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April 12, 2023

Micky Tripathi, Ph.D., M.P.P.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Washington, DC 20416

Dear Dr. Tripathi,

As a national trade association of EHR developers, EHR Association member companies serve the vast majority of hospital, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs and other health IT across the United States. Together, we work to improve the quality and efficiency of care through the adoption and use of innovative, interoperable, and secure health information technology.

On behalf of our nearly 30 member companies, the HIMSS Electronic Health Record (EHR) Association appreciates the opportunity to provide feedback to the ONC on the Draft USCDI v4. We fully support the growth of USCDI and suggest that USCDI continues to expand towards encompassing all EHI, such that actual support of relevant subsets be addressed through targeted standards and implementation guides plus certification requirements.

As we previously communicated in our Comments on the Draft United States Core Data for Interoperability (USCDI) v3, General Considerations and highlighted in our recent *Health Data Management* article, The Rationale for Changing the 'All or Nothing' Approach to USCDI Certification, health IT should only be required to support what is relevant to its use cases, rather than being required to always support all USCDI or not be eligible for certification. For example, specialty EHRs should not be required to support everything an EHR would support to enable a large health system, or data managed in an external administrative system, while a laboratory information system (LIS) or other health IT should not be required to support all clinical data if not applicable for use.

The USCDI v4 includes proposed data classes and elements that are valuable for progressing towards covering all EHI, though some could not be reasonably expected to be supported by all certified health IT. Many suggested data elements are reasonable for scenarios in which they focus on specific data elements, but become challenging when the proposed description and supporting submission reflect large, multi-data class concepts that are unrealistic to achieve in the scope of USCDI v4 or in some cases

multiple versions of USCDI. This is often the case when the draft definition is seemingly focused, though provided examples are caveated with "but not limited to," the Applicable Vocabulary Standard(s) reference a complete code system rather than a specific value set, and the submission describes a wide range of aspects and capabilities beyond an individual data element. We highlight these situations in our detailed comments below.

Sincerely,

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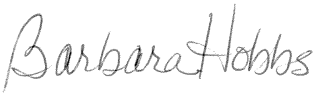
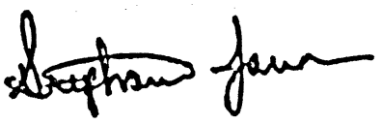


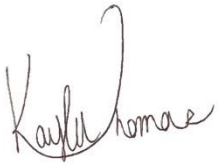
Barbara Hobbs
MEDITECH, Inc.

Cherie Holmes-Henry
NextGen Healthcare



Stephanie Jamison
Greenway Health

Ida Mantashi
Modernizing Medicine



Kayla Thomas
Oracle Cerner

Allergies and Intolerances

Substance (Non-Medication)

The EHR Association supports the addition of a substance (non-medication) data element and suggests clarifying its definition to align with the AllergyIntolerance.code attribute in FHIR US Core that is currently used to support the substance (medication) data element, rather than the substance considered to be responsible for allergy or intolerance. Such clarification would appropriately extend the current support for medications to non-medications in the same context.

Encounter Information

Encounter Identifier

The EHR Association supports the inclusion of the encounter identifier data element as proposed.

Health Status Assessments

SDOH Assessment

The EHR Association supports the movement of the Social Determinants of Health (SDOH) Assessment data element into the Health Status Assessment data class.

Alcohol Use

The EHR Association supports the inclusion of an alcohol use data element and suggests clarifying that this does not include a full assessment tool, any calculations of derived values, nor an unspecified list of potential other LOINC codes and assessment tools as currently implied by “but not limited to.” This caveat creates ambiguity as to what data is within scope. Thus, the applicable Vocabulary Standard(s) should not reference the full LOINC code system, but rather the specific value set as suggested in the submission as relevant:

- 5640-8 Ethanol [Mass/volume] in Blood
- 69721-9 Do you ever drink alcohol - including beer or wine [Reported.PHQ]
- 74013-4 Alcoholic drinks per day
- 11286-2 Alcohol binge episodes per month - Reported
- 74043-1 Alcohol use disorder
- 64718-0 During this pregnancy, did you receive help with an alcohol or drug problem [PhenX]
- 72109-2 Alcohol Use Disorder Identification Test - Consumption [AUDIT-C]

We note that this list not only includes specific LOINC codes for individual assessments but also 72109-2 Alcohol Use Disorder Identification Test - Consumption [AUDIT-C]. That concept is comprised of multiple data elements with a score based on these data elements. We suggest that the calculation of the score is out of scope, while the representation of the score is within scope, as the focus is on interoperability.

