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Submitted electronically to:  
<https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#draft-uscdi-v5>

Re: Draft United States Core Data for Interoperability Version 5 (Draft USCDI v5)

Dear Dr. Tripathi:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on ONC's Draft United States Core Data for Interoperability Version 5 (Draft USCDI v5). HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena.

We appreciate ONC's on-going effort to drive innovation through USCDI. HL7 applauds the continued expansion of data classes and fields made available through USCDI new versions. Additional fields in USCDI widen the scope of data available and open up more potential utility in health-related apps, such as those for patients.

HL7's specific feedback regarding the Draft USCDI v5, related new data classes and elements and USCDI more generally is detailed below. In addition to our leadership and Policy Advisory Committee, HL7 Work Groups and Accelerators contributing to these comments include Clinical Quality Information, Orders and Observations, Patient Administration, Patient Empowerment, Payer/Provider Information and Exchange and the Gravity Project. We also note and highlight comments submitted by our HL7 Fast Healthcare Interoperability Resources (FHIR) Accelerator CodeX, which will be posted at: <https://www.hl7.org/codex/>. 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](mailto: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, appearing to read "Charles Jaffe", with a small circular mark to the right.

Charles Jaffe, MD, PhD  
Chief Executive Officer  
HL7 International

A handwritten signature in black ink, appearing to read "Julia Skapik", written in a cursive style.

Julia Skapik, MD, MPH  
Board of Directors, Chair  
HL7 International

## HL7 USCDI Responses [Including Draft USCDI v5 New Data Classes and Elements]

### Care Team Member: Identity

<https://www.healthit.gov/isa/taxonomy/term/1291/draft-uscdi-v5>

HL7 notes that California and Colorado law require caregivers to record their identity in a public facing provider directory, which is an important consideration. More information specific to California can be accessed at:

[https://leginfo.legislature.ca.gov/faces/billCompareClient.xhtml?bill\\_id=202120220SB923&showamends=false](https://leginfo.legislature.ca.gov/faces/billCompareClient.xhtml?bill_id=202120220SB923&showamends=false)

### Clinical Notes: Emergency Department Note [New Data Element]

<https://www.healthit.gov/isa/taxonomy/term/7786/draft-uscdi-v5>

HL7 observes that adding more Clinical Notes data elements could open the door to many additional, new Notes Document Types. This could create disparate documents and should be carefully considered.

### Health Status Assessments: Mental/Cognitive Status

<https://www.healthit.gov/isa/taxonomy/term/1616/draft-uscdi-v5>

HL7 recommends that Depression Assessment listed under Health Status Assessment as an example screening of interest, recognizing that not all health information technology (HIT) may need to support that when being certified. Depressive disorders are common mental disorders that occur in people of all ages. Major depressive disorder (MDD) is the second leading cause of disability worldwide, affecting an estimated 120 million people. Depression has a large effect on health care costs and on productivity. Adolescents with depression have higher medical expenditures, including those related to general and mental health care, than adolescents without depression. For working-adults, one study showed a relationship between the severity of depression symptoms and work function and found that for every 1-point increase in a Patient Health Questionnaire 9 (PHQ-9) score (a measure of depression severity); patients experienced an additional mean productivity loss of 1.65%. Even minor levels of depression symptoms were associated with decreases in work function. The U.S. Preventive Services Task Force (USPSTF) recommends screening for depression among adolescents 12-18 years and the general adult population, including pregnant and postpartum women.

### Health Status Assessments: Smoking Status

<https://www.healthit.gov/isa/taxonomy/term/811/draft-uscdi-v5>

HL7 recommends changing the name of Smoking Status to Tobacco Assessment and Use. Not all tobacco products are combustible like cigarettes. This category should include the noncombustible products as well, such as e-cigarettes. Both the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) refer to the broader category of Tobacco Use. Please see:

<https://www.cdc.gov/chronicdisease/resources/publications/factsheets/tobacco.htm>

<https://www.fda.gov/consumers/minority-health-and-health-equity-resources/tobacco-use>

In addition, HL7 recommends duration (number of years of use) and quit date included in the list of example data elements. The duration is used to calculate the number of pack years, which is important for quality measurement and understanding risk. In addition, knowledge about when someone quit smoking helps to understand risk for other diseases.

