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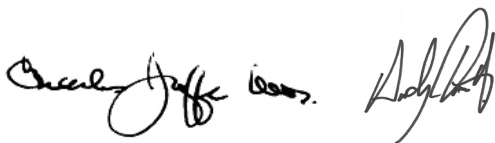

Submitted electronically to:

https://www.healthit.gov/isa/ONDEC

Re: ONC's Draft United States Core Data for Interoperability (USCDI) Version 4

Dear Dr. Tripathi:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on ONC's Draft United States Core Data for Interoperability (USCDI) Version 4 and related data classes standards and elements referenced at https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#draft-uscdi-v4. HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena.

We appreciate this on-going collaborative process. HL7's feedback on the Draft USCDI v4 is detailed below and in our accompanying table. In addition to our leadership and Policy Advisory Committee, HL7 Work Groups contributing to these comments include Clinical Decision Support, Clinical Quality Information, Patient Empowerment and Payer/Provider Information Exchange and Security. The HL7 Accelerator, Fast Healthcare Interoperability Resources at Scale (FAST) Taskforce also provided input. 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.

Sincerely,

Charles Jaffe, MD, PhD   Andrew Truscott

Chief Executive Officer   Board of Directors, Chair

HL7 International   HL7 International

Health Level Seven International (HL7) Response and Input

Comments for United States Core Data for Interoperability (USCDI) Standard (Draft Version 4)

	Comments
Overarching Comments	HL7 emphasizes that USCDI is impactful only to the extent that it clearly describes actual standards and content and not just loosely describes terminology bindings and categories. There is a potentially harmful side effect of lack of specificity in that organizations implement poorly formed content and then have expended costs to maintain it but can't achieve machine-to-machine exchange.

ONC – Comments for United States Core Data Interoperability (draft v4)		
Data Class	**Data Element(s)**	**Comments**
Allergies and Intolerance	**Substance (Non-Medication):** This describes allergens that affect clinical care which are not specifically a drug class or medication (i.e. other data elements within the Allergies and Intolerances data class). https://www.healthit.gov/isa/taxonomy/term/1436/draft-uscdi-v4	HL7 noted in previous USCDI comments that the area of non-medication allergy requires broad stakeholder and expert guidance. We recommended some method be identified to resolve terminology and capture issues, perhaps with a common agreed-upon value set for broad use. Currently, HL7 again urges and recommends an authoritative code system/value set that defines allergies and intolerances related to non-medical substances for inclusion in the USCDI.
Encounter Information	**Encounter Identifier:** Sequence of characters by which an encounter is known. https://www.healthit.gov/isa/taxonomy/term/1371/draft-uscdi-v4	HL7 recommends that the definitions of encounter information and encounter identifier be both enhanced and made more specific to better align with HL7 FHIR. HL7 is available for additional expert feedback on this issue. Regarding encounter identifier, HL7 observes this is a system and

		value. HL7 recommends it should instead, be a unique string to link to other tables, differentiating between encounters. HL7 also emphasizes important overarching issues and questions to be considered within the USCDI context including: How do you identify an encounter? This could be an episode or a date of service. The healthcare industry as a whole has been challenged with a consistent definition. It usually exists as a combination of elements or circumstances linked by a unique id. Depending on which entity conducts the encounter, what is also logically included but could also be considered as a separate encounter, is variable. HL7 poses the question: Does the encounter identifier cover both clinical and administrative/financial for the encounter?
Facility Information	**Facility Identifier:** Sequence of characters representing a physical place of available services or resources. https://www.healthit.gov/isa/taxonomy/term/1136/draft-uscdi-v4 **Facility Name:** Word or words by which a facility is known. https://www.healthit.gov/isa/taxonomy/term/1121/draft-uscdi-v4 **Facility Type:** Category describing available services or resources. Examples include but are not limited to laboratory, pharmacy, hospital, ambulatory providers, long-term and post-acute care, and pharmacy. https://www.healthit.gov/isa/taxonomy/term/1141/draft-uscdi-v4	HL7 urges clarification and more details regarding: • Facility identifier definition • Is facility identifier a National Provider Identifier (NPI) or Tax Identification Number (TIN)? • If the facility identifier is a physical location, does it indicate a location using an address or is the facility identifier something the relevant stakeholders negotiate? Is there an organization that defines what these values could be? HL7 recommends that HHS and the Centers for Medicare and Medicaid Services (CMS) specify a national directory for healthcare providers and services that encompass this information. A possible implementable tool is the HL7 FAST National Directory for Healthcare Providers and Services. More information can be found at: https://build.fhir.org/ig/HL7/fhir-directory-exchange/