Substance Use

The EHR Association supports the inclusion of a substance use data element but is concerned that the current draft definition is insufficient to provide consistent guidance to those needing to support this. We suggest that the scope is more specifically defined, as "but not limited to" creates an unbound list and may include a variety of more or less standardized assessment tools. The submission notes that elements were submitted to Regenstrief for inclusion in LOINC, but that list is not available. The draft definition indicates it could include scores as well.

We suggest that where scoring is involved, there is not an expectation that the calculation of those scores is a requirement, but rather the recording. Generally, we note that alignment on nationally adopted assessment instruments is limited. At this stage, USCDI should include only individual data elements or widely adopted assessment tools that can be shared across a wide range of providers. Absent that, this attribute should be focused on a few, well-accepted, individual data elements with a well-defined vocabulary.

We suggest focusing on the below LOINC-based assessments currently defined in the Interoperability Standards Advisory as the recommendations for representing drug use:

- Drug Abuse Screening Test-10 [DAST-10] (LOINC code 82666-9)
- DAST-10 Total Score LOINC code 82667-7

Physical Activity

The EHR Association is concerned with the adoption of the physical activity data element as the draft definition states some examples to which the definition is not limited. The submission, as well as the recent presentation at HITAC, describes a much more comprehensive FHIR-based implementation guide – for which an equivalent C-CDA-based guide is not available nor necessarily feasible – that includes not only an assessment but also goals, requests, and referrals involving workflow management to enable the performance of a plan. The guide was only recently published and has not yet been adopted widely enough to validate maturity and readiness to scale.

As the proposed Applicable Vocabulary Standard(s) section is referencing the full LOINC code system, it is not clear what the scope of this concept is meant to be. We suggest that the definition is clarified to clearly indicate the LOINC-based value set of interest and reflect the scope as described in the Base Measure of the implementation guide (https://build.fhir.org/ig/HL7/physical-activity/measures.html#base-measure).

Facility Information

General

Providing a data class for facility data elements without the context of which facilities are of interest (where the encounter occurs, the patient is located, etc.) is challenging. The EHR Association suggests that each data class regarding facility indicates a need for that reference and the purpose of that facility, particularly as some data classes may need to reference multiple, different types of facilities (e.g., a room on the third floor of a particular building).

Facility Name

The EHR Association supports the inclusion of a facility name data element.

Facility Type

The EHR Association supports the inclusion of a facility type data element but notes that standardization of facility types across organizations is challenging. We appreciate the absence of a proposed vocabulary but suggest that ONC work with HL7 to evolve a reasonable set of facility types of interest where common use would be beneficial.

Facility Identifier

The EHR Association supports the inclusion of a facility identifier data element but notes that the identifier used should resolve into a unique identifier across organizations. This highlights a known challenge that, while object identifiers (OIDs) can ensure the uniqueness of identifiers such as facility identifiers, many organizations tend to assign OIDs within their own OID branch to entities (including facilities) outside their organization. A good example of organization identifiers is a scenario in which a hospital may be known under many OIDS beyond its own OID. We encourage ONC to clarify that one should use the proper identifiers as assigned by and received from the original owning organizations to ensure facility identifiers are not only unique but usable.

Vital Signs

Average Blood Pressure

We are concerned with the inclusion of an average blood pressure data element, as the definition in combination with the submission creates ambiguity. The submission references the FHIR Vital Signs implementation guide, which provides a more robust definition but only provides one recognized protocol and introduces a level of complexity that many health IT solutions would not support.

We would support the addition if it were limited to an average that was documented (whether calculated by the health IT being certified or not) with a time period that reflects the time period between the first and the last blood pressure.

We suggest that the vocabulary be more specific than a general reference to LOINC, enumerating the scoped LOINC code as provided in the submission with clarified, current long names per LOINC 2.73:

- 96607-7 Blood pressure panel mean systolic and mean diastolic
- 96608-5 Systolic blood pressure mean
- 96609-3 Diastolic blood pressure mean

Head Occipital-frontal Circumference Percentile (Birth-36 months)

The EHR Association recommends that an update is needed for the applicable age range for the preexisting Head Occipital-frontal Circumference Percentile data element. Currently, the element is identified as applicable for children ages birth to 36 months. However, based on existing guidance on the pediatric vital signs data elements, this age range is incorrect.

