** We suggest that ONC reference the planned development of a CDS Hooks-based implementation guide for the "Provide Access to Appropriate Use Criteria" (AUC) interoperability need. Simply pointing to the underlying standards on this topic is not going to be very helpful to end users of the ISA.

- **Data Provenance -** We continue to believe that the need to recognize available data provenance constructs in all three main standards (HL7® V2, HL7® C-CDA®, and HL7® FHIR®) is critical, as the same data is likely to be re-transmitted in various formats where continuity of provenance data is essential.

Da Vinci Project Implementation Guides - With the emergence of the DaVinci Project implementation guides (two currently undergoing ballot), HL7 recommends that these emerging implementation specifications are included in the ISA into section IV as new interoperability needs.

18-2. Over the course of 2018, some new functionality has been added to the ISA, with more enhancements expected through 2018 and 2019. Are there additional features or functionality that would enhance the user experience?

ISA Navigation - The overall navigation and associated links in the ISA are broken in a number of places. A comprehensive review of navigation and links would enhance usability and enable a smoother and more helpful user experience.

Basic Security to Applicable Value Set(s) and Starter Set(s) - HL7 highlights inconsistent or non-existent listings of Basic Security to Applicable Value Set(s) and Starter Set(s) across:

- Section II: Content/Structure Standards and Implementation Specifications;
- Section III: Standards and Implementation Specifications for Services;
- Section IV: Models and Profiles; and

- Section V: Administrative Standards and Implementation Specifications.

Some selected standards have no listings and some have a subset of listings with no particular rationale for what is included or not.

Regarding inconsistent or non-existing listing of Basic Security to Applicable Value Set(s) and Starter Set(s) – the following list should appear appropriately and consistently:

- Secure Communication – create a secure channel for client-to-server and server-to-server communication.
- Secure Message Router – securely route and enforce policy on inbound and outbound messages without interruption of delivery.
- Authentication Enforcer – centralized authentication processes.
- Authorization Enforcer – specifies access control policies.
- Credential Tokenizer – encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos).
- Assertion Builder – define processing logic for identity, authorization and attribute statements.
- User Role – identifies the role asserted by the individual initiating the transaction.
- Purpose of Use - Identifies the purpose for the transaction.

Additionally Security Labels and Consent are also inconsistently added to the Applicable Value Set(s) and Starter Set(s).

HL7 recommends that ONC:

- Develop a complete list of all Applicable Value Set(s) and Starter Set(s) with definitive criteria for when these are included. This would help commenter review; and
- Add HIPAA Right of Access Request/Directive to the set of Consumer Access/Exchange of Health Information specifications, as none of the rest cover that "parent" capability.

18-3. Is the existing ISA format used for listing standards and implementation specifications applicable for listing Models and Profiles? Are there additional or different attributes that should be collected for them? Are there additional models and/or profiles that should be listed? Are models and profiles useful for inclusion in the ISA?

Section Title – HL7 recommends that the Section IV title be changed to Section IV: Models and Functional Model Profiles.

Functional Models - Under IV-A: Functional Models, an introductory paragraph should be inserted that explains what a functional model is and what its intended purpose is. HL7 also observes that gauging adoption level and implementation maturity for Functional Models is inherently challenging and that this issue needs to be better examined and understood. Specifically, Functional Models may be used to inform developers and providers about capabilities, but there are no formal conformance statements that could be measured to gauge adoption and maturity. Such measures would be highly complex, as solutions typically do not, nor need to match the full set of capabilities described.

Information Models - Regarding information models (IV-C) and the request for feedback on "Adoption Level" here, HL7 observes that "Adoption Level" should be conceived of thoughtfully and thoroughly in the ISA. Specifically, ONC should clarify what "Adoption Level" means in an information model and also consider that being in "Production" may not be the

appropriate term in this section under "Implementation." Specifically, information models are primarily conceptual/logical in nature and focus on the ability to communicate across systems. Individual systems may only implement parts of the model, or include additional data, and may represent it in many different ways to support the specific functional requirements of that system. Understanding adoption of the communication standards that are based on these information models provides more value than attempting to measure adoption of the information models by systems.

Domain Analysis Models (DAM) - ONC asks about additional models and/or profiles that should be listed. Related to our organization in particular, HL7 has a much richer and expansive library of Domain Analysis Models (DAM) than what is listed in the ISA. We suggest including more HL7 DAMs in the ISA document. A full list of HL7 Domain Analysis Models can be found by clicking the can Domain Analysis Models "category" on the HL7 Standards Master Grid at: https://www.hl7.org/implement/standards/product_matrix.cfm?ref=nav.