		HL7 recommends regarding facility name, that this data only be considered accurate at the time services were rendered. Provider/Facility names and types may change.
		HL7 asks regarding facility type:
		• Is this a codeset or a free text string?
		• Is there a finite list?
		• Is there an organization that defines what these values could be?
		HL7 notes that there is a dataset in the HL7 FAST National Directory for Healthcare Providers and Services that could be used as a reference for a facility type value set.
Goals	**Treatment Intervention Preference:** `Person's goals, preferences, and priorities for care and treatment in case that person is unable to make medical decisions because of a serious illness or injury. Examples include but are not limited to preferences regarding cardiopulmonary resuscitation, endotracheal intubation, and tube feeding.` https://www.healthit.gov/isa/taxonomy/term/2061/draft-uscdi-v4 **Care Experience Preference:** `Person's goals, preferences, and priorities for overall experiences during their care and treatment. Examples include but are not limited to honoring religious beliefs, and conditions of the care environment.` https://www.healthit.gov/isa/taxonomy/term/2081/draft-uscdi-v4	HL7 inquires regarding treatment intervention preference: • Who is setting the goal (patient, care coordinator, provider, payor, etc.)? • Does this descriptor define for whom the goal applies? • Should treatment intervention preference have care goals? • Are treatment intervention preference linked to referrals, authorizations, diagnosis, assessments, care coordination, etc.? HL7 urges clarification regarding the meaning of care experience preference and inquires: • Is this personal patient feedback? • Whose care experience or preference does this link to?
Health Status Assessment	**Physical Activity:** `Evaluation of a patient's current or usual exercise. Examples include but are not limited to Exercise Vital Sign.`	HL7 recommends for USCDI inclusion and reference, the current HL7 Physical Activity Implementation Guide (Version 1.0.0 ballot). More

https://www.healthit.gov/isa/taxonomy/term/7736/draft-uscdi-v4

Substance Use: `Evaluation of a patient's reported use of drugs or other substances for non-medical purposes or in excess of a valid prescription. Examples include but are not limited to substance use disorder score, and substance use knowledge assessment.`
https://www.healthit.gov/isa/taxonomy/term/2171/draft-uscdi-v4

Alcohol Use: `Evaluation of a patient's consumption of alcohol. Examples include but are not limited to history of alcohol use, alcohol use disorder identification test and alcohol intake assessment.`
https://www.healthit.gov/isa/taxonomy/term/3736/draft-uscdi-v4

Smoking Status: `Assessment of a patient's smoking behaviors.`
https://www.healthit.gov/isa/taxonomy/term/811/draft-uscdi-v4

information can be found at: https://build.fhir.org/ig/HL7/physical-activity/

Providing standardized information on an individual's physical activity would support care planning and quality improvement.

HL7 recommends that the names of the alcohol use and substance use data elements be modified. Relevant screening instruments collect both the use and risk and reflecting this in the USCDI will aid in providing a more complete patient profile that includes and aligns risk within the outcome from screening instruments.

Further, HL7 recommends ONC explore the inclusion of instrument type and collection method when exchanging alcohol and substance use information. Depending on the instrument used, scores can vary by sex and consumption. There are also impacts on the validity of the results, based on the collection method. Instrument type will provide clarity to clinicians when interpreting results.