The ONC's USCDI certification companion guide states that "Pediatric vital signs include both the vital measurements and the percentiles used in the growth charts currently recommended by the Centers for Disease Control and Prevention." Those recommendations are currently to utilize WHO growth standards for children ages 0-2 years, and CDC growth charts for those ages 2 years and older. Based on those recommendations, the WHO's head circumference growth charts for boys and girls ages 0-24 months would be the appropriate charts to center on for the USCDI data element instead of the CDC's head circumference growth charts for boys and girls ages birth-36 months.

Accordingly, the data element should be changed to "Head Occipital-frontal Circumference Percentile (Birth-24 months)" to align with the established growth chart recommendations and implementation guidelines. This would follow suit with an equivalent change for the Weight-for-length Percentile data element that was adopted with USCDI v3.

Laboratory

Result Interpretation

The EHR Association supports the inclusion of a result interpretation data element. This data element is widely supported as part of laboratory result reporting supporting CLIA requirements.

Result Reference Range

The EHR Association supports the inclusion of a result interpretation data element. This data element is widely supported as part of laboratory result reporting supporting CLIA requirements.

Result Unit of Measure

The EHR Association supports the inclusion of a result unit of measure data element. This data element is widely supported as part of laboratory result reporting supporting CLIA requirements.

Specimen Source Site

The EHR Association supports the inclusion of a specimen source site data element when available. This data element is widely supported as part of laboratory result reporting supporting CLIA requirements. We note that not all health IT interested in certification may need to support this level of detail.

Specimen Identifier

The EHR Association supports the inclusion of a specimen identifier data element when available. This data element is widely supported as part of laboratory result reporting supporting CLIA requirements. We note that not all health IT interested in certification may need to support this level of detail.

Specimen Condition and Disposition

The EHR Association is concerned with the introduction of one data element representing these two distinct concepts. Condition is a characteristic of the specimen and may or may not disqualify the specimen's use for certain tests. Disposition is a characteristic of the test, describing whether the specimen collected was suitable for the performance of the test. Either it was, which is typically assumed if not further documented as part of the results reported, or it was not. If it was not, then either the test was still performed – in which case it is critical to communicate the specimen condition with the notation on the test that it was not suitable yet still performed – or the test is not performed and a new specimen needs to be obtained or it is decided not to perform the test at all and cancel it. In

either case, there is no reporting of a non-performed test, as the follow-up steps will yield an appropriate and properly communicated test or canceled test.

In that context, the EHR Association suggests that condition and disposition be addressed as two separate data elements, and ONC should clarify that these are of interest when the specimen is not considered suitable for the test, yet the test is still performed and resulted. Because there is currently no agreed-upon approach for C-CDA and FHIR US Core and further definition of necessary standards is required, we suggest allowing for this to be addressed in time for USCDI v5.

Specimen Collection Date/Time (Clinically Relevant Date/Time)

The EHR Association supports the recommendation by the HITAC Interoperability Standards workgroup to include a specimen collection date/time (clinically relevant data/time) data element. Many dates/times can be associated with different phases of laboratory reporting. We suggest that USCDI adopt the specimen collection date/time as it reflects the clinically relevant date/time essential to interpreting the test result in the context of time. This data element is widely supported as part of laboratory result reporting supporting CLIA requirements.

Result Report Date/Time

The EHR Association supports the recommendation by the HITAC Interoperability Standards workgroup to include a result report date/time data element. Many dates/times can be associated with different phases of laboratory reporting. We suggest that USCDI adopt the laboratory result date time that reflects the date time the report was made available, typically when finalized or at times when shared as a preliminary report. This data element is widely supported as part of laboratory result reporting supporting CLIA requirements.

Procedures

Time of Procedure

The EHR Association supports the inclusion of a time of procedure data element.

Medications

Medication Instructions

The EHR Association is concerned with the addition of a medication instructions data element, as the proposed definition – particularly the context of the submission – creates ambiguity using “but not limited to,” which introduces an unbound scope with a lack of clarity what “directions” may entail.

Specifically, the EHR Association requests clarity on whether this data element encompasses the full set of multiple data elements – not just one as the USCDI proposal should imply – included in the National Council for Prescription Drug Programs’ (NCPDP’s) structured Sig definition or the even more comprehensive Pharmacist Care Plan, or just a patient-focused set of narrative instructions beyond the current free text dosage instructions in FHIR US Core 5.0.0.?

The EHR Association suggests including the patient-focused instructions at a minimum but also recommends adding the route, frequency, number of repeats allowed, and quantity to dispense as

currently being introduced into US FHIR 6.0.0. This data is already widely supported through various prescription transactions.