Secondly on Domain Analysis Models, we suggest adding a specific category for this under Section IV: Models and Profiles or putting Domain Analysis Models under the IV-A: Functional Model section rather than being part of the Information Model section.

18-4. Are there additional informative or educational resources that can be provided to help stakeholders better understand the ISA, health IT standards, interoperability, etc.?

Standards Education Portals and Links - HL7 recommends that, as part of the ISA, ONC highlight and provide links to the educational portals and platforms of standards development organizations (SDOs) and applicable other organizations with fundamental expertise on references standards. The HL7 Education and Training Portal is one example. This portal can be accessed at: http://www.hl7.org/implement/training.cfm?ref=nav.

Appendix 2: Detailed Responses

Introduction

- No comments

Section I

Vocabulary/Code Set/Terminology Standards and Implementation Specifications

A – F

- No comments

G – Immunizations

Representing Immunizations- Historical: https://www.healthit.gov/isa/representing-immunizations-historical

HL7 Comments:

- RxNorm is included as a value set but not in the initial table (as it has been in the past). We urge re-inclusion in the initial table.

Representing Immunizations- Administered: https://www.healthit.gov/isa/representing-immunizations-administered

HL7 Comments:

- RxNorm is included in the initial table but not as a value set. This is opposite to the approach in the historical immunization section. We recommend consistency.
- HL7 recommends updating the NDC comment to indicate that CDC has recommendations of what do with the UoU versus UoS and multi-part vaccines **(https://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/downloads/guidance-documenting-ndc.pdf)**
- HL7 believes the statements on CPT and RxNorm should be stronger and state they may be used locally but should not be used for interoperability purposes.

H – Industry and Occupation

- No comments

I – Lab Tests

Ask-at-Order-Entry Questions: new proposal

HL7 Comments:

- HL7 recommends adding a new interoperability need under Section 1 > Lab Tests to address the vocabulary for Ask-at-Order-Entry (AOE) questions that accompany an order to further inform the Lab about the context of the test to be performed.
    - Interoperability Need: Ask at Order Entry Questions
    - Type: Standard for ask at order entry questions
    - Standards Process Maturity: Final
    - Implementation Maturity: Pilot
    - Adoption Level: 1 bullet
    - Federally Required: No
    - Test Tool Availability: Yes

J – Q

- No comments

R – Sex at Birth, Sexual Orientation and Gender Identity

HL7 Comments:

- HL7 notes in relation to gender identity and healthcare that there is a need to track genotype, phenotype and declared gender information. This level of completeness and detail is not reflected in the current ISA and if continued, will cause unnecessary confusion. An example of its importance is in cervical cancer screening, in which each of the categories must be known to assure accurate diagnosis and treatment. HL7 can be a helpful partner to ONC in addressing these issues.

S – Social, Psychological and Behavioral Data

HL7 Comments:

- HL7 observes there are many coding systems for these data. However, there does not seem to be much alignment across them. HL7 recommends that ONC consider adding a new section and measures for Housing, Food, Water Quality and Environmental Factors in a future version of the ISA. HL7 is happy to assist in this endeavor. As sources of coding systems for these data, ONC can reference:
    - NCVHS Environmental Scan of SDH measures at http://www.ncvhs.hhs.gov/wp-content/uploads/2016/06/NCVHS-Indicators-Envirn-Scan_2016-06-01-FINAL.pdf
    - NCVHS Framework: http://www.ncvhs.hhs.gov/ncvhs-measurement-framework-for-community-health-and-well-being-v4/
    - SIREN Compendium of Medical Terminology Codes for Social Risk Factors at https://sirenetwork.ucsf.edu/tools-resources/mmi/compendium-medical-terminology-codes-social-risk-factors

T – Tobacco Use (Smoking Status)

- No comments

U: Unique Device Identification

HL7 Comments:

- In the interoperability needs Representing Unique Implantable Device Identifiers, as well as Defining a Globally Unique Device Identifier, and Transmitting a Unique Device Identifier, reference is made to an old document HL7 Harmonization Pattern for Unique Device Identifiers. Recently, the HL7 Cross Paradigm Implementation Guide: UDI Pattern, Release 1 completed balloting and is about to be published. This guide will replace the currently referenced harmonization document. We expect this updated document to be published early October. Once referenced, this guide can be categorized as:
    - Standards Process Maturity: Final

