HL7® International

April 15, 2021

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Submitted electronically to:
https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#blocktabs-uscdi_data_class_element_list-2

Re: ONC's Draft United States Core Data for Interoperability (USCDI) Version 2

Dear Dr. Tripathi:

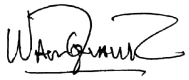
Health Level Seven (HL7) International welcomes the opportunity to submit comments on ONC's Draft United States Core Data for Interoperability (USCDI) Version 2 and related data classes standards and elements. HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena. Our organization 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 this on-going collaborative process. HL7's feedback on the Draft USCDI v2 is detailed below. We offer overarching comments, recommendations to increase the value of USCDI with greater alignment to HL7 FHIR, and a table containing recommendations pertinent to each data class. In addition to our leadership and Policy Advisory Committee, HL7 Work Groups contributing to these comments include Clinical Quality Information, Orders and Observations, Patient Empowerment, Security and Structured Documents, as well as the HL7 FHIR Accelerator Gravity 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 ONC.

Sincerely,

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



Walter G. Suarez, MD, MPH
Board of Directors, Chair
Health Level Seven International

HL7 Overarching Responses to ONC's Draft USCDI v2

HL7's general comments on ONC's Draft USCDI v2 are below.

Recommendation: USCDI and HL7 FHIR Alignment – HL7 recommends that the USCDI v2 should be revised by adding elements of the HL7® FHIR® structure, because the FHIR meta-model would enable ONC and USCDI users to more fully realize the intended purposes and expansion of USCDI.

Much of the information in USCDI provides high-level data requirements. As background and rationale for aligning USCDI data classes to be consistent with HL7 FHIR structure, this would assist with conceptual understanding and with enhancing both USCDI and FHIR adoption, which are stated ONC goals. FHIR Level 1 (Foundation) is likely inappropriate for USCDI which focuses more on data requirements and FHIR Level 2 (Implementation Support and Binding) should be addressed as part of each data class rather than its own USCDI class. However, Level 3 (Administration) includes specific USCDI data elements such that it would represent an appropriate class for USCDI, to include elements such as Patient, Practitioner, Organization, Practitioner Role, Care Team, Device, Healthcare Service. And FHIR Level 4 (Record Keeping and Data Exchange) should be represented in USCDI using its five components as classes (Clinical, Diagnostics, Medications, Workflow and Financial). Lastly, FHIR Level 5 (Clinical Reasoning) should represent another USCDI class.

Recommendation: Pilot Testing of USCDI Candidates – HL7 recommends ONC support pilot testing of USCDI candidates for potential inclusion of certain specific Level 1 items in USCDI version 2 and version 3, as most of these items represent discrete, granular data elements that are significant for direct clinical care, as well as research and clinical decision support and measurement.

It is vitally important to add the recommended new data elements to USCDI V2 so that they can be actively tested, with the intent to obtain input that will inform recommendations for USCDI V3.

Recommendation: Seek Stakeholder and Industry Input on Evaluation Tools – There are a variety of stakeholder perspectives on appropriate solutions to complex USCDI-related evaluation tooling issues such as those with structured assessment questionnaires, and other approaches to gathering necessary evaluation data. HL7 recommends ONC address these questions by seeking stakeholder input and conducting a forum to seek broad industry-wide solutions.

Recommendation: USCDI Data Element Specifications Should Include Required Metadata – HL7 recommends that specifications of USCDI data elements should include required metadata to assure clinical ability for information trending, curation required for research, and clinical decision support and measurement.

The USCDI should have a defined goal of helping to standardize data elements to avoid misinterpretation and variations that result from lack of standard granularity and metadata that ultimately adds burden to the clinical, public health and research communities. Examples of metadata for individual data elements include time (a specific example includes lab physiologic or effective time and issued or reported time), performer (including devices), source (i.e., primary source or reported). Some of the current USCDI recommendations add new data elements to indicate time but each data element should reference such information as metadata rather than separate data elements. While the current approach has begun to address such concerns from a terminology standpoint, it does not fully address metadata requirements for common data usage.