We note that, while EHRs that enable prescribing support such data, other health IT that may wish to be certified would not necessarily need to support this data.

Medication Adherence

The EHR Association is concerned with the addition of a medication adherence data element, as the proposed definition – particularly the context of the submission – creates ambiguity using "but not limited to," which introduces an unbound scope with a lack of clarity what "adherence" may entail.

This may include data conveyed by a patient to a provider for documentation or a patient directly entering that into the provider's health IT.

We suggest focusing the definition on provider-documented adherence as provided by the patient, not the provider's administration of any medication that also would convey adherence. In the absence of well-defined vocabulary to describe the level of adherence, we suggest focusing on narrative notes only for USCDI v4 and considering the addition of more structured data for a future USCDI version when such vocabulary would be further defined.

Goals

Treatment and Intervention Preferences

The EHR Association is concerned with the proposal to add a treatment and intervention preferences data element at this time, given the ambiguity of the proposed definition and supporting submission as to the intended scope.

Considering the context refers to patient-expressed preferences, we strongly suggest this concept be separated from Goals. This section, as currently defined in USCDI, focuses on provider-formulated goals for the plan of care for the patient. In that context, we also suggest clarifying the Patient Goals data element to clearly distinguish Patient Care Goals from SDOH Goals.

Additionally, the concepts of preferences, priorities for care, and treatment seem to go beyond setting personal goals to encompass certain interventions, treatments, and procedures that should or should not be performed under certain conditions. Those are not goals – i.e., targeted outcomes. The examples used reflect intervention preferences that include statements on activities to do or not to do. In that context, it is unclear how this will resolve in the FHIR Advanced Directives implementation guide and the appropriate use of Goals vs. ServiceRequests when it comes to Portable Medical Orders as expressed by the clinician and patient-expressed preferences on specific treatment interventions.

We also note the general reference to LOINC 2.73 without specific vocabulary relevant to this concept where the respective guides have further consideration. Additionally, the guides include a substantially more complex Goal structure that the FHIR US Core Goal does not support. Without further maturation in operational use validating the approaches set forward in the guides, we are concerned that the guidance is not ready for reference in the USCDI. At this time, it is also unclear what reasonable subset is proposed for USCDI v4.

Until this highly complex area is further defined and matured, the EHR Association strongly suggests this concept is not included in USCDI. We recommend that ONC work with the community to more clearly understand the concepts and address how portable medical orders, treatment, and intervention preferences are to be expressed via goals, as currently defined in FHIR vs. service request thus enabling a more robust computable preference approach that can assist providers, patients, and their caregivers as they share their goals and focus of care.

Care Experience Preference

As the comments on the Treatment and Intervention Preference data element equally apply to this proposed data element, the EHR Association strongly recommends that this concept be addressed in a future USCDI version to enable further definition and maturation.

USCDI Level 2 Proposals

We offer the following considerations for various Level 2 proposals that are being considered for inclusion in USCDI v4.

Diagnostic Imaging

USCDI Level 2 includes a submission for three data elements – accession number, requested procedure identifier, and image reference – enabling access view to a specific diagnostic image using an appropriate viewer or to obtain the full image. This would advance access beyond simple images as currently enabled in FHIR US Core and C-CDA in support of USCDI v2. A number of hurdles remain to overcome in order to progress from simple image capture to enable the managing of a DICOM image such that the certified health IT has the appropriate references to the correct image/PACS server and that it can be viewed by a FHIR-based API client accessing that link.

- Sharing the accession number and the requested procedure code/identifier would be reasonable, as those attributes are typically established during the ordering process and shared or provided by the image service, thus widely available. It should be noted, however, that the accession number does not necessarily yield a singular image but could reference a set of studies performed for the same procedure. It also would not necessarily be a globally unique identifier (GUID), thus requiring awareness of the issuing organization to have an opportunity to resolve it into a navigable link.
- Sharing the image references is a challenge, as imaging services do not yet consistently communicate this information to the receiving health IT as part of the diagnostic report, while PACS systems are not required to make image references available as part of the diagnostic report. Additionally, even if the proposed imaging reference data set is aligned with and available through the FHIR ImagingStudy resource as it should be – or if the image reference is not available using a URL constructed with the accession number and awareness of the imaging service involved – this does not yield a transparent, repeatable process across PACS and image service providers.

