



September 23, 2019

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Department of Health and Human Services
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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 2020 "Reference Edition". As you know, HL7 is the global authority on healthcare interoperability and 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. 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 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 2020 "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.

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);
- Community-Based Care and Privacy (CBCP);
- Security;
- Structured Documents; and
- Vocabulary.

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

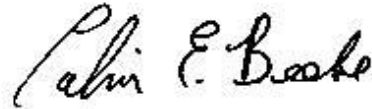
- The proper use and citation of HL7 standards such as FHIR®;
- Incorporating the latest version of HL7 FHIR -- HL7 FHIR R4 (v4.0.0) -- into many of the appropriate individual ISA sections where it is currently not and ONC review of the ISA on this issue;
- Including implementation guides developed by HL7 accelerator projects in the ISA;
- Leveraging existing HL7 educational and other resources;
- Ensuring ISA compatibility with other frameworks that may reference it, such as TEFCA, USCDI and ARCH;
- The importance of ONC working with public health agencies to reduce the number of different public health reporting standards and for those standards to be developed with public health's comprehensive and specific needs in mind; and that
- ONC should implement an annual review cycle that both examines how specific standards are working in practice and their use affects desirable outcomes.

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

19-1. 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 desire to better understand how the ISA is being used. As we have mentioned in our prior comments, 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 in that document and its successors should be adjusted to reflect the status and intent of the ISA as indicated by ONC. Specifically, it should be stated that the ISA is informational only to be used as a reference of available, potential standards, not recommended or mandatory 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 regulation(s) where such requirements exist. Without that further context, the status of "Federally Required" could be misleading to some users of the ISA.

HL7 submitted comments June 14, 2019 on the Trusted Exchange Framework (TEF) Draft 2. The following excerpts from that letter on Principle 1 – Standardization: Adhere to industry and federally recognized standards, policies, best practices, and procedures, are relevant to the ISA and coherence across federal frameworks:

- We urge that any standardization efforts conducted under (TEF) Draft 2 Principle 1 are carried out in an open and transparent manner, consistent with ANSI essential requirements, with broad stakeholder engagement and governance that appropriately balances relevant interests.
- Relevant adopted standards should comprise exclusively accredited American National Standards, or consortia consensus standards that meet all provisions of the WTO TBT Agreement or the ANSI Essential Requirements (per NTTAA and OMB circular 119). Unaccredited implementation guidance for these standards, such as data specifications for government quality measures, should be promulgated only through sub-regulatory publications that can be updated when needed.

ISA, USCDI and ARCH - USCDI and ARCH should address additional FHIR resources that are significant for clinical decision support, electronic clinical quality measurement and reporting as experienced by the Da Vinci Project, FHIR connectathons, or other relevant initiatives. These items are also included in the QI-Core implementation guide of FHIR; it, in turn, references US Core to the extent possible. These recommendations are further explained in our detailed comments.

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

- HL7 urges that the latest version of HL7 FHIR [HL7 FHIR R4 (v4.0.0)] be incorporated into the appropriate individual ISA sections, where it is not currently and, at the proper level of Standards Process Maturity and Implementation. For example, the ISA section on View, Download and Transmitting data from EHRs does not mention FHIR R4 at all. HL7 recommends a comprehensive ONC review of the ISA regarding the proper use of HL7 FHIR R4. HL7 leaders and FHIR experts stand ready to offer their perspective and assistance.
- 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 more precise use in these appendices. 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. The HL7 FHIR implementation specifications are highly relevant along with the underlying HL7 FHIR standard.

HL7’s Prior ISA Input - HL7 has provided detailed input in response to prior ONC ISA calls for comments on the ISA. We highlight a key recommendation that has yet to be included in the ISA and for which we continue to advocate.

- Data Provenance - We continue to believe that the need to recognize available data provenance constructs in all three main HL7 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. We encourage ONC to continue to work with HL7 on the *Basic Provenance Implementation Guide*, including more thorough review with the clinician and healthcare consumer communities, to determine whether the minimum provenance should include:
 - Healthcare consumers and their representatives as authors;
 - When information has been transformed, the organization responsible for the transformation should be identified along with the device or software that made the transformation and a timestamp of the transformation. This need includes indicating when security labels -- such as Controlled Unclassified Information (CUI) marks -- have been reclassified or declassified (where the originator’s security labels have not been persisted).