Recommendations: Overarching USCDI Data Element Issues –

HL7 recommends that:

- USCDI data elements derived from a validated evaluation tool or questionnaire, should reference the specific tool used to generate the data element value (i.e., one LOINC code per tool) to reduce variation and assure all clinicians use the same tool, thus enabling comparison over time and across patient care organizations.
- Data elements derived from validated evaluation tools should be incorporated into USCDI as a requirement for the infrastructure, (Questionnaire/QuestionnaireResponse) so that different federal and private sector programs can define which evaluation tool to use, and better manage changes to tools as evidence supports such changes without having to update USCDI.
- Data elements marked as "required/SHALL/must support" in both HL7® FHIR® US Core and HL7® CDA® C-CDA for the document types referenced in the 2015 Certification Edition Cures Update be included in USCDI v2, unless the USCDI data need not be represented in both (which should then be highlighted).

Recommendations by Data Class

HL7's comments on ONC's Draft USCDI v2 by data class are in the chart below.

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
Advance Directives	**Advance Directive Observation**	HL7 recommends Advance Directive Observation be moved into USCDI version 2. **Rationale and Maturity:** Advance Directives interoperability is a critical area that involves many stakeholders. Advance directives and the associated observations are key to patients and their care. More than 50% of patients 65 years or older have an advance

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
		directive status recorded as structured data. Important work is underway on this topic. At HL7, a FHIR implementation guide (IG) is being addressed by Work Groups including Patient Empowerment, Patient Care, Community Based Care and Privacy, and Orders & Observations. Their main goal in establishing a framework for the development of FHIR IGs is to facilitate health information exchange to support clinical practice and the management, delivery and evaluation of health services. The Post-Acute Care Interoperability (PACIO) Community has adopted this FHIR IG as a project use case. The PACIO Community has a strong interest in the topic of advance directives and will support the community engagement and technical FHIR IG development needed for advance directives interoperability. **Use Case Support:** o Revisions for C-CDA R2.1 Advance Directives Templates o **PACIO Project: PSS for Advance Directives** o Implementation Guide: **https://paciowg.github.io/advance-directives-ig/** o **ADI (Adv Dir Interop) in FHIR Materials** o Orientation to the Initiative § **Advance Directive Interoperability (ADI) in FHIR Project Need** § **Patient Empowerment as a Sponsoring Workgroup**
Allergies and Intolerances	**Substance (Medication)**RxNorm, January 4, 2021 Full Release Update **Substance (Drug Class)** updated U.S. Edition, September	HL7 agrees with updating to code system releases.

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
	2020 Release **Reaction** updated U.S. Edition, September 2020 Release	
	Level 2: **Substance (Food)** **Substance (Non-Medication)**	HL7 recommends that non-medication substances (food and non-medication) should be included because they have a significant effect on clinical care and specific items are important to determining exclusions and different pathways with respect to providing clinical decision support and measuring clinical quality performance. The information is also applicable to specific clinical trial criteria. HL7 believes inclusion of these level 2 elements in USCDI will assist with more specific CDS, eCQMs, clinical research and clinical trial participant identification.
Applicable Standards		HL7 recommends renaming the term Applicable Standards in USCDI to Vocabulary Standards or Terminology Standards as they are only intended to reference vocabulary/terminology standards, not syntax or transport standards which are defined elsewhere. HL7 recommends that the Applicable Standards, i.e., Vocabulary Standards, referenced in USCDI should be updated to reflect the most current version available at the time of publishing USCDI version 2. As USCDI expands, not all USCDI data should be required to be supported by all stakeholders. Such stratification in specific use cases must be clearly documented.
Assessment and Plan of Treatment	**Assessment and Plan of Treatment**	HL7 notes that Assessment and Plan of Treatment is a specific concept and recommends that it should be part of ClinicalNote. HL7 also recommends that Assessment and Plan of Treatment should reference Goal as an element of it. HL7 recommends Care Plan as a distinct USCDI class under which Goals should be included as an element and