  The references shared are only feasible for use when the organization or person wishing to use the reference to initiate a viewer to display the image(s) has a business relationship and established shared infrastructure with the image holder. It is not publicly re-usable as with FHIR-

based APIs or the recipient of a C-CDA with such information in the absence of a common trust framework and security infrastructure.

Until the source systems – such as PACS and diagnostic report generators – share the imaging references without requiring specific, point-to-point business relationships and infrastructure, it is premature to essentially require all certified health IT to support this capability, without the necessary support by the image source systems. Adding an accession number and requested procedure code/identifier would be feasible but would not achieve the desired effect of improving access to the images themselves.

The EHR Association recommends that ONC progresses with the accession identifier and requested procedure identifier while delaying the adoption of the imaging reference until these critical implementation barriers have been addressed.

Care Plan / Advanced Directives / Treatment Intervention Preferences

USCDI Level 2 includes proposals to advance Care Plans and Advanced Directives. Considering the presence of various Care Plan-related data classes already in USCDI, The EHR Association supports the progression of this data class in USCDI v4. We specifically suggest the following approach:

- Rename the "Summary and Plan" data class to "Patient Care Plan"
- Rename the "Assessment and Plan of Treatment" to "Care Plan Summary"
- Introduce a care plan type data element that enables further categorization of care plans, including Advanced Directive
- Introduce a supporting information data element that enables referencing documentation such as a .pdf or scanned image representing a living will or other documentation relevant to the advanced directive
- Address a plan for progression from a mainly narrative plan summary to more structured content for the next USCDI version – such as structured goals, care team, planned/preferred interventions, and other components

We note that USCDI currently includes separate data classes for structured components of a Care Plan. However, it is essential for such structured content to evolve, which is best accomplished by including references to the relevant and prioritized data classes in the Care Plan data class. This will further enable clarity on the context in which those references are relevant.

As structured components are being considered, we recommend focusing on the fundamental commonalities across the various types of care plans, such as clinician-defined and managed general care plans, long-term care plans, multi-chronic care plans, pharmacist care plans, and patient-expressed advanced directives – including intervention preferences, care experience preferences, and other structured components. The currently proposed Treatment Intervention Preferences should also be evaluated with that consideration; the concept is not a Goal as currently proposed. Rather, it expresses more a preference for specific actions that should or should not be performed, which a clinician would translate into appropriate portable medical orders. Resolving these alignment challenges would establish a robust USCDI Care Plan data class that further specialized care plans, whether clinician or patient-authored, can build upon.

Test Kit Unique Identifier

USCDI Level 2 includes a proposal to add a test kit unique identifier to USCDI v4. The EHR Association is concerned with introducing the data element as proposed, as it suggests support for the Unique Device Identifier (UDI), which requires support not only of the necessary components of a UDI (device identifier and the available production identifiers) but also a model name and manufacturer name, which are not part of a UDI but are more commonly available.

We recognize the interest to have such data available for a number of purposes, such as provider organizations determining whether to trend data from different devices for the same test together as well as analysis and research in public health, the FDA, and other organizations. Given the current data flow from an analyzer through the laboratory, capturing test kit identifying information remains a challenge. A model name and manufacturer name are most commonly made available from a laboratory. However, obtaining the device identifier and other production identifiers is not yet practical until such information is automatically transmitted with the result or easily scanned from the test kit. Thus, including support for the UDI is premature until such implementation challenges have been addressed – particularly the ability to collect the necessary data by the laboratory and resolve when a laboratory should share that data care-focused health IT and/or directly with the research-focused health IT.

The EHR Association recommends postponing the inclusion of both the model and manufacturer names and the UDI for a future USCDI version once the implementation challenges have been addressed. We further suggest that not all health IT needs to support these elements to be certified.

Vaccination Event Record Type

USCDI Level 2 includes a proposal to add a vaccination event record type in USCDI v4, particularly to indicate whether the vaccination is a historical recording or a current vaccination being documented. The EHR Association notes that systems recording and reporting on vaccinations widely support this distinction, thus including it in USCDI v4 is a reasonable addition to the Immunization data class.

Medication Administration

USCDI Level 2 includes a proposal to add a medication-administered code data element in USCDI v4. The EHR Association is concerned with the addition of this data element, as it effectively introduces the Level 2 Medication Administration data class/element. Many health IT systems do not document the actual administration of a prescribed medication unless administered by the health care provider. Considering that medication adherence has been proposed and can be more widely adopted, we recommend that medication administration is addressed once USCDI is not required for all health IT, and that it should only be applicable for administrations performed by a provider.