V - W

- No comments

Section II

Content / Structure Standard and Implementation Specifications

A - B

- No comment

C – Clinical Decision Support

Sharable Clinical Decision Support: https://www.healthit.gov/isa/sharable-clinical-decision-support

HL7 Comments:

- HL7 Cross-Paradigm Specification: Clinical Quality Language, Release 1, STU Release 2 (1st entry in the current table)
    - Remove the second appearance of the word "Release" so the title becomes "Hl7 Cross-Paradigm Specification: Clinical Quality Language, Release 1, STU 2"
    - Adoption Level: Should be updated to 3.
    - Update link to http://cql.hl7.org/STU2
- Add an entry for Standard
    - HL7 Cross-Paradigm Specification: Clinical Quality Language, Release 1, STU 3
    - Link to http://cql.hl7.org/STU3
    - Standards Process Maturity: Balloted Draft
    - Implementation Maturity: Production
    - Adoption Level: 3
    - Federally Required: No
    - Cost: Free
    - Test Tool Availability: Yes
- HL7® FHIR®Profile: Quality (QI Core), DSTU Release 1 (2nd entry in current table)
    - Title should be updated to "HL7® FHIR® Profile: Quality Improvement Core (QI Core), Release 1, STU3
    - Link should be updated to http://hl7.org/fhir/us/qicore/STU3
    - Adoption level should be updated to 2

- HL7® FHIR® Implementation Guide: Clinical Quality Framework (CQF on FHIR®), DSTU Release 1 (5th entry in the current table)
    - Title should be updated to "HL7 Fast Healthcare Interoperability Resources (FHIR(R)) STU 3, Clinical Reasoning Module
    - Link to http://hl7.org/fhir/STU3/clinicalreasoning-module.html
    - Adoption level should be updated to 2
- HL7® FHIR® Profiles: Quality Improvement Core (QI Core), Release 2 (6th entry in the current table)
    - Remove this entry, as it has been replaced with the latest release of QI Core
- HL7 Fast Healthcare Interoperability Resources (FHIR®) Clinical Reasoning STU Release 3 (7th entry in the current table)
    - Remove this entry, as it is now an Implementation Specification, rather than an Emerging Implementation Specification

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:

- QICore/QuICK, Draft Standard for Trial Use HL7® FHIR® Profile: Quality (QI Core), STU Release 2 (3rd entry in the current table)
    - Change title to HL7® FHIR Profile: Quality Improvement Core (QI Core), Release 1, STU 3
    - Change link to http://hl7.org/fhir/us/qicore/STU3
    - Change Adoption Level to 2
- QICore/QuICK, Draft Standard for Trial Use HL7® FHIR® Profile: Quality (QI Core), STU Release 2 (4th entry in the current table)
    - Remove this entry as it is replaced with the STU 3 publication.
- HL7 Cross-Paradigm Specification: Clinical Quality Language (CQL), Release 1, STU Release 2 (5th entry in the current table)
    - Change the title to "HL7 Cross-Paradigm Specification: Clinical Quality Language, Release 1, STU 3
    - Change the link to http://cql.hl7.org/STU3
    - Change the adoption level to 3
    - Change Test Tool Availability to Yes
- HL7 Fast Healthcare Interoperability Resources (FHIR® Implementation Guide) Clinical Reasoning STU Release 2 (6th entry in the current table)
    - Remove this entry as the recommended standard for this use case is CDS Hooks
- Add an entry for Emerging Standard
    - HL7 Cross-Paradigm Specification: CDS Hooks, Release 1, STU 1
    - Standards Process Maturity: Balloted
    - Implementation Maturity: Pilot
    - Adoption Level: 3
    - Federally Required: No
    - Cost: Free
    - Test Tool Availability: Yes

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:

- Note that the titles for this section and the following seem to be reserved. This section is standards for questions raised by clinicians, while the next section is standards for questions raised by patients.
- HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. ("Infobutton"), Knowledge Request, Release 2. - Update Adoption level to 4 (should be at least as high as the implementations of the standard)

A Standard Mechanism for Clinical Information Systems to Request Context-Specific Clinical Knowledge From Online Resources
https://www.healthit.gov/isa/a-standard-mechanism-clinical-information-systems-request-context-specific-clinical-knowledge

HL7 Comments:

- See note about the titles, the title for this section seems to be switched with the previous**.**
- HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. ("Infobutton"), Knowledge Request, Release 2.- Update Adoption level to 4 (should be at least as high as the implementations of the standard)