### **Health Status Assessments: Social Determinants of Health (SDOH) Assessment**

<https://www.healthit.gov/isa/taxonomy/term/1801/draft-uscdi-v5>

HL7 applauds the inclusion of SDOH elements in USCDI. HL7 supports moving SDOH to its own data class with SDOH Problems/Health Concerns and SDOH Interventions as data elements. The American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP) and the American Dental Association (ADA) all recommend surveillance of risk factors associated with SDOH. HL7 also urges appropriate ONC recognition -- within the USCDI framework -- that SDOH is a cross-cutting data class and relies on existing elements across data classes such as: demographics, health status, social needs, social history and diagnoses. We observe that a new USCDI SDOH data class could act as metadata that aids in filtering across data classes.

Designating a distinct SDOH category emphasizes its critical importance. HL7 provides in the SDOH Clinical Care Implementation Guide a number of assessment and screening tools that should be considered by implementers of USCDI where they are relevant to their user community. More information can be found at: <https://build.fhir.org/ig/HL7/fhir-sdoh-clinicalcare/>.

### **Laboratory: Specimen Condition Acceptability**

<https://www.healthit.gov/isa/taxonomy/term/7691/draft-uscdi-v5>

HL7 notes that with the introduction of Specimen Condition Acceptability in USCDI v4 there has been confusion about what exactly is intended to be included: either the condition of the specimen as-is, or the reason why a test was not performed given the acceptability of the specimen, also known as [Criteria for CLIA Specimen Acceptability and Rejection](#). HL7 notes that various conditions of a specimen (e.g. lipemia) may not prevent a test from being performed, while other conditions make the specimen unacceptable for any test (e.g., compromised/broken tube). HL7 recommends that ONC update the name of Specimen Condition Acceptability to Specimen Condition and update the definition to reflect the focus on the actual specimen condition. This would align with the actual implementation of this concept in both HL7 FHIR US Core 7.0.0, HL7 Clinical Document Architecture (CDA) and HL7 Consolidated Clinical Document Architecture (C-CDA). We also ask that ONC applies this to USCDI v4 as an errata, clarifying intent, to ensure that those reviewing and interpreting USCDI v4 without reviewing the supporting FHIR US Core and implementation guides for CDA and C-CDA do not yield different expectations, than those implementing the FHIR US Core and implementation guides for CDA and C-CDA.

### **Laboratory: Tests [General]**

<https://www.healthit.gov/isa/taxonomy/term/676/draft-uscdi-v5>

HL7 notes that the name does not differentiate between the test that was ordered versus the test that was performed and this should be changed to avoid confusion. HL7 recommends updating the name to "Laboratory Performed Test Code" and clarifying the binding to be to "LOINC: Lab class (Obs only or Both)."

### **Laboratory: Tests [Panel Code]**

<https://www.healthit.gov/isa/taxonomy/term/676/draft-uscdi-v5>

HL7 recommends that that Laboratory Test/Panel Code in Level 2 could be elevated to USCDI v5, but only if the name and definition are updated as listed below. Update the name to "Ordered Laboratory Test / Panel Code"

- Update the definition to "A code that identifies the test or group of tests (panel or profile), including reflexive tests being ordered for the analysis on a specimen derived from humans, which provide information for the diagnosis, prevention, treatment of disease, or assessment of health."

This will correspond to the coded version of the CLIA element in §493.1291(c)(4).

This change will also provide better clarity since the current name is misleading and given there are no results for any orders such as a panel. The change also provides improved distinction with the element "Tests" when that is updated as proposed in our Tests comments.