HL7 Project Implementation Guides - HL7 recommends that implementation guides developed by its accelerator projects be included in the ISA. Information about HL7 accelerator projects is available at: <http://www.hl7.org/about/fhir-accelerator/>. Some examples of implementation guides that should be included are:

- Relevant Da Vinci Public Implementation Guides
<https://confluence.hl7.org/display/DVP/Da+Vinci+Public+Implementation+Guides>
- HL7 FHIR US Core Implementation Guide CI Build (FHIR R4, STU3)
<https://build.fhir.org/ig/HL7/US-Core-R4/#introduction>
- CARIN Blue Button 2.0 Draft Implementation Guide
<https://build.fhir.org/ig/HL7/carin-bb/toc.html>

HL7 stands ready and willing to engage with ONC to assist in its use of these guides.

19-2. Are there additional features or functionality ONC could make to the ISA website that would enhance the user experience?

Standards Education Portals and Links - HL7 recommends that, as part of the ISA, ONC highlight and provide links to authoritative educational portals and materials published by standards development organizations (SDOs) and applicable other organizations with expertise on referenced 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>.

19-3. The adoption level, along with other informative characteristics about standards/implementation specifications, was introduced to the ISA in 2015 and currently represents ONC's "best guess" at current adoption based on a number of factors. Is the adoption level characteristic as it stands valuable information for stakeholders or should it be retired or replaced with other information?

Objective Adoption Level Methodology - As we note below in more detail, the Adoption Level choices and judgments for individual ISA and standards entries can be too subjective. More examples and decision points for objective Adoption Level determinations are needed. The current strategy of giving equal weight to different system implementations for Adoption Level determination should be reconsidered. Adoption should be primarily measured by quantitative factors such as number of patient records handled, number of users and percentage of potential users using the standard, geographic dispersion of use, and number of transactions using a standard. Segregation by use cases may also be helpful.

19-4. The specialty care/settings pages were added in 2019, and represent a collection of related Interoperability Needs that pertain to a particular setting or type of specialty care (i.e. pediatrics, treatment for opioid use disorder). Are there additional specialty care/settings specific collections that would be beneficial for inclusion?

Specialty Care Recommendations - HL7 recommends adding community care, long-term community care and services and a freestanding behavioral health category, distinct from opioids, as new specialty care/settings.

Appendix 2: Detailed Responses

Table of Contents

ONC Standards

A- U.S. Core Data for Interoperability (USCDI)

USCDI v1 Summary of Data Classes and Data Elements

<https://www.healthit.gov/isa/us-core-data-interoperability-uscdi>

HL7 Comments:

- HL7 notes that, where clinical note types are listed, the specific LOINC codes to be used should be identified. LOINC codes are needed for Narrative Laboratory Reports and Narrative Pathology Reports.
- HL7 emphasizes that the USCDI and ARCH should also address additional FHIR resources that are significant for clinical decision support and electronic clinical quality measurement and reporting as experienced by the Da Vinci work, connectathons and others. These items are also included in the QI-Core implementation guide of FHIR; it, in turn, references US Core to the extent possible. Many are included in CMS eCQM measures.

- a. AdverseEvent
- b. Communication
- c. Coverage
- d. DeviceRequest – also in US Core
- e. DeviceUseStatement
- f. Encounter – also in US Core
- g. MedicationAdministration
- h. MedicationDispense
- i. MedicationRequest
- j. ServiceRequest
- k. Task

Introduction to ISA

Structure

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

A- Standards Process Maturity

HL7 Comments:

- HL7 notes that the Standards Process Maturity framework and process does not adequately address either HL7 FHIR or C-CDA. FHIR has both normative “final” content and content in development. STU content is not the same as “Draft” since it typically represents content of a higher maturity level. Level 0 would likely be “Draft”. Many of the individual ISA references such as those to FHIR, CQL, QI Core and others should be rated as more mature than “Balloted Draft.”
- ONC should have an additional category to capture standards that are used in a final form without being formally Normative, such as C-CDA or annual updates to quality data standards. Allowing multiple maturity levels for a given standard and adding some additional values could improve the Standards Process Maturity process.