Regarding both the alcohol and substance use data elements, HL7 observes that there are privacy concerns with disclosure of a person's use history and this could have unplanned consequences if shared outside the person's healthcare team.

Regarding smoking status, HL7 suggest ONC consider USCDI inclusion of detailed smoking history information that is widely captured in electronic health records (EHRs) and that is needed for identifying eligibility for lung cancer screening. The current US Core smoking status data is insufficient because it doesn't capture how long a patient has smoked and how much they smoked during that period. Many EHRs already capture this information. This information is also needed for important quality measures (e.g. HEDIS) and risk assessments, where it is important to represent smoking duration and smoking amount as separate elements. Through a public health lens, these are very important pieces of information that are routinely captured, making them standardized as part of USCDI and USCore. In addition, there are existing standards for capturing this

		information like LOINC and NHANES. More information can be found at: https://wwwn.cdc.gov/nchs/nhanes/2011-2012/SMQ_G.htm https://wwwn.cdc.gov/Nchs/Nhanes/2013-2014/SMQ_H.htm
Medications	**Medication Adherence:** `Medication is consumed according to instructions. Examples include but are not limited to taking as directed, taking not as directed, and not taking.` https://www.healthit.gov/isa/taxonomy/term/3446/draft-uscdi-v4	HL7 inquires related to this USCDI item: • Is there interest in just exchanging/documenting attestation of medication adherence? • Is there interest in computing medication adherence from medication data? HL7 observes that there is significant work that may be of interest conducted by the HL7 Clinical Decision Support (CDS), Clinical Quality Information (CQI) and Pharmacy Work Groups related to calculating cumulative medication duration as part of determining adherence and usage addressing prescribed, dispensed, and administered medications, primarily using daysSupplied as documented or calculated from frequency and quantity supplied. More information can be found at: https://github.com/cqframework/ecqm-content-qicore-2022/blob/master/input/cql/CumulativeMedicationDuration.cql
Patient Demographics and Information	**Patient Demographics/Information:** `Data used to categorize individuals for identification, records matching, and other purposes.` https://www.healthit.gov/isa/uscdi-data-class/patient-demographicsinformation#draft-uscdi-v4	HL7 recommends under the patient demographics/information data class that the HL7 Identifier specified in the HL7 Interoperable Digital Identity and Patient Matching Implementation Guide be incorporated as a data element into the final USCDI v4. There is no comparable data element in USCDI Version 3. HL7 Identifiers will be used both in organization to organization and in consumer-directed healthcare queries in which single high confidence person matches are needed. An individual can control the use of the identifier in consumer-directed workflows and identity services implementing the identifier may share it with the individual's consent. Due to the inability for identifiers to be

		passively assigned at industry standard assurance levels, most industry stakeholders would be capable of implementing this identifier and would likely upgrade their enterprise identifiers or local database indexes to reflect unique individuals. More information can be found at: https://build.fhir.org/ig/HL7/fhir-identity-matching-ig/ https://confluence.hl7.org/display/PA/Patient+Matching+PSS
Procedure	**Procedures:** `Activity performed for or on a patient as part of the provision of care.` https://www.healthit.gov/isa/taxonomy/term/781/draft-uscdi-v4 **Time of Procedure:** `Time and/or date a procedure or other action is performed.` https://www.healthit.gov/isa/taxonomy/term/1456/draft-uscdi-v4	HL7 recommends the USCDI procedures data class should more precisely define the term "procedure", particularly because the current definition could include almost any action, including drawing blood. HL7 supports the ONC USCDI efforts to address and reflect procedures time and date. Lack of information related to these data elements has resulted in challenges expressing and retrieving data related to quality measures. Regarding time of procedure, HL7 observes it is important to include time-zone offset data, as it could be important for patient safety.
Provenance	**Author**: https://www.healthit.gov/isa/taxonomy/term/1171/level-2 **Author Role**: `Author Role(s), in context of action taken and/or in context of USCDI dataset or data element authorship.` https://www.healthit.gov/isa/taxonomy/term/2201/comment **Signature**: `(Per https://www.hl7.org/fhir/provenance.html):` "`Provenance.signature: A digital signature on the target Reference(s). The digital signature, inclusive of a hash on the resource being signed.`" https://www.healthit.gov/isa/taxonomy/term/2196/comment **Purpose of Capture:** `Purpose of Capture describes why a dataset or data elements were originated (collected, captured, sourced), updated, verified,`	HL7 recommends advancing and progressing further the specific provenance data elements that are listed below. **Author (Currently Level 2)** - Author time and organization lacks context without the author, particularly related to non-institutional data sources. As America transitions to more patient centered care, the importance of other data contributors such as patients and non-clinician caregivers will come into focus. **Signature (Currently Comment Level)** - Documents and other information, such as end of life Portable Medical Orders (POLST), need to be signed in order to be trusted and used. Without a signature there is no way to validate the veracity of data that may not be coming from a direct trusted source. **Author Role (Currently Comment Level)** - The role in which data is