### **Laboratory: Test Kit Unique Device Identifier (UDI) [New Data Element]**

<https://www.healthit.gov/isa/taxonomy/term/3731/draft-uscdi-v5>

HL7 notes that the definition is referencing UDI and the name includes "unique". Relevant standards and guidance such as HL7 Version 2 (HL7 v2), Integrating the Healthcare Enterprise Laboratory Analytical Workflow (IHE LAW), HL7 FHIR US Core, HL7 Clinical Document Architecture (CDA) and HL7 Consolidated Clinical Document Architecture (C-CDA) can use the full UDI as defined by the FDA for certain, limited use cases. However, the necessary guidance to support it -- from the source instrument all the way to systems such as electronic health records (EHRs) and those in public health -- are not yet attainable in practice. The full UDI of the test kit or the instrument (where applicable) is not a reality. The following are challenges that must be addressed:

- The laboratory may have some of the UDI components on paper but not necessarily all, and typically not electronically within their laboratory information systems (LIS).
- The relevant HL7 v2 standards and IHE LAW profiles support some but not all requirements to fully enable instruments and LIS to communicate the necessary UDI components. Even just the

name and model of the instrument with a manufacturer name and/or the name of the test kit/reagent and manufacturer is a challenge. Specifically:

- IHE Law profiles are not widely adopted by instrument manufacturers and LIS vendors.
- While those using IHE LAW include an instrument name and/or model, the formal Device Identifier is typically not included.
- Guidance on correctly including UDI components into the appropriate IHE LAW profile fields is insufficient.
- Guidance on correctly including multiple UDIs (instrument plus test kit/reagents) for an individual test is insufficient within standards frameworks such as HL7 v2, IHE LAW, and profiles and Implementation Guides relating to Laboratory Results Information (LRI) and Electronic Lab Reporting (ELR). If only one can be communicated, which one should be included?
- It is unclear how the test kit / reagent UDI components can be electronically obtained in the LIS for a specific test, as an instrument can use different test kits/reagents from different manufacturers. Inherent challenges are: either the instrument cannot communicate which test kit/reagent is in use for a given test, and/or the LIS cannot assert which combination is being used for the test result received.
- Even if current standards are adopted for new instruments, older instruments would not support them.
- LIS does not typically store these elements nor make it available and usable for further reporting, thus it would not be possible to include these on the results report to the EHR or in Public Health.

Until the UDI components can be consistently populated in the LIS with the results and communicated to the ordering provider, public health, and/or other recipients, inclusion of the UDI or related components is premature.

However, recognizing the timeline by which USCDI v5 would start to be implemented, it is appropriate to consider inclusion of a minimum set of UDI components, followed by additional components in subsequent USCDI versions. ONC should also consider using USCDI+ Public Health (PH) Laboratory Reporting to include additional components as this would facilitate a more focused audience and could be used to incent laboratories and LIS in particular to support the necessary documentation and communication of the full UDI for test kit and instrument used.

Short term, HL7 therefore suggests that a focus on the name and model of the main instrument and its manufacturer (when an instrument is used) is applied. This can be followed over time with the name of the test kit/reagent and its manufacturer and progress towards the full UDI for both the test kit/reagent(s) and instrument used. Furthermore, HL7 suggests that ONC work with FDA, the Centers for Medicare and Medicaid Services staff responsible for implementing the Clinical Laboratory Improvement Amendments (CLIA), public health agencies, laboratories, and instrument manufacturers to establish a practical roadmap for adoption and the necessary incentives to achieve that. Having the source systems, e.g., instrument, test kit, and LIS, be able to share this information will enable receiving HIT (e.g., EHRs, Public Health) to provide support where needed. Additionally, an approach should be established for tests where UDI are not present, to understand what was used to perform the test.

Lastly, HL7 observes this related gathering UDI on test kits, whether the exchange would be captured across all healthcare entities (i.e., electronic medical records, Payer's State or Federal Agencies) should be examined. Ensuring this cohesion is critical. Entities responsible for tracking and reporting this data should also be considered.

### **Laboratory: Values/Results [General]**

HL7 notes that the definition and vocabulary of Values/Results focuses on qualitative values and results. The variances in vocabulary are notable particularly given the nominal scale uses SNOMED CT in organism hierarchy with example value set:

<https://phinvads.cdc.gov/vads/ViewValueSet.action?id=64089FFA-B015-4DC7-B470-F20DF5B13BFA>, while the ordinal scale uses SNOMED CT from a qualifier hierarchy:

<https://phinvads.cdc.gov/vads/ViewValueSet.action?id=815C6DD4-C5A6-DF11-9BDD-0015173D1785>). Additionally, the structure of quantitative results (e.g., relationship with the Result

Unit of Measure) of interest should be further clarified.