D – Clinical Quality Measurement and Reporting

Reporting Aggregate Quality Data to Quality Reporting Initiatives:
https://www.healthit.gov/isa/Reporting_Aggregate_Quality_Data_to_Federal_Quality_Reporting_Initiatives

HL7 Comments:

- Replace HL7 Implementation Guide for CDA Release 2 Quality Reporting Document Architecture – Category III (QRDA III) DSTU Release 1 with HL7 Implementation Guide for CDA Release 2 Quality Reporting Document Architecture – Category III (QRDA III) STU Release 1
- Re-classify the Emerging Implementation Specification to Implementation Specification and:
    - Adjust the implementation guide to HL7 CDA R2 Implementation Guide: Quality Reporting Document Architecture – Category III (QRDA III) STU Release 2.1
    - Standards Maturity – Final
    - Implementation Maturity – Production
    - Adoption Level – 4 bullets
    - Federally Required – Yes
    - Cost – Free
    - Test Tool Availability – Yes
- Add a new Implementation Specification:
    - HL7 Fast Healthcare Interoperability Resources (FHIR) Clinical Reasoning STU 3
    - Standards Maturity – Balloted Draft
    - Implementation Maturity – Pilot
    - Adoption Level – 1 bullets

    - Federally Required – Yes
    - Cost – Free
    - Test Tool Availability – Yes
- Add a new Emerging Implementation Specification
    - HL7 Fast Healthcare Interoperability Resources (FHIR) Clinical Reasoning STU 4
    - Standards Maturity – Balloted Draft
    - Implementation Maturity – Pilot
    - Adoption Level – 1 bullets
    - Federally Required – No
    - Cost – Free
    - Test Tool Availability – Yes
- Add to to Limitations, Dependencies, and Preconditions for Consideration:
    - Implementation Maturity:
        - STU Release 1: Used for 2017-2018 reporting
        - STU Release 2.1: Being used for reporting 2018, 2019 data
    - HQMF includes templates based on V3; QRDA is based on C-CDA; Clinical Reasoning is based on FHIR

Reporting Patient-Level Quality Data to Quality Reporting Initiatives: https://www.healthit.gov/isa/reporting-patient-level-quality-data-quality-reporting-initiatives

HL7 Comments:

- Replace Implementation Specification HL7® CDA R2 Implementation Guide: Quality Reporting Document Architecture – Category I (QRDA I) DSTU Release 3.1 (US Realm) with HL7® CDA R2 Implementation Guide: Quality Reporting Document Architecture – Category I (QRDA I) STU Release 4
- Replace HL7® CDA R2 Implementation Guide: Quality Reporting Document Architecture – Category I (QRDA I) STU Release 4 with HL7® CDA R2 Implementation Guide: Quality Reporting Document Architecture – Category I (QRDA I) STU Release 5 and:
    - Type – Implementation Specification
    - Standards Process Maturity – Final
    - Implementation Maturity – Production
    - Adoption Level – 4 bullet
- Introduce an Emerging Implementation Specification with
    - HL7® CDA R2 Implementation Guide: Quality Reporting Document Architecture – Category I (QRDA I) STU Release 5.1
    - Standards Maturity – Balloted Draft
    - Implementation Maturity – Pilot
    - Adoption Level – 1 bullets
    - Federally Required – Yes
    - Cost – Free
    - Test Tool Availability – Yes
- Introduce an Emerging Implementation Specification with
    - HL7 Fast Healthcare Interoperability Resources (FHIR) Clinical Reasoning STU 3
    - Standards Maturity – Balloted Draft
    - Implementation Maturity – Pilot

    - Adoption Level – 1 bullets
    - Federally Required – No
    - Cost – Free
    - Test Tool Availability – Yes
- Introduce an Emerging Implementation Specification with
    - HL7 Fast Healthcare Interoperability Resources (FHIR) Clinical Reasoning STU 4
    - Standards Maturity – Balloted Draft
    - Implementation Maturity – Pilot
    - Adoption Level – 1 bullet
    - Federally Required – No
    - Cost – Free
    - Test Tool Availability – Yes
- Add to to Limitations, Dependencies, and Preconditions for Consideration:
    - Implementation Maturity:
        - STU Release 1: Used for 2017-2018 reporting
        - STU Release 2.1: Being used for reporting 2018, 2019 data

HQMF includes templates based on V3; QRDA is based on C-CDA; Clinical Reasoning is based on FHIR
Sharing Quality Measure Artifacts for Quality Reporting Initiatives: https://www.healthit.gov/isa/isa/sharing-quality-measure-artifacts-quality-reporting-initiatives