`attested, transformed.` https://www.healthit.gov/isa/taxonomy/term/2236/comment **Source:** `The Source of information received by an organization. The Source defines at a high level the standard used to exchange the information.` https://www.healthit.gov/isa/uscdi-data-class/provenance#level-1	captured is important to more fully understand that information. It is critical to know not only what organization or author created the data but the capacity in which they were operating under in order to properly understand the data. **Purpose of Capture (Currently Comment Level)** - Information is gathered from numerous sources for a myriad of specific purposes. The level of detail, completeness, and quality of the information is highly dependent on the interests of those capturing the information. Understanding more about these contextual issues is critical to shedding light on the data and how it can be further used for things such as population and public health. **Source (Level 1)** - HL7 recommends not only advancing the source data element from Level 1 but also to rename it "Source Format" as its real use is to convey the format of content prior to being transformed or integrated into the target content. HL7 observes that promoting these Provenance data elements to USCDI V4 serves many useful purposes and addresses Trusted Exchange Framework and Common Agreements (TEFCA) end user needs to establish a level of confidence and trust in the information received, given the many touch points on exchange paths that require traceability. Lastly, regarding author and author role, HL7 urges ONC to: • Clarify the type of actor, such as patient, especially where information is contributed by individuals. • Accommodate device-generated data such as wearables. HL7 also observes that updates are important to understand whether data has changed either from the point of creation or in exchange to better understand the origin and changes to data that can occur with or without exchange, and improve Provenance with context that identifies the type of actor or system creating or updating data.

Vital Signs	**Average Blood Pressure (ABP):** Mean value of two or more blood pressure readings in a specified time period. Usage note: Must include both systolic and diastolic components of the mean and specify the relevant time period of measurements. https://www.healthit.gov/isa/taxonomy/term/1391/draft-uscdi-v4	Well-accepted specific guidance and guidelines for calculating both clinician measured and self-measured average blood pressure (ABP) has grown out of American College of Cardiology (ACC) and the American Heart Association (AHA) Task Force on Clinical Practice Guidelines work. More information can be found at: https://www.jacc.org/doi/abs/10.1016/j.jacc.2017.11.005 The ABP concept is not equivalent to mean arterial pressure nor is it appropriate to calculate a mean from two readings. HL7 recommends the USCDI data class statement for average blood pressure be further specified to align with the ACC/AHA Task Force recommendations, providing specific calculation parameters for a reliable and clinically valid ABP artifact that can be electronically exchanged for effective hypertension management.
Additional Considerations		Regarding race and ethnicity standards, HL7 recommends that the USCDI demographic categories should align with any changes the U.S. Office of Management and Budget (OMB) makes to its own categories through the Proposals For Updating OMB's Race and Ethnicity Statistical Standards, in order to ensure consistency.