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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,

On behalf of our 29 member companies, the HIMSS Electronic Health Record (EHR) Association appreciates the opportunity to provide feedback to the ONC on the Draft USCDI v5. 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 is addressed through targeted standards, implementation guides, and certification requirements.

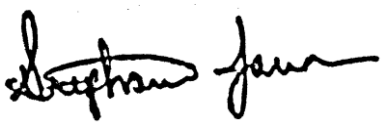
As the national trade association of EHR developers, EHR Association member companies serve the vast majority of hospital, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs and other health IT across the United States. Together, we work to improve the quality and efficiency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

As we previously communicated in our Comments on the Draft United States Core Data for Interoperability (USCDI) v4 and highlighted in our *Health Data Management* article, The Rationale for Changing the 'All or Nothing' Approach to USCDI Certification, health IT should be required to support only the functionalities relevant to its specific use cases, rather than being required to support all USCDI to be eligible for certification. For example, specialty EHRs should not be required to perform all of the functions an EHR would support to enable a large health system, nor data managed in an external administrative system. Similarly, a laboratory information system (LIS) should not be required to support all clinical data if not applicable to its use.

The USCDI v5 includes proposed data classes and elements that are valuable for progressing toward covering all EHI. However, some could not be reasonably expected to be supported by all certified health IT. Many of the suggested data elements are reasonable for narrow, highly specific scenarios, 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 v5 – 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 scenarios in our detailed comments below.

Sincerely,



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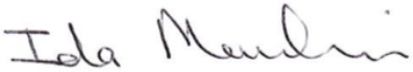
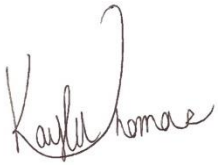


Ida Mantashi
Modernizing Medicine



Kayla Thomas
Oracle Health

General Comments

The EHR Association offers the following general feedback to better align USCDI's perceived scope and the actual scope outlined in the supporting standards and implementation guides used in ONC's certification program. These adjustments would also enhance the ability of specialty EHRs and other health IT systems that would benefit from certification to be certified to the focused scope of such health IT.

USCDI Alignment with Supporting Standards and Implementation Guidance

The EHR Association notes that the use of USCDI upon its publication to update the HL7 FHIR US Core and HL7 CDA C-CDA implementation guides leads to a clearer intent of data classes and elements, yet also introduces discrepancies between the definitions in USCDI and those in HL7. We strongly urge ONC to update the applicable USCDI versions where these discrepancies were introduced, as well as subsequent versions, to ensure users of either standard can reach the same interpretations and expectations regarding scope and intent. This is particularly important for certified health IT as the certification effectively requires conformance to both sets of standards, and for most readers and users, it is not clear which interpretation prevails.

We have identified the following instances in which the differences are significant enough to necessitate updates and clarifications in USCDI. The EHR Association requests written confirmation from ONC regarding our interpretations below, where there are gaps in standards support and USCDI guidance. While many of these have been acknowledged verbally, these interpretations are unlikely to be implemented consistently in the absence of written clarification.

Procedures

USCDI v3 defines procedures as any activity performed for or on a patient as part of care provision. This definition encompasses a wide range of activities that are not typically classified as "procedures" in FHIR and/or C-CDA. The EHR Association recommends narrowing the scope of procedures to only include activities explicitly categorized in dedicated data classes such as laboratory, immunization, clinical tests, diagnostic imaging, and vital signs. For activities not specifically mentioned, we propose incorporating them into the Procedures definition, similar to the approach for SDOH interventions. Furthermore, we suggest that surgical procedures be explicitly included within the Procedures category, as they are commonly recognized as procedures, and for many, they might be the only activities considered as "procedures."

Procedures Performance Time

USCDI v4 includes medication administration times as an example for the Procedures Performance Time data element, which implies the need for recording an administration. Particularly considering Immunizations is a specifically recognized data class, we recommend removing the medication example.

Facility Information

USCDI v4 includes Facility Information as a standalone data class without any references to the data classes and context where this is considered relevant. While facility and location information may be relevant in many contexts, the intent is to identify where the encounter occurred. In FHIR US Core and C-CDA, this information is generally associated with the Encounter and identifies the data classes that reference Encounter. This association enables the inference of location through that linkage. When the Encounter location is not applicable, the information should (not shall) be provided within the resource itself, using the attribute or possibly the event-location extension to encourage consistent placement of the location. This approach is adopted in several profiles, including:

- US Core DiagnosticReport Profile for Laboratory Results Reporting
- US Core Immunization Profile
- US Core MedicationDispense Profile
- US Core Observation Clinical Result Profile
- US Core Procedure Profile
- US Core ServiceRequest Profile

The EHR Association suggests updating USCDI to more accurately reflect this targeted scope and adjusting it as the scope expands over time.

Workflow Context

In the context of workflows, USCDI's broad definitions of data classes can lead to interpretations that extend beyond merely viewing or accessing data (such as verifying the presence of an order). These interpretations could encompass actions that initiate or manage workflows, including the placement of an order or reporting results in response to that order. To address this, the EHR Association recommends including a statement of purpose as part of an introduction, explicitly stating that the USCDI's current focus is on enabling access and viewing of documented data classes and elements within certified health IT. Additionally, if USCDI is intended to support other use cases that do not directly relate to the certification scope for health IT, these uses should be clearly delineated to avoid confusion.