HL7 comments:

- Replace standard HL7® V3: Representation of the Health Quality Measures Format (eMeasure) DSTU Release 2.1 with HL7® V3: Representation of the Health Quality Measures Format (eMeasure) Normative (R1) and:
    - Standards Maturity – Final
    - Implementation Maturity – Production
    - Adoption Level – 4 bullets
- Replace standard HL7® FHIR® Profile: Quality (QI Core) DSTU Release 1 with HL7® FHIR® Profile: Quality (QI Core) STU Release 3 and:
    - Standards Maturity – Final
    - Implementation Maturity – Production
    - Adoption Level – 2 bullets
- Replace standard HL7 Cross-Paradigm Specification: Clinical Quality Language (CQL) Release 1 STU Release 1.1 with HL7 Cross-Paradigm Specification: Clinical Quality Language (CQL) Release 1 STU Release 3 and
    - Standards Maturity – Final
    - Adoption Level – 4 bullets
- Replace implementation specification HL7® V3 Implementation Guide: Quality Data Model (QDM)-based Health Quality Measure Format (HQMF) Release 1.4 DSTU 4 (based on HQMF 2.1) US Realm with HL7® V3 Implementation Guide: Quality Data Model (QDM)-based Health Quality Measure Format (HQMF) Release 1.4 STU 4 (based on HQMF 2.1) US Realm and
    - Standards Maturity – Final
    - Adoption Level – 4 bullets
- Replace implementation specification HL7® V3 Implementation Guide: Clinical Quality Language (CQL)-based Health Quality Measure Format (HQMF) Release 1 DSTU 2 (based on HQMF 2.1) US Realm with HL7® V3

Implementation Guide: Clinical Quality Language (CQL)-based Health Quality Measure Format (HQMF) Release 1 STU 3 (based on HQMF 2.1) US Realm and
    - Adoption Level – 4 bullets
- Include as an implementation specification HL7 Fast Healthcare Interoperability Resources (FHIR) Clinical Reasoning STU 3 and
    - Standards Maturity – Final
    - Implementation Maturity – Production
    - Adoption Level – 4 bullets
    - Federally Required – No
    - Cost – Free
    - Test Tool Availability – Yes
- Delete emerging implementation specification HL7® V3 Implementation Guide CQL-Based HQMF Release 2 DSTU 32 – US Realm
- Delete emerging implementation specification HL7® FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR)
- Add emerging implementation specification HL7® FHIR® Clinical Reasoning STU 4 and
    - Standards Maturity – Balloted Draft
    - Implementation Maturity – Pilot
    - Adoption Level – 1 bullet
    - Federally Required – No
    - Cost – Free
    - Test Tool Availability – Yes
- Add emerging implementation specification Data Exchange for Quality Measure (DaVinci) and
    - Standards Maturity – Balloted Draft
    - Implementation Maturity – Pilot
    - Adoption Level – 1 bullet
    - Federally Required – No
    - Cost – Free
    - Test Tool Availability – Yes
- Add to to Limitations, Dependencies, and Preconditions for Consideration:
    - Implementation Maturity:
        - STU Release 1: Used for 2017-2018 reporting
        - STU Release 2.1: Being used for reporting 2018, 2019 data
    - HQMF includes templates based on V3; QRDA is based on C-CDA; Clinical Reasoning is based on FHIR

E – L

- No comments

M – Laboratory

HL7 Comments:
Receive Electronic Laboratory Test Results: https://www.healthit.gov/isa/receive-electronic-laboratory-test-results

HL7 Comments:

- Update the reference to the Laboratory Results Interface Implementation Guide to HL7 V2.5.1 Implementation guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm.

Ordering Labs for a Patient:: https://www.healthit.gov/isa/ordering-labs-a-patient

HL7 Comments:

- Update the reference to the Laboratory Orders Interface Implementation Guide to HL7 V2.5.1 Implementation Guide: Laboratory Orders from HER (LOI), Release 1, STU Release 3 – US Realm.

Support the Transmission of a Laboratory's Directory of Services to Provider's Health IT or EHR System: https://www.healthit.gov/isa/isa/support-transmission-a-laboratorys-directory-services-providers-health-it-or-ehr-system

HL7 Comments:

- Update the reference to the electronic Directory of Services Implementation Guide to HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework (eDOS), Release 2, STU Release 3 – US Realm.

General comments across all Laboratory interoperability needs

- All three guides share the same Value Set Companion Guide and associated value set, which should be referenced now as: HL7 Version 2 Implementation Guide: Laboratory Value Set Companion Guide, Release 1 STU 3 – US Realm.