### **Laboratory: Values/Results [Date and Timestamps]**

<https://www.healthit.gov/isa/taxonomy/term/681/draft-uscdi-v5>

HL7 recommends that rather than listing a general date and timestamps, that the specific dates and timestamps of interest should be enumerated. HL7 specifically suggests elevating the following Level 2 data elements into USCDI v5:

- **Specimen Collection Date/Time:** The clinically relevant time - provides clinical temporal context about the state of the patient as it relates to the performed lab test. In the case of observations taken directly from a subject, it is the actual date and time the observation was obtained. In the case of specimens obtained from the patient, it is the date and time, the specimen was collected in accord with [CLIA](#).
- **Laboratory Test Performed Date:** The clinically relevant date/time of the observation. In the case of observations taken directly from a subject, it is the actual date and time the observation was obtained. In the case of a specimen-associated study, this field should represent the date and time the specimen was analyzed and results obtained. This is often the LIS verification date/time, whether by an automated process or via a human.
  - HL7 recommends adjust the definition to state: "Date (and optionally time) when testing was conducted by the laboratory performing the testing". This date is not necessarily the clinically relevant data/time as that would be the specimen collection date/time for lab tests. This date may be important when multiple tests are part of a report and is also helpful in identifying updated results, when only some results are updated in a report.

HL7 notes these dates are widely supported and available. We therefore support inclusion in USCDI v5. Additionally, HL7 recommends that Report Date/Time (similar to Date of Report in Case Reporting in USCDI+) is defined as "The date and time at which the LIS system releases the results to the provider

and other recipients” which meets [CLIA test report date](#) as well, as a critical date and timestamp. This applies to any report, whether preliminary, final or corrected and is widely communicated already.

### **Observations (General) - [New Data Class]**

<https://www.healthit.gov/isa/uscdi-data-class/observations#draft-uscdi-v5>

HL7 notes that the distinction between the new Observations data class and other data classes such as Laboratory and Vital Signs, is unclear considering Laboratory Test Results are categorized as Observations, as are Vital Signs. HL7 suggests that Vital Signs and Laboratory Test Results are included under Observations as references and also as specific data elements that are listed under Observations. This approach would provide greater clarity regarding to which other data classes they would apply.

### **Observations: Advanced Directive Observation [New Data Element]**

<https://www.healthit.gov/isa/uscdi-data-class/observations#draft-uscdi-v5>

HL7 applauds the inclusion of an Advanced Directive Observation. We also encourage ONC to advance the Level 1 and Level 2 Advance Directive class, so as to more fully support the Advance Directive concept.

### **Observations: Sex Parameter for Clinical Use [New Data Element]**

<https://www.healthit.gov/isa/taxonomy/term/4611/draft-uscdi-v5>

Overall, HL7 encourages ONC to align Sex Parameter for Clinical Use with the current HL7 Gender Harmony recommendations. Background information can be found at:

<https://hl7.org/xprod/ig/uv/gender-harmony/background.html>

[http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=564](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=564)

HL7 highlights that the Sex Parameter for Clinical Use definition is ambiguous. HL7 recommends the Sex Parameter for Clinical Use definition be changed to reflect that this Observation provides guidance on how a recipient should apply settings or reference ranges and provide context for further interpretation of diagnostic tests. Also to be noted is that where relevant, the Sex Parameter for Clinical Use for a particular diagnostic test is derived from observable information such as an organ inventory, recent hormone lab tests, genetic testing, menstrual status, obstetric history, etc.

### **Orders (General) - [New Data Class]**

<https://www.healthit.gov/isa/uscdi-data-class/orders#draft-uscdi-v5>

HL7 notes that the distinction between the new Orders data class and other data classes such as Laboratory, Procedures, and Medication is unclear considering lab tests, procedures, and medications can all be ordered and a variety of the already defined data elements are relevant when ordered. HL7 recommends that the general Orders data class include data elements relevant across all order types. Individual data classes should reference these general data elements and their respective standards while adding data elements specific to that data class when being ordered.