B- Implementation Maturity

HL7 Comments:

- HL7 notes that, under Implementation Maturity, there is also a need for more granularity as noted above. A standard may be in production but only at a very small number of sites. An indication of the extent of production use is needed, as the FHIR Maturity Model does, for example.

C- Adoption Level

HL7 Comments:

- HL7 notes that, on Adoption Level, the choices and judgments for individual ISA and standards entries sometimes are too subjective. More examples and decision points for objective Adoption Level determinations are needed. Segregation by use cases may also be helpful. The EHR API for patients may be at a higher adoption level right now than for payers, for example. The first version of a standard use case should be as simple as possible, with details and functionality added in future versions.
- HL7 notes that, before health IT standards and interoperability rules are adopted, pilot testing, evaluation, and subsequent implementation must be conducted in a way to avoid and/or mitigate any adverse effects on patient care, privacy, security, clinical team workflow, and burden. It is important that standards reach the front line clinician and that the actual impact is thoughtfully examined at critical points in the process. Interoperability efforts should be focused on the adoption and consistent implementation of health IT standards. Assessment of the value of data to clinical care is paramount. ONC should implement an

annual review cycle that examines how specific standards are working in practice and how their use impacts desirable outcomes.

Section I

Vocabulary/Code Set/Terminology Standards and Implementation Specifications

A – Allergies and Intolerances

Representing Patient Allergies and Intolerances; Food Substances

<https://www.healthit.gov/isa/representing-patient-allergies-and-intolerances-food-substances>

HL7 Comments:

- The Value Set [Common dietary substances for allergy and intolerance documentation \(2.16.840.1.113762.1.4.1186.3\)](#)(SNOMED CT® disorder and finding value set-Steward HL7 Patient Care Work Group) is not disorders and findings; it is substances.

Representing Patient Allergies and Intolerances; Medications

<https://www.healthit.gov/isa/representing-patient-allergies-and-intolerances-medications>

HL7 Comments:

- Standards Process Maturity of the Emerging Standard [Medication Reference Terminology \(MED-RT\)](#) should be noted as Final, not In-Development.
- ISA language under Limitations, Dependencies and Preconditions for Consideration states that “MED-RT is meant to replace the VA’s NDF-RT with is being sunsetted in 2018.” HL7 notes that NDF-RT was sunsetted in 2018.
- Under “Representing Adverse Reactions/Intolerances Propensity to adverse reactions to drug (disorder) (SNOMED CT 419511003), this points to a 2017-03 version of SNOMED CT in VSAC. HL7 notes there have been changes since 2017.

H – Immunizations

Representing Immunizations – Administered

<https://www.healthit.gov/isa/representing-immunizations-administered>

HL7 Comments:

- Regarding the Standard [HL7 Standard Code Set CVX—Clinical Vaccines Administered](#), HL7 notes CDC is the steward for CVX (<https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx>) and MVX (<https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=mvx>) codes. We suggest rewording throughout the document so it does not appear that HL7 is the steward.
- HL7 asks if HCPCS should also be listed as a standard here (<https://coder.aapc.com/hcpcs-codes-range/139>).

J – Laboratory

Representing Laboratory Tests

<https://www.healthit.gov/isa/representing-laboratory-tests>

HL7 Comments:

- HL7 notes that the Applicable Value Set(s) and Starter Set(s) [LOINC Top 2000+ Lab Observations - US Version OID: 1.3.6.1.4.1.12009.10.2.3](#) points to LOINC website, not a Value Set in VSAC or PHIN VAD.

P – Procedures

Representing Dental Procedures Performed

<https://www.healthit.gov/isa/representing-dental-procedures-performed>

HL7 Comments:

- HL7 notes Value Sets are not provided.

Section II

Content/Structure Standard and Implementation Specifications

B – Care Plan

Documenting and Sharing Care Plans in A Single Clinical Context

<https://www.healthit.gov/isa/documenting-and-sharing-care-plans-a-single-clinical-context>

HL7 Comments:

- Change Implementation Specification [HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes \(US Realm\), Draft Standard for Trial Use, Release 2.1](#) from Pilot to Production.