- HL7 currently is balloting an implementation guide based on HL7® FHIR® that enables communication from a device manufacturer to a laboratory to provide guidance to the laboratory staff who configures the mapping from a device's IVD test code to a LOINC code to be included on the result. We suggest that the ISA include in Section 2, Laboratory, Identify Linkages Between Vendor IVD Test Results and Standard Codes a reference to the emerging specification:

    - Type: Emerging Implementation Specification
    - Standard/Implementation Specification: HL7® FHIR® LIVD Implementation Guide
    - Standards Process Maturity: In Development
    - Implementation Maturity: No comment.
    - Adoption Level: No comment.
    - Federally Required: No
    - Cost: Free
    - Test Tool Availability: No

N - Q

- No comments

R - Public Health Reporting

Exchanging Immunization Data with Immunizations Registries: https://www.healthit.gov/isa/exchanging-immunization-data-immunization-registries

HL7 Comments:

- It is not clear what the content in the Applicable Value Sets and Starter Sets is intended to represent. HL7 therefore recommends clarifying what these sets refer to and how they are to be used.
- The release 1.4 test tool link is broken. The community is moving towards Release 1.5, so we may not even need this tool link anymore.
- The Transport Adoption Level should be increased to 4 circles as 40 IIS support the CDC WSDL.

Electronic Transmission of Reportable Lab Result to Public Health Agencies: https://www.healthit.gov/isa/electronic-transmission-reportable-lab-results-public-health-agencies

HL7 Comments:

- Adoption Level for the HL7 v 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 with Errata and Clarification and ELR 2.5.1 Clarification Document for EHR Technology Certification should be changed to reflect Indicates high or widespread adoption.
- Emerging Implementation Specification- HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), Draft Standard for Trial Use, Release 1.1 should be removed.
- The following statement should be removed from the Limitation, Dependencies, and Preconditions for Consideration column: "The Emerging Implementation Specification: "HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public health, Release 2 (US REALM), Draft Standard for Trial Use, Release 1.1" listed above was in a Draft Standard for Trial use status, but was not renewed or balloted as normative. However, a recommendation was received to leave it listed here until there is wider adoption/experience with other listed specifications."
- Emerging Implementation Specification HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2- US Realm should be replaced with HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI) Release 1, STU Release 3- US Realm, Standard for Trial Use, Published June 2018 using the following link: *http://www.hl7.org/documentcenter/public/standards/dstu/V251_IG_LRI_R1_STU3_2018JUN.pdf*

Case Reporting to Public Health Agencies: https://www.healthit.gov/isa/case-reporting-public-health-agencies

HL7 Comments:

- HL7 recommends deleting "HL7® CDA® R2 Implementation Guide: Consolidated CDA® Templates for Clinical Notes (US Realm) DSTU Release 2.1 (with errata)" from the list for Case Reporting. This is the standard that the eICR was built from but this standard in itself cannot meet certification criteria for eCR.
- HL7 recommends deleting "IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation" from the list for Case Reporting. This standard cannot be used for automated case reporting. Since it cannot be used on its own to support case reporting, and there is no way in the ISA to indicate it could be used for supplemental data collection, it should be deleted.
- HL7 recommends deleting "IHE IT Infrastructure Technical Framework, Volume 1 (ITI TF-1): Integration Profiles, Section 17: Retrieve Form for Data Capture (RFD)". This standard cannot be used for automated case reporting.

Since it cannot be used on its own to support case reporting, and there is no way in the ISA to indicate it could be used for supplemental data collection, it should be deleted.

- The following are the best available standards for inclusion in this documentation:

  Standard: HL7® CDA® R2 Implementation Guide: Public Health Case Report, Release 2, STU Release 1.1 – the Electronic Initial Case Report (eICR) – US Realm January 2017.
  - Link: http://www.hl7.org/documentcenter/public/standards/dstu/CDAR2_IG_PHCASERPT_R2_STU1.1_2017JAN.zip
  - Type: Implementation Specification
  - Standards Process Maturity: Published
  - Implementation Maturity: Pilot
  - Adoption Level: low to medium adoption (2 dots)
  - Federally required: No
  - Cost: Free
  - Test Tool Availability: Yes

  Standard: HL7® CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.0 US Realm
  - Link: http://www.hl7.org/documentcenter/public/standards/dstu/CDAR2_IG_PHCR_R2_RR_D1_2018JAN.zip
  - Type: Implementation Specification
  - Standards Process Maturity: Published
  - Implementation Maturity: Pilot
  - Adoption Level: low to medium adoption (2 dots)
  - Federally required: No
  - Cost: Free
  - Test Tool Availability: Yes

