HL7 International

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Acting National Coordinator for Health Information Technology
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Submitted electronically to:
https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi#draft-uscdi-v6

Re: Draft United States Core Data for Interoperability Version 6 (Draft USCDI v6)

Dear Acting Assistant Secretary Posnack:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on ASTP/ONC's Draft United States Core Data for Interoperability Version 6 (Draft USCDI v6). HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena.

We appreciate ASTP/ONC's historic and on-going effort to drive innovation through USCDI and in particular, the stated effort with Draft USCDI v6 to decrease implementation burden for standards development organizations and other critical healthcare stakeholders. HL7 applauds the continued expansion of data classes and fields made available through USCDI new versions.

HL7's specific feedback regarding the Draft USCDI v6, 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 Empowerment and the Post Acute Care Interoperability (PACIO) Project. 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 ASTP/ONC.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
HL7 International

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

HL7 USCDI Responses [Including Draft USCDI v6 Overarching Comments, New Data Classes and Elements]

Overarching Comments

https://www.healthit.gov/isp/sites/isp/files/2025-01/Draft-USCDI-Version-6-January-2025-Final.pdf

HL7 appreciates the contribution USCDI makes in ensuring standardized vocabularies are used with the transmission of health-related data. However, HL7 highlights there are many implementation challenges related to guaranteeing the appropriate context of these data are available to allow for validation of health data, particularly in supporting patient care and secondary use cases. The current Draft USCDI v6 continues an emphasis on terminology bindings and this alone does not support interoperability effectively. HL7 encourages ASTP/ONC to go beyond the use of terminology bindings in future USCDI versions, towards formal standards that reference structured metadata. This will provide the context and structure that informs more successful exchange.

Medical Devices: Unique Device Identifier (UDI) [Existing Data Element]

https://www.healthit.gov/isp/taxonomy/term/7917/draft-uscdi-v6

HL7 is supportive of expanding use of UDI as it relates to health data and USCDI v6, and particularly in ASTP/ONC's interest in expanding the use of UDI beyond implantable devices in USCDI v6. However, our organization is concerned with readiness for such a broad expansion, particularly from a standards perspective. HL7 importantly notes that even a narrower extension of UDI beyond implantable devices in USCDI v6 would be problematic. Relevant core standards have the ability to support communication the UDI for a device --HL7 Version 2 (v2), HL7 Clinical Document Architecture (CDA) and HL7 FHIR in particular-- and the USCDI approach used for implantable devices is expandable to other use cases. The UDI is in, e.g., FHIR, part of the device resource definition. Thus, if a device is documented as part of a lab result, procedure, therapy, or otherwise, then that result, procedure, or therapy can reference a device, using the same device resource as is used for implantable devices. Therefore, if the UDI is available, it can be communicated in a well-defined manner. However, a major roadblock still remains. Electronic health records (EHRs) --still the most common health information technology (HIT) subject to certification --are typically not the primary system in which such data would be captured, particularly for high-interest device use such as test kits/reagents, instruments, robotics, imaging devices, and many point of care devices.

HL7 emphasizes that initial capture of the relevant devices used and their UDI should be at the source of the documentation, not further downstream when it is harder or impossible to know the device used. As it cannot be assumed that today the source device is capable of including its UDI (many older devices will not be upgraded/replaced for many years to come), an intermediate HIT, like a laboratory information systems (LIS), that directly communicates with the source could be configured to include the UDI but moving any further downstream, the user or system would have no understanding of the UDI used, short of manual entry with UDI communicated to the user in some other fashion. Therefore the focus should first be on source systems and near-source intermediaries such as instruments, LIS, radiology information systems (RIS) and/or Point-of-Care (PoCs) systems to capture UDI automatically and be able to include them into downstream communications. Then it can be

reasonable for EHRs to capture and maintain such data, and be able to forward it to other systems for secondary data use such as public health and research.

HL7 notes that for most EHR users, UDI is not relevant for immediate care delivery and coordination, although clearly in select settings and context it would be helpful. The larger benefit is in secondary use such as recalls and comparative research analysis. For point-of-care devices, one may consider that such data may be directly enterable into the EHR. It is, but absent the PoC device electronically communicating that data directly to the EHR as part of the result(s), it would add substantial effort and time to a clinician in transcribing a meaningful UDI correctly into the record.

HL7 also recommends that the journey to a full UDI being captured and communicated in USCDI should begin with a focus on device model, not the full UDI. For many purposes the device model may be sufficient and easier to ingest into the documentation flow as a starting point. Lastly, HL7 emphasizes the important recognition that current UDIs typically reflect a logistics point of view --not a clinical/operational point of view--which would lead to capture and communication of a less or non-relevant UDI. For example, the UDI of a Reagent might change because of:
language of the included Documentation (i.e. Package Insert)
- package size (the same reagent is filled in different package sizes)
- orderable "boxes" containing the Reagent Packs