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
		CarePlanactivity.outcomeCodeableConcept should also be included as an element. HL7 recommends that Care Plan be defined as "describes the intention of how one or more practitioners intend to delivery care for a particular patient, group or community for a period of time, possibly limited to care for a specific condition or set of conditions."
Care Team Members	**Care Team Member(s)** **Provider Identifier** **Provider Name**	HL7 recommends: • Provider name should be modeled as Person name in FHIR (not as an identifier). • Provider identifier should include NPI and other identifiers – note HL7 FHIR US Core ("US Core") options – Practitioner identifier all slices (system, value) and separately NPI. • Differentiating Practitioner from Organization (and avoid the term "provider" which can be confusing and refer to either practitioner or organization). • Enabling non-physicians in the care team by using Practitioner. HL7 recommends recognizing that not all caregivers will have an NPI or other provider identifier whether or not they are formal health professionals, and that this should be accommodated in the Care Team Data class. Similarly, NUCC defined roles may not exist for all care team members.
	Level 2: **Provider DEA Number** **Provider Identifier** **Provider Location**	HL7 recommends adding an electronic address as required by the CMS Interoperability and Patient Access Rule (CMS-9115-F). HL7 recommends including Provider NPI, Provider Identifier and Provider Location in USCDI version 2. **Rationale:** Recent discussions regarding US Core surfaced an issue that practitioners may be identified with an identifier or

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
	Provider Name **Provider NPI** **Provider Role** **Provider Telecom Information**	with a location but not both. Hence, the US Core ballot created an invariant to allow location or identifier code (e.g., NPI). USCDI should allow the same options. The Practitioner DEA number is important for considering CDS with respect to controlled substances and coordination of information with Physician Drug Monitoring Programs (PDMP). The Provider Role (should be practitioner) is important with respect to determining that an appropriate type of practitioner performed the activity required to meet guideline performance supported by CDS and eCQMs and research.
Clinical Notes	**Consultation Note** **Discharge Summary Note** **History & Physical** **Procedure Note** **Progress Note**	HL7 agrees with a more concise list of notes and that some have been moved to more specific classes consistent with their meaning and use.
Diagnosis		
Diagnostic Imaging	**Diagnostic Imaging Narrative** **Diagnostic Imaging Order** **Diagnostic Imaging Report**	HL7 supports promoting Diagnostic Imaging Order as proposed, and offers several related comments: HL7 recommends clarifying that Diagnostic Imaging applies to colonoscopies, retinal images, cardiac ultrasounds, etc., all of which carry images and not just radiology images. More guidance is needed about when to use the code. These same

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
		issues exist for narrative pathology and laboratory reports. HL7 recommends proposed Diagnostic Imaging Report and Diagnostic Imaging Narrative be merged into one data element, Diagnostic Imaging Report, and clearly define that the report is inclusive of the relevant/applicable narrative, numeric, and encoded data in a structured format, while it excludes the actual diagnostic image (although that may be referenced or included). A precise definition of discrete data within this context must be provided. **Rationale:** The Diagnostic Imaging Report (DIR) contains a consulting specialist's interpretation of image data. It conveys the interpretation to the referring (ordering) physician and is for use in Radiology, Endoscopy, Cardiology, and other imaging specialties. US Core addresses diagnosticreport-note that provides related metadata, report code and report type and reference to Observation as a result.
	Level 2: **Diagnostic Imaging Order** **Diagnostic Imaging Report**	HL7 recommends that the Diagnostic Imaging Order should represent a ServiceRequest available in base FHIR but not US Core. **Rationale:** The addition of Diagnostic Imaging Order is also important since many protocols require an image indicating pathology prior to providing treatment. Still other protocols require a trial and failure of treatment before ordering an imaging study (e.g., DEXA scans). The information is important to clinical care processes, CDS and eCQMs as well as clinical research.
	Level 2: **Diagnostic studies and exams with results**	HL7 recommends adding Diagnostic Studies and Exams with Result to USCDI Version 2, especially specific to ejection fraction and eye/disc/macular findings. **Rationale:** It is difficult to separate these from Diagnostic Imaging if such imaging is inclusive of endoscopy, cardiology, ophthalmology, etc. This item should likely be in the same class