Vocabulary

References to vocabulary are mostly to the overall code system rather than to specific subsets or branches that are applicable. Although there are instances, such as with Clinical Notes, where references are made to very specific LOINC codes, the absence of a more targeted intermediate set of codes presents challenges. For example, questions arise regarding what Clinical Tests should be considered, the full scope of Procedures, and which SDOH assessment tools are recognized widely enough to be supported for viewing, if not documentation. The EHR Association suggests the vocabulary within USCDI be more precisely defined and tailored to ensure the appropriateness of its scope.

Document vs. Note

USCDI v1 began conflating the concepts of a structured document and narrative summary note by using the same LOINC code for both. For instance, the same LOINC code is used for the C-CDA Document Type Discharge Summary and the Discharge Summary narrative note. This overlap is

now leading to the anticipated challenges that were raised, as it is not possible to query for either type of document where necessary. Furthermore, this situation highlights the importance of categorizing related or similar LOINC codes, enabling the retrieval of all items related to, for example, discharge summaries whether they are notes or documents. The EHR Association suggests that ONC work with Regenstrief to identify appropriate categories and specific LOINC codes to distinguish narrative summaries from structured documents and adjust USCDI accordingly.

Patient Expressed vs. Authored

In USCDI, various data classes and elements indicate "Patient Authored" though "Patient Expressed" would be a more encompassing term. “Patient Expressed” captures information conveyed by the patient but documented or authored by a clinician, such as in the case of various preference data elements. Using "patient authored" implies that the health IT must enable patients to directly input their information. We understand that this requirement is not the ONC's intent, but is a potential interpretation. The EHR Association proposes adopting "patient-expressed" as the standard terminology and clarifying that the current scope does not necessitate health IT systems to support direct patient authorship of content (for example, through FHIR writes, portal-based forms, etc.). Instead, it should be specified that if health IT systems do support direct patient inputs, such information should be accessible.

Specimen Condition Applicability

USCDI v4 provides a definition that implies a focus on the applicability of a specimen for a particular test based on its condition. During ballot reconciliation of FHIR US Core 7.0.0, it was clarified that the emphasis should be on the condition of the specimen, which then informs its applicability for particular tests. The approach acknowledges that certain conditions would still allow for a test to be valid, or performed with annotations, while other conditions would be unsuitable to perform certain tests. The EHR Association recommends updating USCDI v4 to align with this clarified understanding and renaming the term to more accurately reflect its intent and scope.

Given the focus on USCDI v3 moving forward, the EHR Association suggests that this refresh process should not be limited to starting with USCDI v5 but also be applied to USCDI v3 and v4. This approach ensures that the foundational and subsequent versions of USCDI align with current understanding and expectations.

Additionally, it is advised that the introductory sections of USCDI explicitly state that, where specific standards have been identified, certification will be based on demonstrating and implementing USCDI’s intended purposes through these standards. This clarification will help in determining conformance to USCDI, ensuring that the application of standards is both clear and consistent across different versions and implementations of USCDI.

Specialty EHR and Other Health IT Certification Opportunity

The EHR Association supports the growth and eventual expansion of USCDI to include the ability to electronically access all PHI using agreed-upon interoperability standards. As USCDI continues to grow, however, it becomes increasingly evident that not all health IT systems that could benefit from

certification can feasibly achieve it. The introduction of USCDI+ has not significantly altered this situation. While this issue doesn't directly undermine USCDI's utility, resolving it within the ONC's certification program could enhance USCDI's value.

We suggest that ONC refine USCDI's focus on ePHI as the superset and modify the certification program accordingly, requiring health IT to only be certified to the data it actively manages. This would entail requiring health IT systems to demonstrate the capability of representing that data at the discrete level of standards used in certification supporting USCDI, rather than solely as received in narrative text or documents – which can be made available in their entirety for viewing purposes only. Until that time, health IT that are appropriate sources of PHI, such as laboratory systems and specialty EHRs, will remain uncertifiable, thus providing limited availability of predictable and consistent access to relevant data for both patients and providers.

Clinical Notes

Emergency Department Note

The EHR Association endorses the inclusion of an "Emergency Department Note" data element but proposes a modification to its definition. Instead of defining it as a "Summary of care delivered in an emergency department," we suggest defining it as a "Narrative summary of care delivered in an emergency department." This change emphasizes the element's purpose for narrative summaries rather than documents, which would align more closely with a document reference.

Furthermore, we recommend specifying that the suggested LOINC code could be replaced with another LOINC code that offers a clearer distinction between a narrative note and a full document. This replacement should be considered in future updates to the HL7 FHIR US Core and HL7 CDA C-CDA implementation guides.

Operative Note

For the "Operative Note" data element, we similarly advocate for a revision of the definition. Rather than "Summary of a surgical procedure," we propose "Narrative summary of a surgical procedure" to underscore the element's use for narrative purposes as opposed to documentation.