Yet clinically/operationally it is still the same device, so the UDI of the device should be communicated, not the package it comes in. Unfortunately, the UDI and Global Trade Item Number (GTIN) of a medical device might be related to the ordering and the logistics behind it and inadvertently be used. Logistics focused UDI remains relevant for certain use cases, but would not necessarily be the one relevant to the main use cases to track UDIs with the clinical documentation on a patient. HL7 therefore strongly urges ASTP/ONC to not include the UDI expansion into USCDI v6. Rather, HL7 recommends ASTP/ONC should work with the appropriate regulatory and certification entities governing the source systems to enable those to capture and communicate this data. Once this has sufficient traction, then the ability of other HIT to receive and share that data can be advanced. HL7 notes that inclusion of UDI expansion into USCDI v6 now would also risk a reduction of the HIT entities that would have an interest in certification, as inclusion in USCDI would reduce the HIT that could fully support all, e.g., (g)(10) APIs as they have no ability to certify to what they actually manage. HL7 continues to urge ASTP/ONC to take a more modular approach so that USCDI can continue to grow, but certification can focus on what specific HIT actually manages.

Medications: Route of Administration [Existing Data Element]

https://www.healthit.gov/isp/taxonomy/term/7846/draft-uscdi-v6

HL7 recommends that ASTP/ONC consider adding more aspects of Medication Administration -- beyond the current Route of Administration data element-- in USCDI v6. Medication Administration is key in healthcare quality measurement and clinical decision support. More robust information would be optimal.

Orders: Portable Medical Orders [New Data Element]

https://www.healthit.gov/isp/taxonomy/term/3626/draft-uscdi-v6

HL7 supports the inclusion of the Portable Medical Order data element in the Order data class of USCDI v6. HL7 recommends that the description of what this data element represents be modified. Justification and background on that change is provided below.

HL7's suggested changes include:

Portable Medical Order Definition

- Current Description: Provider-authored request for end-of-life or life-sustaining care for a person who has a serious life-limiting medical condition.
- Proposed New Description: Information about a provider-authored portable medical order document indicating its location, content, type, version of document (current versus superseded for example) and verification status.

The proposed change to the description, modeled after the Advance Directive Observation data element, supports the need for patients and their providers to access and honor these important documents as the healthcare industry moves from paper-based and unstructured document (PDF) workflows to more efficient, verifiable, and person-centered digital data exchange/access document workflows.

As HL7 FHIR US Core and CDA currently support exchange and access to unstructured data and documents, the projects that are quickly moving to balloted FHIR and CDA Implementation Guides (IGs) for these kinds of documents can provide the needed guidance to support structured data exchange without risk of leaving these critical life-and-death, legally enforceable documents behind.

Portable Medical Order Usage Note

- Current Usage Note: These are meant to follow a person regardless of when and where such an order might be needed (e.g., hospital, care facility, community, home). There are variations in requirements and names for portable medical orders based on jurisdiction.
- Proposed New Usage Note: May include structured or unstructured data, whether a person has one or more portable medical order documents, the type of portable medical order, the location of the document, and whether it has been verified. Such documents may be used should a person be unable to communicate to a treating provider, during an emergency or health crisis, their preferences for CPR and/or life-sustaining treatment interventions. These documents often also include goals of care.

Portable Medical Order Examples

- Current Examples: Examples include but are not limited to POLST (Portable Medical Order for Life-Sustaining Treatment), MOLST (Medical Orders for Life-Sustaining Treatment), and out-of-hospital DNR (do-not-resuscitate).

- Proposed New Examples: Examples include but are not limited to an indication that a POLST, MOLST, DNR or similar document is on file, a reference to the location of the portable medical order document, and the validating provider.

Rationale for More Detail for the Portable Medical Order Data Element

Below is background on the current understanding, structure and state of play for the Portable Medical Order, which underlie our HL7 recommendations and additions above. HL7 observes that a portable medical order communicates an order or set of legally valid, actionable orders, authored by a practitioner in collaboration with the patient or their designee, for specific emergency care the patient wishes to receive if they are unable to communicate with the medical team directly for any reason.

- "Portable" means that the order or set of orders are valid both inside and outside the originating provider's location, similar to a drug prescription, intended to travel with the patient across care settings and providers.
- "Medical Order" means the order(s) in the document have the legal validity required by care teams to act upon the specific direction contained therein.
- A portable medical order (PMO) is legally binding when signed by the practitioner and patient or designee, however, in some states or jurisdictions depending on the type of PMO there are requirements for additional authenticators such as witnesses or notaries. This kind of additional step is needed for DNR or DNAR documents, which contain only an instruction for the provision of CPR when such is the appropriate medical intervention.
- Portable medical orders have been in place, on paper, in the U.S. for decades and have many names they are referred to by:
    - POLST Physician Order for Life-Sustaining Treatment
    - MOLST Medical Orders for Life-Sustaining Treatment
    - POST Physician Order for Scope of Treatment
    - MOST Medical Order for Scope of Treatment
    - TPOPP Transportable Physician Orders for Patient Preferences
    - DNR Do-Not-Resuscitate
    - DNAR Do-Not-Attempt-Resuscitation
    - DNH Do-Not-Hospitalize
    - DNI Do-Not-Intubate
    - EMS-CC Emergency Medical Services Comfort Care Order
- Portable medical orders are intended to represent the practitioner's instructions for CPR and life-sustaining treatment for a limited population of patients, typically those who are seriously ill or have a life-limiting condition, such that the practitioner would expect life expectancy to be 12 months or less.
    - It should be noted that some jurisdictions extend that life expectancy to 18 months or less, and other jurisdictions require that a portable medical order be in place for any individual who is being admitted to a nursing home, hospice or other type of facility regardless of life expectancy.
- Best practice is to review any existing advance directive documents against the portable medical order for consistency. In fact, most portable medical orders in place across the U.S. enable