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
		– Diagnostic Imaging. The specific intent here is to capture discrete, granular, coded data such as ejection fraction, eye/disc/macular findings, etc. Those examples have need to be a basic requirement since they significantly drive care plans and clinical care decision-making. Such numerical or coded data should be part of USCDI and incrementally adding elements over time starting with cardiac ejection fraction and macular/disc circumference and finding.
Encounter Information	**Encounter Diagnosis** **Encounter Time** **Encounter Type**	HL7 recommends both Encounter.diagnosis and Encounter.reasonCode as elements under the Encounter class in USCDI version 2. HL7 recommends that Encounter Type should be clarified and that Encounter.class be added, in addition to Encounter.type consistent with the definitions in US Core and base FHIR. HL7 recommends not including Principal and removing the word Primary, while including more precise definitions for: • Encounter Diagnosis • Reason for Visit • Chief Complaint **Rationale:** Encounter diagnosis is captured today and must be retrieved to report existing eCQMs. However, US Core requires Encounter.reasonCode (reason the encounter takes place – often a chief complaint). USCDI needs to differentiate reasonCode from Encounter.diagnosis, which includes a list of diagnoses addressed during the encounter that might have a specific use (billing, admission, discharge, etc.) and a rank order. The Encounter.use = billing and Encounter.rank = 1 correlates well to *principal diagnosis* required for Medicare billing and *may* help with *primary diagnosis* that is not addressed in standards due to the lack of a consistent definition that persists over time. Encounter type identifies the "code" for the encounter. However, Encounter.class (present in US Core) further allows classification such as inpatient, ambulatory, emergency, virtual (e.g., telehealth), etc.

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
		Encounter.participant is important from a measurement and research and public health point of view and for data analytics to indicate the practitioner responsible for the encounter (i.e., Encounter.participant.type primary and secondary) to assist with attribution of care and care events. Note that an Encounter participant should be applicable to a practitioner or an organization for the purposes stated. · Encounter time is an important concept that provides essential metadata for performing research by adding context of activities in relation to other activities. So, for data reuse and limiting curation requirements for research, encounter times must be high on the list of requirements. It is also essential in expressing clinical decision support and eCQMs for the same reasons, e.g., determining if conditions existing prior to the start of the encounter, or if activities occurred within or after the end of an encounter. For example, the eCQM stakeholders determined that actual encounters may not be closed until all documentation has been completed (potentially days after the end of an ambulatory encounter); however, implementation sites have methodology to determine and record the beginning and end of a specific visit (arrival/triage time and departure time) and such information is available. For direct clinical use this information is also important for the subsequent care provider to understand the sequence of events during an encounter and after its end.
	Level 2: **Encounter Diagnosis** **Encounter Disposition** **Encounter Location** **Encounter Time** **Encounter Type**	HL7 recommends adding Encounter diagnosis, Encounter disposition, Encounter Location, Encounter Time and Encounter type, and Encounter class, to USCDI version 2. HL7 recommends and Encounter Provider (Practitioner) Identifier. This would be the same as the Provider Identifier under Care Team, but it is important to tie the encounter to the practitioner. **Rationale** • Encounter Diagnosis – see comments above in UCSDI v2 section.

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
		• Encounter type – see comments above in USCDI v2 section (suggesting Encounter class instead). • Encounter time – see comments in above USCDI v2 section. • Encounter disposition is an indication of patient status at the end of an encounter (mostly relevant to inpatient encounters). It is important for Medicare and Medicaid reporting and thus it is available today. It is also used in eCQMs and as data points for decision making with CDS. It is a basic set of data already present and should be included in USCDI v2. • Encounter location – location is significant in that the location may have relevance to the practitioner identifier (see Provider identifier section) or organization identifier. The location at which the encounter occurred may provide evidence for the attributable organization. It also provides metadata useful for research that may reduce the high-burden curation requirement to determine relevance of the information for research data sets.
	Level 2: **Facility Address** **Facility Contact Information** **Facility GPS Coordinates** **Facility Identifier** **Facility Managing Organization Identifier** **Facility Name**	HL7 recommends adding Facility Identifier, Facility Managing Organization Identifier and Facility Type to USCDI version 2. **Rationale:** Specific metadata for facilities (referenced as Organization in FHIR) is required to determine performers of activity (encounters, procedures, images, general observations, etc.). Essential metadata for such use includes Facility Identifier, Managing Organization Identifier, Facility Type.

