



October 5, 2023

Micky Tripathi, PhD, MPP
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
Department of Health and Human Services
Hubert Humphrey Building, Suite 729
200 Independence Avenue SW Washington, DC 20201

Submitted electronically to: <https://www.healthit.gov/isa/>

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

Dear Dr. Tripathi:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on ONC's Interoperability Standards Advisory (ISA) as ONC prepares to update the ISA for the 2024 "Reference Edition". HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena.

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. In addition to our leadership and Policy Advisory Committee, HL7 Work Groups contributing to these comments include: Orders and Observations and Payer/Provider Information Exchange.

As ONC prepares to finalize the ISA for the 2024 "Reference Edition", we offer both general considerations and detailed suggestions regarding interoperability needs. We encourage ONC additionally to:

- Leverage existing HL7 educational and other resources;
- Ensure ISA compatibility with other frameworks that may reference it, such as TEFCA and USCDI; 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,

A handwritten signature in black ink that reads "Charles Jaffe" with a stylized flourish at the end.

Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International

A handwritten signature in black ink that reads "Andrew Truscott" with a stylized flourish at the end.

Andrew Truscott
Board of Directors, Chair
Health Level Seven International

HL7 Recommendations

HL7's specific comments on ONC's ISA Annual Update are below.

Comments: HL7 Da Vinci CDex Implementation Guide

HL7 recommends that the [HL7 Da Vinci Clinical Data Exchange \(CDex\) Implementation Guide](#) (CDex IG) be added into appropriate sections of the ISA. ONC, the Centers for Medicare and Medicaid Services (CMS) and others have recognized the growing intersection of clinical and administrative data, which have been historically separated. The CDex IG demonstrates use of HL7 FHIR and interoperability, in general, to support this intersection. As such, CDex should be added to the ISA and can be considered for one or multiple ISA sections outlined below.

Given CDex's potential use in claims attachments and other administrative transactions, it could be included in:

- Section IV: [Administrative: Administrative Transactions to Support Clinical Care]

Given CDex's overall clinical capability, it could be included in:

- Section II: [Content/Structure (For example: Care Coordination, Summary Care Record)]

Given CDex is a modern, restful FHIR-based guide, it could be included in:

- Section III: [Service/Exchange: "Push" Exchange and Query]

Comments: ISA Section I: Vocabulary/Code Set/Terminology Laboratory: Representing Laboratory Test Ordered

Presently, the ONC ISA represents Current Procedural Terminology-Proprietary Laboratory Analyses (CPT-PLA) as an available vocabulary for laboratory orders in the [Representing Laboratory Test Ordered | Interoperability Standards Advisory \(ISA\) \(healthit.gov\)](#) section in [Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications | Interoperability Standards Advisory \(ISA\) \(healthit.gov\)](#). This placement is raising concerns. It could be interpreted as appropriate for use when ordering a lab test, yet the consensus of the HL7 Orders and Observations (OO) Work Group is that CPT-PLA is not intended for actual ordering of lab tests. Rather it is focused on reporting lab tests ordered for reimbursement purposes in certain situations. See <https://www.ama-assn.org/about/cpt-editorial-panel/help-create-cpt-proprietary-laboratory-analyses-codes> for further context.

When mapping a laboratory test order, the preferred encoding is a Logical Identifiers Names and Observations [LOINC(R)] code. The current language in the ISA is not making this distinction, and thus could lead the reader to believe that CPT-PLA is an appropriate alternative to LOINC codes for placing orders for lab tests. HL7 suggests that either:

Option #1

The existing [Representing Laboratory Test Ordered](#) is updated as follows:

- Update the Limitations, Dependencies, and Preconditions for Consideration to replace the current language with:
 1. LOINC codes are used to provide the clinical concept that the test ordered represents enabling consistent interpretation across systems and organizations regardless of an internal code specific to a laboratory that is typically used to actually order a test. The LOINC code used as part of the order may not be the same LOINC code as the one for the performed test when the performed test code is more specific in one of the LOINC parts (e.g., method or system) or when the order combines multiple tests into a panel.

2. CPT-PLA classifies/encodes lab tests ordered for the relevant internal and reimbursement processes that require conveyance of the clinical information contained in the CPT-PLA code. CPT-PLA codes identify the specifics of the procedure used to perform the test as developed by a particular laboratory or in vitro diagnostics (IVD) vendor.

Option #2

Alternatively, some would suggest ONC consider adding a new page instead, preferably under the ISA *Procedures Section* to be named *Representing Laboratory Test Procedures* page where the existing *Representing Laboratory Test Ordered* page only includes references to LOINC with the limitation suggested per (1) above, while the new *Representing Laboratory Test Procedures* pages would focus on the CPT-PLA encoding using the suggested limitation text per (2) above.

Lastly, given ISA comments that there is confusion over referencing Order Control Reason Code (ORC-16), HL7 recommends that ONC add a statement relating to referencing ORC-16 that states:

- References in the comments on the use of ORC-16 do not accurately reflect the use of that field. We refer the reader to [the HL7 implementation guides for laboratory orders](#) clarifying that ORC-16 represents the reason for the order, not a code such as LOINC, Systemized Nomenclature of Medicine-Clinical Terms of (SNOMED-CT), or CPT-PLA. Further guidance on how and when to communicate LOINC and/or CPT-PLA codes would be identified in that guide as well.

While HL7 could submit a comment reflecting this, we believe that having this clarification made by ONC would provide more clarity. If ONC believes that HL7 should make that comment instead of or in addition to ONC's statement directly on this page, please let us know.