capture of a review of existing advance directive information and conformance of the portable medical order instructions as part of the creation process.
    - The standard options are:
        - yes, the advance directive was reviewed and no conflict exists OR
        - yes, the advance directive was reviewed, conflict exists and the patient was notified OR
        - the advance directive exists but was not available to review OR
        - no advance directive exists.
- It is worth stating that in many jurisdictions there is a prohibition against acting on PMOs that are not the treating state's version of a PMO.
    - Massachusetts for example states on their web site: The MOLST instructions may be honored in some states, but not in others. However, a MOLST form is always a good record of a person's treatment decisions. Likewise, MOLST/POLST/POST forms from other states are not considered valid medical orders in Massachusetts, but they may be considered as evidence of a patient's preferences. Patients who reside in (or spend time regularly in) multiple states are recommended to discuss MOLST orders with clinicians in both states.
    - Signature requirements for PMOs can also cause a lack of reciprocity between states, since some states allow Nurse Practitioners to sign PMOS while others do not. The same consideration applies to Advance Practice Nurses that can sign PMOs in some states but not others, which further constrains a PMO's legal use across state lines.
        - It is important to note that in every instance we could find, a PMO from another state that is not legally binding in the treating state still provides important information that the treating provider should use to inform the individual's treatment.

DNR orders are not actionable across state lines, necessitating that if an individual creates a DNR with their practitioner in one state and moves to another state, they should create a new DNR in that new state since their previous DNR can't be legally honored in any other state than the one it was created for. https://worldpopulationreview.com/state-rankings/do-not-resuscitate-laws-by-states

Patient Summary and Plan: Care Plan [New Data Element]

https://www.healthit.gov/isp/taxonomy/term/7596/draft-uscdi-v6

HL7 supports the inclusion of Care Plan as a new data element in USCDI v6. The expansion of support for the Care Plan data element and related information is a critical step in supporting patient preferences, patient and care team goals, key health concerns and planned care activities. The use of Care Plan extends across multiple contexts in HL7 and its expanded support and emphasis can better facilitate structured and interoperable exchanges in areas such as clinical care pathways, care coordination and payer to payer and payer to provider exchanges.

HL7 recommends including the Systematized Nomenclature of Medicine – Clinical Terms (SNOMED) as an applicable vocabulary standard for the Care Plan data element, which is in alignment with current

HL7 Fast Healthcare Interoperability Resources (FHIR) US Core terminology bindings. Additional US Core terminology information can be found at: https://build.fhir.org/ig/HL7/US-Core/terminology.html.

Problems: Date of Onset [New Data Element]
https://www.healthit.gov/isp/taxonomy/term/1246/draft-uscdi-v6

HL7 supports the inclusion of Date of Onset as a new data element in USCDI v6.

Problems: Family Health History [New Data Element]
https://www.healthit.gov/isp/taxonomy/term/1266/draft-uscdi-v6

HL7 supports the inclusion of the Family Health History data element in USCDI v6, as well as the applicable vocabulary standards to support it.

Procedures: Performance Time [Existing Data Element]
https://www.healthit.gov/isp/taxonomy/term/1456/draft-uscdi-v6

HL7 appreciates the efforts made in USCDI v6 in providing clarity to implementers through updated definitions, usage notes or examples. While a definition change has been proposed with the data element Procedures: Performance Time, HL7 notes that it is not clear what the proposed change is. Furthermore, HL7 remains concerned that the current Procedures: Performance Time USCDI data class implies a much larger scope than is actually managed in HIT. For example, lab tests and immunizations are not considered "procedures". Thus, Performance Time should not be expected to apply to Laboratory tests. Conversely, HL7 strongly urges that the USCDI v6 Laboratory data class includes a data element "date/time of analysis." These actions cannot happen in isolation, as other date/times are important as well for laboratory tests and it is critically important these are not conflated. Specifically, HL7 strongly urges ASTP/ONC to include for the Laboratory data class the following data times as well:

- Specimen collection date/time: Date/time when clinical specimen was collected from subject patient. This is the clinically relevant date time of an observation when a specimen is collected for a test.
- Test result date/time: when the analysis is performed on the specimen(s) creating the observation, or when the result is calculated on existing observation.
- Reporting date/time: when the results are verified and released for reporting.

All these elements are currently widely implemented through HL7 v2 laboratory result messaging in support of CMS Clinical Laboratory Improvement Amendments (CLIA) regulations and all three are also part of USCDI+ Public Health. HL7 recommends that if these data elements are not included in USCDI, that they still be elevated to Level 2 given their wide adoption and availability and are required under CMS CLIA regulations.