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
	Facility Type	
Goals	**Patient Goals**	HL7 recommends moving this element under Care Plan class and adding Provider Goals and Patient Goals.
Health Concerns	**Health Concerns**	HL7 recommends continuing with SNOMED CT and LOINC as with USCDI v1.
Immunizations	**Level 2** **Coverage Period** **Coverage Type** **Group Number** **Member Identifier** **Payer Identifier** **Payer Name** **Policy Number** **Subscriber Identifier**	HL7 recommends adding Coverage Type, Payer Identifier, and Coverage Period to USCDI version 2. **Rationale:** The following items are essential for aggregate performance analysis with stratification by payer and payer type and for identifying gaps in care and to provide CDS to support improvement in care delivery: o Payer identifier o Coverage type · Coverage period
	Immunizations	HL7 recommends updating CVX and NDC value sets. **Rationale:** CVX is continuously updated, so USCDI v2 should not cut it off at Nov 2020 or even the date that v2 is published. Continued updates to CVX should be allowed.
	Level 2 **Immunization Administered Date** **Immunization Code**	HL7 recommends adding Immunization Administered Date (which is a duplicate of Vaccine Administration Date), Immunization Code, Immunization Status, Reason Immunization Not Performed and Vaccination Event Record Type in USCDI Version 2. **Rationale:** Immunizations alone describe the immunization

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
	Immunization Status **Reason Immunization Not Performed** **Vaccination Administration Date** **Vaccination Event Record Type**	product (CVX and NDC codes). However, essential to clinical care and assuring appropriate, timely and effective immunizations requires information shared with immunization registries (public health) to assure community immunity and to reduce the level of vaccine-preventable disease. These data are especially pertinent during outbreaks and pandemics. Determining the correct immunization forecast for an individual requires all of the information included in the Level 2 list. Immunization status is essential; however, the examples of completed, entered in error, and not done may be confusing with the currently used V2 Vaccine Event Record Type, which is modeled differently in FHIR. HL7 suggests harmonizing the modeling as illustrated below. Immunization administered data (note that vaccination administration date is an identical element and should not duplicate the concept) • Vaccination event record type • Reason immunization not performed (to determine if follow up should occur to attempt immunization again) • Immunization code • Immunization Lot Number • Performer Organization (see http://build.fhir.org/ig/dvci/vaccine-credential-ig/branches/main/StructureDefinition-vaccine-credential-immunization.html)
Laboratory	**Laboratory Report Narrative** **Pathology Report Narrative** **Tests** **Values/Results**	HL7 agrees with change of Laboratory Report Narrative moved from clinical report. HL7 agrees with change of Pathology report reclassified from clinical report. HL7 observes that values/results must include reference to units. FHIR requires UCUM units for all quantiles (with a few exceptions) https://www.hl7.org/fhir/datatypes.html#Quantity. C-CDA also specifies UCUM.

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
		HL7 strongly supports Dan Vreeman's comments on the Laboratory and Pathology Report narrative at: https://www.healthit.gov/isa/uscdi-data/laboratory#level-2. We suggest clarification of elements as he noted.
	Level 2: **Laboratory Result Status** **Laboratory Result Value** **·Laboratory results: date and timestamps** **Laboratory Test Performed Date** **Laboratory Test/Panel Code**	HL7 recommends including Laboratory Result Status, test result date timestamp, test performed date/time, result interpretation from level 2 into USCDI Version 2, as this data is already widely supported and included in laboratory results. HL7 notes that Test Performed date/time is misleading/ambiguous and recommends that it be renamed to Clinically Relevant Time (which for laboratory tests is also the specimen collection date/time). This should be highlighted in the definition of the term. Additionally HL7 recommends adopting the Level 2 proposals with a modification to rename Values/Results and Tests to Result Value and Test/Panel Code respectively and clarify that Result Value should include UCUM for units where applicable. HL7 recommends that Laboratory Report Narrative and Pathology Report Narrative be refocused to be Laboratory Report and Pathology Report, clearly defining that each report is inclusive of the relevant/applicable narrative, numeric, and encoded data in a structured format. HL7 strongly recommends including Observation.interpretation to address critical, critical high, critical low, abnormal high, abnormal low, and reference range high, reference range low. **Rationale:** • Laboratory Result Status (specifically interim, final, etc.) is significant when interpreting results • Laboratory Result Value – noted above in v2 section needs to include UCUM units. Laboratory test/panel code is essential to know which test (or panel) was ordered and which was performed. • Laboratory Results: date and timestamps – Observation.effectiveTime represents the physiologic