Documenting and Sharing Medication-Related Care Plans by Pharmacists

<https://www.healthit.gov/isa/documenting-and-sharing-medication-related-care-plans-pharmacists>

HL7 Comments:

- HL7 questions why there a cost "\$" identified for the Implementation. Guide. There is no cost for the [HL7 CDA® R2 Implementation Guide: Pharmacist Care Plan Document, Release 1 - US Realm, Volume 1](#).

Domain or Disease-Specific Care Plan Standards

<https://www.healthit.gov/isa/domain-or-disease-specific-care-plan-standards>

HL7 Comments:

- HL7 notes that many standards are being developed well in advance of current clinical practice. We emphasize that clinical requirements should drive standards development – not the reverse. We are concerned that clinicians will be subject to data collection requirements or use without enough needs assessments and real-world testing. This adoption dynamic is undesirable.
- Regarding the reference to Implementation Specification [HL7 CDA® R2 Implementation Guide: Clinical Oncology Treatment Plan and Summary, Release 1 – US Realm](#), HL7 is not aware that ASCO will continue supporting this guide.
- HL7 encourages ONC to check with IHE about the on-going support for the [IHE Quality, Research, and Public Health Technical Framework Supplement, Early Hearing Detection and Intervention \(EHDI\), Rev 2.1 Trial Implementation](#).

C – Clinical Decision Support

Provide Access to Appropriate Use Criteria: <https://www.healthit.gov/isa/provide-access-appropriate-use-criteria>

HL7 Comments:

- The CDS Hooks specification is a published Standard for Trial Use (STU), so HL7 believes this should be a Standard and not an Emerging Implementation Specification.
- Update CDS Hooks Services link by changing it to <http://cds-hooks.hl7.org>.
- Regarding the Implementation Maturity on CDS Hooks Services, production implementations exist.
- HL7 suggests low-medium adoption (two stars) of CDS Hooks Services.

- HL7 notes [HL7 FHIR Clinical Reasoning Module, FHIR STU Release 3](#) is a published Standard, rather than an Implementation Specification.

Regarding Limitations, Dependencies and Preconditions for Considerations:

- Note that there is an active stakeholder initiative (Argonaut project) to support Protecting Access to Medicare Act (PAMA) requirements related to Guideline Appropriate Ordering using CDS Hooks.
- The following sentence should be removed, since it applied to the transition between DSTU2 and STU3: “Note that the FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR) in STU 3 was incorporated into FHIR as a core implementation guide, FHIR Clinical Reasoning.”
- Regarding the sentence, “The FHIR Maturity Model and each of the levels may vary is described on the HL7 Wiki”, point instead to the FHIR Maturity Model content in the specification.

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

HL7 Comments:

- Regarding the Implementation Specification, change to [HL7 FHIR Implementation Guide Clinical Reasoning Module, FHIR R4](#).

Regarding Limitations, Dependencies and Preconditions for Considerations:

- Update the sentence, “The FHIR Maturity Model and each of the levels is described on the HL7 Wiki” and point to the FHIR Maturity Model link in the specification.
- Add the sentence, “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.”

D – 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:

- Change the Implementation Specification [HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture - Category III \(QRDA III\), STU Release 1](#) from Final to Balloted Draft (Standards Process Maturity).
- Change the Implementation Specification [HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category III \(QRDA III\) STU Release 2.1](#) from Final to Balloted Draft.
- Change the Implementation Specification [HL7 Fast Healthcare Interoperability Resources \(FHIR\) Clinical Reasoning STU 3](#) from Final to Balloted Draft.
- Change the Emerging Implementation Specification [HL7 Fast Healthcare Interoperability Resources \(FHIR\) Clinical Reasoning STU 4](#) to an Emerging Standard and change the reference to HL7 FHIR R4, not STU 4.

Regarding the Emerging Implementation Specification [HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I \(QRDA I\) STU Release 4 \(US Realm\)](#)

- Note this standard is no longer Emerging.
- Change from In Development to Balloted Draft.
- Change from Pilot to Production.
- Change Adoption Level to medium-high (4 circles).