HL7 highlights that the addition of orders in Draft USCDI v5 improves transition of care so that the receiving provider is aware of orders put in by the sending provider. HL7 observes one important scenario to recognize and accommodate, is to ensure that orders for a patient going to a skilled nursing facility (SNF) are received in a timely manner and not lost. This is linked to critical implements and accommodations a patient could need on arrival at an SNF including medications, special diets, special bed, etc. This could also provide avenues for a patient or caregiver to trace back to what was ordered and compare to what was delivered, as well as a way a patient can show another organization what was ordered in case during the transition of care, the order was lost (for example, an order for pain medication for a cancer patient when transitioning from acute care to post-acute care).

### **Patient Demographics/Information: Interpreter Needed [New Data Element]**

<https://www.healthit.gov/isa/taxonomy/term/7903/draft-uscdi-v5>

HL7 agrees that interpreters are needed and should be captured in provider electronic systems (i.e. EMR). Interpreters can assist providers with non-English-speaking patients in reviewing charts, scheduling appointments and care management.

HL7 observes that whether a patient needs an interpreter can also vary based on circumstance. For example, a Spanish-speaking patient that has an appointment with a specialist that only speaks English may need an interpreter. However, if that same patient has an appointment with their primary care physician who speaks Spanish, no interpreter would be necessary. Exchanging the patient's spoken language proficiency allows systems to determine whether a patient needs an interpreter for specific appointments or encounters based on the language proficiency of the other participants. The spoken language proficiency is the proposed alternative, rather than written language proficiency, as the existing "Preferred Language" data element enables systems to determine what language is preferred for written materials.

HL7 recommends that ONC:

- adopt "Spoken Language Proficiency" as a patient demographic.
- consider/clarify how "Interpreter Needed" should be used in cases where providers may offer different languages.
- clarify how "Interpreter Needed" relates to the existing "Preferred Language" data element.

### **Patient Demographics/Information: Name to Use [New Data Element]**

<https://www.healthit.gov/isa/taxonomy/term/4586/draft-uscdi-v5>

HL7 supports the inclusion of Name to Use in USCDI. We note that existing HL7 standards already support the exchange of this information.

Additionally, HL7 highlights that payer and provider specific systems may or may not have these Name to Use data elements captured currently. There is notable variance.

### **Patient Demographics /Information: Pronoun [New Data Element]**

<https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#draft-uscdi-v5>

HL7 supports the inclusion of Pronouns in USCDI. Our additional recommendations on this issue include recommending ONC:

- adopt patient pronouns in USCDI as proposed.
- delegate the work of identifying and defining vocabulary standards to consensus-based groups, such as US Core, as the vocabulary standards for this element are relatively new.

Lastly, HL7 observes shared data should not replace a person's name, but may offer a supplement. Both names and pronoun are not widely used nor included within systems. HL7 recommends that Caregiver(s) should also be included as a source of pronoun information.

### **Provenance: Author and Author Role [New Data Elements]**

<https://www.healthit.gov/isa/taxonomy/term/1171/draft-uscdi-v5>

<https://www.healthit.gov/isa/taxonomy/term/2201/draft-uscdi-v5>

HL7 applauds the addition of Author and Author Role so that now individual clinicians can be identified, as well as patients and their caregivers. The ability to recognize patients and caregivers as authors paves the way to including more patient contributed health data in a medical record. The ability to individually identify a data author provides richer information to patients. HL7 highlights one nuance to consider: if an author is external to an organization or leaves an organization, they might not have an organizational ID or system ID. Patients and caregivers would most likely also not have identifiers while clinicians may have an NPI/license number/certificate number. An author could potentially be a device as well, such as a patient's Fitbit. HL7 recommends that it be made more explicit in USCDI v5 that a device could author data.

In addition, the inclusion of new fields in the Provenance class can better enable communication of patient generated health data. However, in USCDI v5 as in v4, several of the new fields represent data types that might be especially sensitive to the patient. Some examples in V5 include Pronoun, Name to Use, and Sex for Clinical Use. ONC should consider appropriate protection of these specific data items, while balancing all healthcare stakeholder interests.