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
		time when the specimen was obtained and that is the important time with respect to the patient's statue. Result (when made available) time is also important to determine retrospectively if care processes addressed the result. • Observation.interpretation interpretation values are essential for advising clinicians with respect to the values reported. All clinical systems have at least critical and abnormal flags now as discovered curing an analysis performed by the eCQM team. Since reference ranges vary by laboratory as do what represents critical and abnormal values, any reuse of the data for research, clinical decision support or measurement reporting requires this level of metadata. It cannot be inferred from the value alone. • Laboratory Report and Pathology Report refocusing - While a typical laboratory report may not contain as much narrative as a pathology report, just providing narrative separately from the encoded and/or numeric data is not appropriate.
Medical Device or Equipment	**Level 2:** **Devices used (applied)**	HL7 recommends adding Devices Used (as observations or procedures) in USCDI version 2. HL7 recommends addressing the device use as an observation, rather than the specific FHIR profile DeviceUseStatement, which has limited use and may be inappropriate for many uses. **Rationale:** Use of a device should address any device – implantable and non-implantable – including assistive devices. There are an increasing number of wearable and patient-use devices providing valuable data used in clinical care. Knowledge of which device and its metadata, how it is used, and the observations (with timings) provided by the device is essential to address clinical care monitoring. Only a limited number of implantable devices are covered by UDI and the US Core implantable device profile. Evidence of device use requires careful review of available standard profiles. Most wearable and other devices provide

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
		observations with the devices as a reporter. The addition of device use would add significant impetus to some device manufacturers to move from proprietary, limited data availability to standard availability for patients to engage in their own care and incorporate result data to better achieve care goals, for example, makers of continuous positive airway pressure (CPAP) machines.
Medication	**Medications**	HL7 agrees that the USCDI version 2 updates the RxNorm release.
	Level 2 **Date Medication Administered** **Date Medication Prescribed** **Discharge medications** **Dosage** **Medication Administered Code** **Medication Administered Performer** **Medication Administered Reason Reference** **Medication Administration** **Medication Administration Dose**	HL7 recommends adding Data Medication Administered, Data Medication Prescribed (must have code, dose and units), Discharge Medications, Dosage (must include units), Medication Administered Code, Medication Administered Performer; Medication Administered Reason Reference, Medication Administration, Medication Administration Dose (how is this different from dose), Medication Dispensed; and Not given reason. **Rationale:** Medication is appropriate as a class; however, the class requires more elements to be more useful. Any given medication may be present in a record as part of active treatment, past treatment, planned / anticipated treatment (e.g., orders), etc. Specifically, US Core guidance is to use MedicationRequest (the order) with status=active to represent active medications and intent = order for physician-ordered medications, and intent=plan for patient-reported medications (with respective requester indicating physician or patient). Ideally clinical systems should have evidence of ordered (prescribed) and dispensed medications, with the ability to reconcile the two to determine probable usage. USCDI v2 should include Medication Order and Medication Dispensed at a minimum since software that sends orders should be able to receive dispensing information from SureScripts and the addition encourages software to include medication dispensed events to match with the order and decrement ordered supply to assist with managing medication regimens. This information is equally important as data for longitudinal analysis of patient adherence with medication

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
	Medication Administration Dose Units **Medication Prescribed Code** **Medication Prescribed Dose** **Medication Prescribed Dose Units** **Medication Prescribed Reason Reference** **Medications Dispensed** **Negation Rationale**	usage to enable care plans, assist with measuring performance of patients, practitioners and organizations, and for research. Ideally, administered medications should be included as well to assure granular data is available in clinical summaries to support medication lists for all of the patient's clinical care practitioner and organizations.
	Level 2: **Observation Code** **Observation Performer** **Observation Subject** **Observation Timing** **Observation Value**	HL7 recommends adding general observations as listed in Level 2 in USCDI version 2. **Rationale:** The USCDI Provenance class is beneficial in that it allows metadata about the timing, the source and the performer of the message or document being shared through interoperability. However, the individual elements within that message or document also require metadata to allow appropriate use on the receiving end. To be able to trend observations over time for clinical purposes or even just to determine the effect of medical or patient-driven actions the performer, timing, subject and value (in UCUM units) of each observation must be included. Moreover, to enable re-use for research and to significantly reduce the burden of human curation as well as to evaluate data for clinical decision support and performance measurement, such data-level metadata are