- Add new row in this section for Category I (QRDA I) STU Release 5.1 (US Realm) – Balloted Draft – Production – Adoption Level of medium-high (4 circles).
- Add a new row in this section for STU Release 5.2 – In Development, Pilot – Adoption Level of low (1 circle). Reference information is at: <https://ecqi.healthit.gov/ecqi-tools-key-resources?qt-teste=1>.
- Add a new row in this section for Emerging Standard Date Export for Quality Measures (DEQM) – In Development, Pilot – Adoption Level of low (1 circle).

Sharing Quality Measure Artifacts for Quality Reporting Initiatives: <https://www.healthit.gov/isa/sharing-quality-measure-artifacts-quality-reporting-initiatives>

HL7 Comments:

- HL7 notes that the Standard [HL7 V3: Representation of the Health Quality Measures Format \(eMeasure\), DSTU Release 2.1](#) is now Normative and should be noted as Published – Production (Implementation Maturity).
- HL7 notes that 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](#) is retired and was no longer in use after the 2018 reporting period.
- The standard [HL7 Cross-Paradigm Specification: Clinical Quality Language \(CQL\), Release 1, STU Release 1.1](#) should be updated to STU 1.3 with an adoption level of medium (three circles). Add a column here also for HL7 Cross-Paradigm Specification: CQL STU Release 1.4. Note as a Balloted Draft – Production (for use in 2020).
- Delete the Implementation Specification [HL7 Version 3 Implementation Guide: Clinical Quality Language \(CQL\)-based Health Quality Measure Format \(HQMF\), Release 1.1 DSTU 2 \(based on HQMF 2.1 - US Realm](#). It is no longer in use.
- Regarding the Emerging Implementation Specification [HL7 Version 3 Implementation Guide: Clinical Quality Language \(CQL\)-based Health Quality Measure Format \(HQMF\), Release 2 DSTU32 \(based on HQMF 2.1 - US Realm](#) CQL-based HQMF Implementation Guide R1 STU 3 based on HQMF R1 (normative) – In Development – maturity = Production. Add two new lines here, first for a CQL-based HQMF Implementation Guide STU 4 based on HQMF R1 (normative), noting it as In Development – Production (Implementation Maturity). Add a second new line for Emerging FHIR Quality Measure IG STU 1, noting it as In Development – Pilot (Implementation Maturity).
- Update Standard [HL7 FHIR Profile: Quality \(QI Core\), DSTU Release 1](#) to HL7 FHIR Profile: Quality (QI Core) STU 3.2 and note as Pilot. Add a new line here for the Emerging HL7 FHIR profile: Quality (QI Core) STU 4.0, noted as Balloted Draft – Pilot. Add comment in this section that QI Core Profiles are used to express the data involved in a sharable measure and depend on US Core profiles.
- Regarding the Emerging Implementation Specification [HL7 Fast Healthcare Interoperability Resources \(FHIR\) Clinical Reasoning STU Release 3](#), add line for HL7 Fast Healthcare Interoperability Resources (FHIR) Clinical Reasoning STU Release 4.

E – Data Provenance

Establishing the Authenticity, Reliability, and Trustworthiness of Content Between Trading Partners:

<https://www.healthit.gov/isa/establishing-authenticity-reliability-and-trustworthiness-content-between-trading-partners>

HL7 Comments:

- Regarding [HL7 CDA® Release 2 Implementation Guide Data Provenance, Release 1 - US Realm](#), HL7 notes that there is a new Implementation Guide on this topic in progress.