  Standard: HL7® FHIR® Implementation Guide: Electronic Case Reporting (eCR), Release 1 – US Realm
  - Type: Emerging Implementation Specification
  - Standards Process Maturity: Balloted Comment Only
  - Implementation Maturity: Pilot
  - Adoption Level: low to medium adoption (2 dots)
  - Federally required: No
  - Cost: Free
  - Test Tool Availability: Yes

- Regarding "Updates to the Limitations, Dependencies, and Preconditions for Consideration" in this section, HL7 recommends changing the sentence that says "Electronic case reporting is not wide spread and is determined at the state or local jurisdiction." to "Electronic case reporting involves reporting to State and/or Local jurisdictions and is not yet widespread."

Reporting Syndromic Surveillance to Public Health (Emergency Department, Inpatient, and Urgent Care Settings): https://www.healthit.gov/isa/reporting-syndromic-surveillance-public-health-emergency-department-inpatient-and-urgent-care

HL7 Comments:

- HL7 comment: PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0 and Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015; Erratum to the CDC PHIN 2.0 Messaging Guide, April should be listed as an Implementation Specification, not an Emerging Implementation Specification. The adoption level should be updated to reflect medium adoption.

Sending Information to Public Health Agencies: https://www.healthit.gov/isa/sending-health-care-survey-information-public-health-agencies

HL7 Comments:

- HL7® CDA® R2 Implementation Guide: National Health Care Surveys (NHCS), R1 DSTU Release 1.1 was not described as a standard and format for Health Care Surveys/"(f) (7)" in the modified State 2/ Stage 3 final rule, nor the "2015 Edition" final rule, nor other the updated CCG guide for Health Care Surveys/"(f) (7)" where Release 1.2 was allowed as a standard and format, the row in the table for Implementation Specification: *HL7® CDA® R2 Implementation Guide: National Health Care Surveys (NHCS), R1, DSTU, Release 1.1- US Realm* should be removed.

- Regarding "Updates to the Limitations, Dependencies, and Preconditions for Consideration" in this section change: Stakeholders should refer to the National Health Care Survey Program at: http://www.cdc.gov/nchs/nhcs/how_to_participate.htmWeb Site Disclaimers for information on participation to: Stakeholders should refer to the National Health Care Survey Registry at: https://www.cdc.gov/nchs/dhcs/nhcs_registry_landing.htm Web Site Disclaimers for information on participation.

Reporting Death Records to Public Health Agencies: https://www.healthit.gov/isa/reporting-death-records-public-health-agencies

HL7 Comments:

- The following link is incorrect:
  IHE Quality, Research and Public Health Technical Framework Supplement Vital Records Death Reporting (VRDR) R 3.1
  It should be corrected to the following link:
  https://www.ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_VRDR.pdf

- For *HL7® CDA R2 Implementation Guide: Vital Records Death Reporting, Release 1 STU 2 - (US Realm) (Standard for Trial Use),* there is now a test tool available. The Test Tool Availability should be changed from "No" to "Yes".

Reporting Birth and Fetal Death to Public Health Agencies : https://www.healthit.gov/isa/reporting-birth-and-fetal-death-public-health-agencies

HL7 Comments:

- Remove the row: Standard: *HL7 Version 2.5.1 Implementation Guide: Birth & Fetal Death Reporting, Release 1 (US Realm).* It is no longer available.

- The following name is incorrect: *IHE Quality, Research and Public Health Technical Framework Supplement 10 Birth and Fetal Death Reporting-Enhanced (BFDR-E) .* It should be: *IHE Quality, Research and Public Health Technical Framework Supplement Birth and Fetal Death Reporting-Enhanced (BFDR-E) Rev 3.1*. The link is also incorrect. It should point to: *https://www.ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_BFDR-E.pdf*
- *HL7 Version 2.6 Implementation Guide: Birth and Fetal Death Reporting, Release 1 STU Release 2 (US Realm - Standard for Trial Use)* Link is incorrect. It should point to: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=320*
- *HL7 Version 3 CDA R2 Implementation Guide: Birth and Fetal Death Reporting, Release 1 (US Realm - Standard for Trial Use)* Link is incorrect. It should point to: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=387*

S – U

- No comments

Section III

Standards and Implementation Specifications for Services

A – I

- No comments

J – Consumer Access/Exchange of Health Information

HL7 Comments:

- HL7 urges consideration of the need to establish methods for unique app identification (similar to UDI for medical devices) as it relates to mobile healthcare apps (for both consumers and providers). Mobile Health apps are increasingly becoming the new point of care for many health episodes and there is a critical need to capture the provenance of data custody from the originating app and instance as the data flows from the app to the Health IT ecosystem including EHRs and HIEs.