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
		essential.
	Level 2: **Types of orders for medical care/services**	HL7 recommends adding Orders and Types of Orders in USCDI version 2. **Rationale:** The USCDI Provenance class is beneficial because it allows metadata about the timing, the source and the performer of the message or document being shared through interoperability. However, the individual elements within that message or document also require metadata to allow appropriate use on the receiving end. To be able to use details about orders for medical care and services for clinical purposes or even just to determine the effect of medical or patient-driven actions the performer, timing, subject and value (in UCUM units) of each order must be included. Moreover, to enable re-use for research and to significantly reduce the burden of human curation, as well as to evaluate data for clinical decision support and performance measurement, such data-level metadata are essential.
Patient Demographics	**Birth Sex** **Current Address** **Date of Birth** **Email Address** **Ethnicity** **First Name** **Last Name** **Middle Name (including middle initial)** **Phone Number** **Phone Number Type**	HL7 recommends adding necessary data elements within Patient Demographics to reflect the full range of sexual orientation and gender identity (SOGI) information and key elements within social determinants of health, as well as the Medicare ID. HL7 recommends Patient, Sexual Orientation, and Gender Identity, which are at Level 2, should be moved to USCDI Version 2. **Rationale:** (Patient Identifier) Electronic case reporting requires a Patient identifier. This data is exchanged as part of the extensive implementation of electronic case reporting in the US. The target is nationwide, currently 5400+ sites are reporting. There are between 56 and 2400 public health agencies using this data. It is used extensively in production environments to support the majority of anticipated stakeholders. Electronic case reporting is also cited in the Cares Act regulations. The applicable standard is FHIR US Core.

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
	Preferred Language **Previous Address** **Previous Name** **Race** **Suffix**	(Coded Representation of a Patient's Stated Gender Identity) It is important for healthcare providers and staff to record patients' administrative sex and gender identity separately and accurately. Although administrative sex may affect gender-specific care (e.g., mammograms), a patient's gender identity may also affect care and health outcomes. For example, transgender patients are known to face health disparities, and lack of adherence to preferred names and pronouns can lead to embarrassment and even discrimination in healthcare. Technical outcome – A user can record a patient's gender identity according to HL7® FHIR R4, HL7® version 3, SNOMED CT®, and LOINC codes specified in the "standard(s) referenced" column. The user must be able to record whether the patient declined to specify gender identity. Note that while gender identity was included in the 2015 Edition "demographics" certification criterion and the 2015 Edition Base EHR definition, it was not included in the Common Clinical Data Set definition. This means that gender identity is not required to be exchanged using certain standards, only that systems enable a user to record, change, and access gender identity. [see also 80 FR 62619]. Users of the 572 certified health IT products, out of 901 total products certified to ONC's 2015 Edition, that successfully tested to the 170.315(a)(5) demographics certification criterion has the ability to record, change, and access gender identity data within these products. Applicable standards are: LOINC, SNOMED CT, HL7 version 3.
	Level 2: **Birth time** **Deceased date** **Gender Identity**	HL7 recommends Gender identity should be in USCDI version 2 and reference the published ballot for HL7 Gender Harmony for the recommended code set.

Data Class	USCDI v2 (Draft)	Recommendations with Rationale, Use Case and Other Information
	Identifier **Medicare Patient Identifier** **Mother's Maiden Name** **Multiple Birth Order** **Sexual Orientation**	
Problem	**Date of Diagnosis** **Date of Resolution** **Problems**	HL7 recommends bringing in two more dateTime elements if Date of Diagnosis and Date of Resolution are included in USCDI v2. These elements are: •Onset Date •Recorded Date HL7 recommends more precise definitions for each dateTime element. HL7 recommends that for Date of Onset, diagnosis and resolution date systems should allow recording of past dates. HL7 also urges more guidance on how C-CDA can represent all of these elements.
	Level 2: **Date of Diagnosis** **Date of Onset** **Date of Resolution** **Problems, defined by ICD-10-CM terminology**	HL7 recommends Date of Diagnosis, Date of Onset, and Date of Resolution use descriptions as defined in related FHIR resource (Condition). **Rationale:** Investigation into availability of Date of Onset for a condition (problem) in data retrieved for electronic clinical quality measures suggests there is significant variation among EHRs and implementations. While some EHRs have a field titled Date Noted or something similar, the definition of Noted is ambiguous - i.e., the date the symptoms or signs started that eventually led to the diagnosis, or the date the condition was