- HL7 notes that provenance seems focused on the author, time stamp and organization responsible for an interoperable message. When historical data are required for clinical decision support and clinical quality measures, the level of detail at which provenance is known may be very significant. For example:
 - The time and performer of an immunization administration is essential to determine if the patient is protected from the respective infectious agent. A summary of prior immunizations sent August 1, 2019 needs to include the dateTime of the respective immunizations included in the summary report.
 - Information about a left ventricular ejection fraction within a clinical summary needs to specify the dateTime and the ejection fraction measurement occurred (and preferably the imaging procedure used to measure it). E.g., a clinical summary August 1, 2019 could refer to an ejection fraction performed January 3, 2010 and another June 5, 2018. The time of the data within the clinical summary is critical to determining next steps in care, especially when such data originate outside the clinical organization actively treating a patient.
 - As noted previously, USCDI and ARCH should also address additional FHIR resources that are significant for clinical decision support and electronic clinical quality measurement and reporting as experienced by the Da Vinci work, connectathons and others. These items are also included in the QI-Core implementation guide of FHIR; it, in turn, references US Core to the extent possible.

H – Electronic Prescribing

Allows a Prescriber to Request a Patient’s Medication History from a State Prescription Drug Monitoring Program (PDMP): <https://www.healthit.gov/isa/allows-a-prescriber-request-a-patients-medication-history-a-state-prescription-drug-monitoring>

HL7 Comments:

- Regarding the listed Emerging Implementation Specification [CDS Hooks Services](#), the CDS Hooks Services specification is a published Standard for Trial Use (STU), so HL7 believes this should be a Standard and not an Emerging Implementation Specification.
- Update the CDS Hooks Services link by changing it to <http://cds-hooks.hl7.org>
- Regarding the Implementation Maturity on CDS Hooks Services, production implementations exist.
- HL7 suggests low-medium Adoption (two stars) of CDS Hooks Services.

P – Patient Preference/Consent

Recording Patient Preferences for Electronic Consent to Access and/or Share their Health Information with Other Care Providers: <https://www.healthit.gov/isa/recording-patient-preferences-electronic-consent-access-and-or-share-their-health-information-other>

HL7 Comments:

- HL7 notes this link is broken in the ISA document.
- Remove 1st word in title "Emerging Implementation Specification" for [HL7 Implementation Guide for CDA®, Release 2: Consent Directives, Release 1](#)
- HL7 notes Carequality is working to develop a technical method for distributing and identifying consent forms to be used as part of their [Patient Consent Framework Web Site Disclaimers](#).

Q – Public Health Reporting

Case Reporting to Public Health Agencies

<https://www.healthit.gov/isa/case-reporting-public-health-agencies>

HL7 Comments:

- A different standard is being proposed for each public health reporting interoperability need. ONC should work with public health agencies to reduce the number of different standards for reporting to public

health agencies. When the CDA-based quality reporting standards were being developed, public health stakeholders insisted that that standards be broadened to encompass the needs of public health reporting. The public health requirements were incorporated into the quality standards; however, overall public health agencies did not choose to use these broadly adopted standards. Public health stakeholders are now calling for HL7 FHIR-based reporting standards under development by quality and payer reporting groups to be expanded to encompass public health reporting needs. The goal in all these efforts is for public health agencies to truly use common reporting standards developed with their comprehensive and specific needs in mind.

Reporting Antimicrobial Use and Resistance Information to Public Health Agencies:

<https://www.healthit.gov/isa/reporting-antimicrobial-use-and-resistance-information-public-health-agencies>

HL7 Comments:

- Regarding [HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm.](#), HL7 asks if this Reporting Antimicrobial Use and Resistance Information use case is the right version that should be cited. ONC may want to check and verify with the CDC program that is responsible. HL7 notes there are more current versions of this standard available.

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

HL7 Comments:

- HL7 suggests that ONC consistently either cites the base standard [HL7 Clinical Document Architecture \(CDA®\), Release 2.0, Final Edition](#) or not.

R – Research

Data Collection for Submission to Registries and Reporting Authorities: <https://www.healthit.gov/isa/data-collection-submission-registries-and-reporting-authorities>

HL7 Comments:

- HL7 asks is it intentional that sometimes there is a base standard [HL7 Clinical Document Architecture \(CDA®\), Release 2.0, Final Edition](#) cited in this section? We recommend citing a specific CDA Implementation Guide.