- The concept of both hardware and software as "devices" and as "authors/actors" is already supported in HL7 standards such as HL7® C-CDA® and HL7® FHIR®, so these capabilities should be extended to support app identification for Mobile Health. The HL7 Consumer Mobile Health Application Functional Framework (cMHAFF) Standard for Trial Use (STU) establishes the framework to begin incorporation of methods for establishing data provenance (see section 3.4.6 of cMHAFF) in relation to mobile health apps (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=476).

Recording Patient Preferences for Electronic Consent to Access and/or Share their Health Information with Other Care Providers

HL7 Comments:

- HL7 is very supportive of the inclusion of a variety of platform-specific consent directive implementation specification options given that any one of them may be more suitable to an exchange ecosystem. There are HIEs in which participants are using multiple standards from each HL7 product family to conduct key exchange workflows in which access control systems have to be able to uniformly apply authorization logic.

- For that reason, HL7 Service Oriented Architecture is leading, and HL7 Security and CBCP Work Groups are co-sponsoring a VA-resourced project, "HL7 Cross Paradigm Interoperability Implementation Guide Extension Project" to develop Cross-Paradigm models intended to facilitate transforms across any two HL7 platform specific consent directive/security label specifications.

  We recommend that the community of interest be encouraged to update the HL7 v2 Consent Segment so that v2 exchange ecosystems are able to use that specification to capture and exchange consent directives without having also implement non-v2 consent directive standards.

Section IV

Models and Profiles

HL7 Comments:

- Section Title – HL7 recommends that the Section IV title be changed to Section IV: Models and Functional Model Profiles.

A – Functional Models

HL7 Comments:

- Under the Functional Models section, an introductory paragraph should be inserted that explains what a functional model is and its intended purpose. HL7 also observes that gauging adoption level and implementation maturity for Functional Models is inherently challenging and that this issue needs to be better examined and understood.
- The HL7® FHIR® Quality Improvement (QI) Core HL7's Reference Model for Quality Measure and Reporting; HL7 recommends including it in this section of Models and Profiles
  - URL for QI-Core**:** http://www.hl7.org/fhir/current/qicore/
- HL7 suggests that the ISA include reference to the HL7 Consumer Mobile Health Application Functional Framework (cMHAFF) STU.
  - The primary goals of cMHAFF are to provide a standard against which a mobile app's foundational characteristics -- including but not limited to security, privacy, data access, data export, and transparency/disclosure of conditions -- can be assessed.
  - The framework is based on the lifecycle of an app, as experienced by an individual consumer, from first deciding to download an app, to determining what happens with consumer data after the app has been deleted from a smartphone.
  - cMHAFF establishes conformity assessment objectives, certification guidance, and requirements development across multiple stakeholders including regulatory bodies, healthcare providers (for prescribing health apps), health app developers and vendors, the consumer mobile app marketplace, and consumers/patients.
  - URL to HL7 cMHAFF STU http://www.hl7.org/implement/standards/product_brief.cfm?product_id=476

B – Functional Profiles

- No comments

C – Information Models

HL7 Comments:

- Regarding the Information Models section and the request for feedback on "Adoption Level" here, HL7 observes that "Adoption Level" should be conceived of thoughtfully and thoroughly in the ISA. Specifically, ONC should clarify what "Adoption Level" means in an information model and also consider that being in "Production" may not be the appropriate term in this section under "Implementation."

Other – Domain Analysis Models

HL7 Comments:

- ONC asks about additional models and/or profiles that should be listed in the ISA. Related to our organization in particular, HL7 has a much richer library of Domain Analysis Models (DAM) than what is listed in the ISA. We suggest including more HL7 DAMs in the ISA document. A full list of HL7 Domain Analysis Models can be found by clicking the can Domain Analysis Models "category" on the HL7 Standards Master Grid at: https://www.hl7.org/implement/standards/product_matrix.cfm?ref=nav.
- Secondly on Domain Analysis Models, HL7 suggests adding a specific category for this under Section IV: Models and Profiles or putting Domain Analysis Models under the IV-A: Functional Model section.

Section V

A – F

- No comments

Appendices

- No comments