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	standards **SNODENT**	identified by the clinician, or the date entered into the EHR. The field may default today's date in the field meaning that the actual Date Noted exists in the record only if the clinician entering the information changes the default date before clicking on enter. Thus, date of onset is inconsistent at best. However, by requiring such information in USCDI, ONC will emphasize that the concept is significant and important, thus driving better documentation. Work will need to be done to assure common understanding of the concept. Date of Resolution may also be available only occasionally since it depends on a clinician to specifically indicate that a condition is over, or abated. Perhaps for diagnoses such as active pregnancy, an end date is clear at the time of partruition (although not necessarily documented in a problem list). A clear message from ONC that this is an important data element will help drive better documentation. While there are concerns about documentation burden, the information is essential for clinical decision support, measurement and research. Consensus work to provide guidance regarding common recommended methods to determine such data for critical conditions using phenotypes, or expressions that combine different data sources will be critical to these efforts without inducing any burden on the clinician and providing significant benefit.
Procedures	**Procedures**	
	Level 2: **Location of Procedure** **Procedure Timing**	HL7 recommends adding Location of Procedure and Procedure Timing to USCDI version 2. **Rationale:** The USCDI Provenance class is beneficial because it allows metadata about the timing, the source and the performer of the message or document being shared through interoperability. However, the individual elements within that message or document also require metadata to allow appropriate use on the receiving end. To be able to trend procedures over time for clinical purposes or even just to determine the effect of medical or patient-driven actions the

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		performer, timing, subject and result of each procedure must be included. Moreover, to enable re-use for research and to significantly reduce the burden of human curation as well as to evaluate data for clinical decision support and performance measurement, such data-level metadata are essential. Note that performer may be a device.
Security Label	**Security Label Confidentiality Tag** **Security Label Purpose of Use Tag**	HL7 recommends elevating the Security Label Confidentiality Tag and Security Label Purpose of Use Tag data elements from Level 1 to Level 2, so that these may be considered for USCDI Version 3. **Rationale:** Both Security Label tags are widely used in health information exchange (HIE) including by eHealth Exchange trading partners. Confidentiality tag codes are mandatory C-CDA elements at the Document class level. Purpose of Use codes are mandatory in NHIN Authorization Framework Specification v 3.0. See pages 17 forward.
Social Determinants of Health		
	Level 2: **Assessment** **Goals** **Interventions** **Outcomes** **Problems/Health Concerns**	HL7 agrees with the organization, data element structure and activities under the current SDOH data class and is supporting the SDOH Implementation Guide. The structure enables continuous addition of domains and code sets as they become available. HL7 recommends inclusion of the SDOH data class and elements in USCDI v2 now, as it is critical. Better and more equitable healthcare across a broad array of use cases and settings will result.
Social History		
	Level 2: **Alcohol Use** **Drug Use** **Refugee Status**	HL7 recommends adding Questionnaire/Questionnaire response to USCDI version 2 to handle all of these type 2 issues and more - the infrastructure of Questionnaire and Questionnaire response provided capabilities to enable such information for use in determining adherence with care plans, documenting diagnoses and risk factors, and for determining outcomes. HL7 recommends adding Questionnaire/Questionnaire response

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	Sexual Activity **Social History Observation**	capability, which would support Social History and Social Determinants of Health. **Rationale:** Methods to capture this information generally involve validated evaluation tools, sets of questions such that the risk category assignment derives from some mathematical calculation of all responses. The evaluation tool used for any of these items varies over time as they come in and out of vogue; still others are used specifically based on characteristics of the patient. Specifying an individual evaluation tool provides limited value and becomes outdated quickly. However, requiring capability to process questionnaires and questionnaire responses (both FHIR resources) enables use of such structured sets of questions and their answers for the examples listed in Level 2 and other social history concerns. The ability to capture such information and use it in determining risk and in making patient care decisions is invaluable.
Specimen	**Level 2:** **Specimen collection date** **Specimen source site** **Specimen type**	HL7 recommends requiring Specimen collection date (which may differ from the Laboratory test performed date), specimen source site and specimen type in USCDI version 2. **Rationale:** These are essential metadata elements regarding laboratory tests and this set of elements should be included under the Laboratory Class in USCDI rather than its own class, Specimen.