Submission of Clinical Research Data Contained in EHRs and Other Health IT Systems for General Purpose or Preserving Specific FDA Requirement:

<https://www.healthit.gov/isa/submission-clinical-research-data-contained-ehrs-and-other-health-it-systemsgeneral-purpose-or>

HL7 Comments:

- HL7 asks is it intentional that sometimes there is a base standard [HL7 Clinical Document Architecture \(CDA®\), Release 2.0, Final Edition](#) cited in this section? We recommend citing a specific CDA Implementation Guide.

S – Segmentation of Sensitive Information

Data Segmentation of Sensitive Information: <https://www.healthit.gov/isa/data-segmentation-sensitive-information>

HL7 Comments:

- HL7 asks is it intentional that sometimes there is a base standard [HL7 Clinical Document Architecture \(CDA®\), Release 2.0, Final Edition](#) cited in this section? We recommend citing a specific CDA Implementation Guide.

T – Summary of Care Record

Support a Transition of Care or Referral to Another Health Care Provider: <https://www.healthit.gov/isa/support-a-transition-care-or-referral-another-health-care-provider>

HL7 Comments:

- Regarding the Implementation Specification [HL7 Consolidated CDA® Release 1.1 \(HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 - US Realm\)](#), HL7 recommends this standard should be sunsetted. HL7 does not recommend using this old standard but instead, these references should be used: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=492.
- Regarding [HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes \(US Realm\), Draft Standard for Trial Use, Release 2.1](#), HL7 notes the "Emerging" reference as this specification should be removed as it is in wide spread adoption/production in the US.
- Regarding the statement in the Limitations, Dependencies and Preconditions for Consideration section "Implementers should explore use of emerging [CDA on FHIR](#) and C-CDA on FHIR to support this interoperability need", HL7 recommends that the "CDA on FHIR" reference be removed and only "C-CDA on FHIR" be referenced, as later defines the specific implementable constraints.

Section III

Standards and Implementation Specifications for Services

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:

- HL7 recommends adding entries for STUs 3 and 4 in the section regarding the Standard, [HL7 Cross-Paradigm Specification: Clinical Quality Language, Release 1, STU 2](#).
- Regarding the listed Emerging Implementation Specification, the [CDS Hooks Services](#) specification is a published Standard for Trial Use (STU) so HL7 believes this should be a Standard and not an Emerging Implementation Specification.
- Update CDS Hooks Services link by changing it to <http://cds-hooks.hl7.org>
- Regarding the Implementation Maturity on CDS Hooks Services, production implementations exist.
- HL7 suggests low-medium Adoption (two stars) of CDS Hooks Services.

Section IV

Administrative Standards and Implementation Specifications

E – Health Care Attachments to Support Claims, Referrals and Authorizations: <https://www.healthit.gov/isa/health-care-attachments-support-claims-referrals-and-authorizations>

HL7 Comments:

- Regarding [HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes \(US Realm\) Draft Standard for Trial Use Release 2.1](#), the Standards Process Maturity should indicate Production and not Pilot.

Final ISA Section

Propose a New Interoperability Need

<https://www.healthit.gov/isa/suggest-isa-standards?tour=1>

HL7 Comments:

Project Implementation Guides - HL7 recommends that implementation guides developed by its accelerator projects be included in the ISA. Information about HL7 accelerator projects is available at:

<http://www.hl7.org/about/fhir-accelerator/>. Some examples of these implementation guides that should be included are:

- Relevant Da Vinci Public Implementation Guides
<https://confluence.hl7.org/display/DVP/Da+Vinci+Public+Implementation+Guides>
- HL7 FHIR US Core Implementation Guide CI Build (FHIR R4, STU3)
<https://build.fhir.org/ig/HL7/US-Core-R4/#introduction>
- CARIN Blue Button 2.0 Draft Implementation Guide
<https://build.fhir.org/ig/HL7/carin-bb/toc.html>

HL7 also recommends that the HL7 implementation guide for the Electronic Long-Term Services & Supports (eLTSS) Dataset for the collection, exchange and sharing of Home and Community Based Services (HCBS) data, clinical data and provider service plans be included in the ISA. Guidance includes eLTSS Dataset FHIR mappings for service plan information, non-clinical and clinical data. The IG can be found at: <http://hl7.org/fhir/us/eltss/>.

HL7 stands ready and willing to engage with ONC to assist in its use of these guides.