Again, it is suggested that the recommended LOINC code may be substituted with a LOINC code that better differentiates between a narrative note and a complete document, potentially during future revisions of the HL7 FHIR US Core and HL7 CDA C-CDA implementation guides.

Immunizations

Lot Number

The EHR Association supports the addition of the "Lot Number" data element with the following modifications:

- Amend the proposed definition from "quantity" to "lot" to more precisely convey the element's intent, which is to identify a specific batch of a product rather than its quantity.

- Eliminate the reference to LOINC vocabulary for this element, given that it will be represented as a discrete field in both FHIR and CDA standards. This change recognizes the element's standardization in these frameworks and negates the need for a LOINC code.

We further request that the ONC emphasize that the requirement for this data element, as with others, applies prospectively. It should not be mandatory for historical immunizations, recognizing that complete information may not be available for immunizations recorded from a patient's recollection or obtained from older records.

Laboratory

Test Kit Unique Device Identifier

The EHR Association advises against incorporating the “Test Kit Unique Device Identifier” data element at this stage due to its developmental immaturity and the significant operational challenges its inclusion would entail. The collection of this data is currently limited within EHR systems and, more critically, within laboratory systems. Introducing this element would necessitate new workflow steps for collecting, storing, and transmitting these identifiers, compelling LIS systems and laboratory operators to devise new methods for data entry into LIS systems before this information could reliably be made available in EHRs and beyond.

Moreover, these unique device identifiers vary significantly in their implementation and specificity, potentially leading to multiple identifiers for a single test kit based on the combination of instruments and reagents used. This variability could increase the burden of mapping these identifiers and exacerbate inconsistencies across the healthcare industry.

The EHR Association suggests that the ONC collaborate with laboratory interoperability workgroups, including the FDA and SHIELD, as well as LIS stakeholders, to identify and mitigate infrastructure gaps that currently hinder the capture and transmission of test kit and instrument identifier components in non-certified health information technologies, such as LIS.

Considering the present circumstances, initiating with the complete Unique Device Identifier (UDI) system, as defined by the FDA and applied to implantable devices, would be overly ambitious. Instead, we recommend that the ONC, in partnership with the FDA and CMS (CLIA), initially focus on enabling LIS systems to capture and communicate basic information such as reagents and manufacturer names. Subsequently, efforts can gradually extend towards incorporating the full UDI, including accounting for multiple UDIs that represent various reagent and instrument components, which cannot be collectively identified through a single UDI.

Medications

Route

The EHR Association expresses its support for including the "Route" data element. To ensure clarity and accuracy, we recommend specifying in the definition that this element refers to the prescribed route of medication administration as it is indicated on the medication request or order.

Observations

The EHR Association recommends the removal of the "Observations" data class in favor of using more specific and already defined data classes for the two data elements below.

Advance Directive Observations

The EHR Association supports the inclusion of the "Advance Directive" data concept to identify the existence of advance directive information and appreciates ONC's clarity in the definition to call out that this data element should represent the document's existence, not the document itself. To enhance the understanding and applicability of this data element, we propose the following steps:

- Rename the element to "Advance Health Directive" to better reflect that the concept is not limited to advance directives only, but also living wills, durable powers of attorney, and other types of directives related to end-of-life care and healthcare services more generally.
- Prioritize including the type of advance healthcare directive and its status (whether it is present or absent) in USCDI v5. This focus will help clarify the presence of such directives without delving into the specifics of the documents themselves.
- In future versions of USCDI, consider adding details such as the date and time the directive was signed, the name of the signee, and the location of or reference to the actual document.
- Establish a distinct data class titled "Advance Healthcare Directive" to house relevant data. This class would clearly separate advance directive information from concepts like "Care Plan" and "Goals and Preferences."
- Enable the referencing of the same data element across multiple data classes. For example, POLST orders (once categorized as a type of order) could be referenced both as Orders and within the context of Advance Healthcare Directives and/or Care Plans.

Sex Parameter for Clinical Use

The EHR Association supports the ONC's objectives in accurately representing a person's sex and gender in contexts relevant to tests, procedures, or services. As such, we offer the following recommendations:

1. Include a "Sex Parameter for Clinical Use" data element in USCDIv5 with a clear definition that this is a patient-level characteristic that enables the performance and/or interpretation of a test, procedure, or service in the relevant context.
2. Beyond USCDI v5, we recognize the necessity for additional industry efforts to refine how this concept could be accurately captured across different workflows or over time. Currently, the understanding and application of this concept at a contextual level are relatively undeveloped. Implementing it prematurely may lead to inconsistent implementation.

Orders

The EHR Association is supportive of expanding USCDI to include order information and proposes that the new "Orders" data class should focus on elements common to all types of orders. These elements include the ordering provider, order code, ordering date/time, and order status. Meanwhile, data specific to the type of order, such as route and frequency for medications, laterality for images, etc.,

should be documented within the respective data classes like Laboratory, Medication, Diagnostic Imaging, and Nutrition.

Incorporating ordering information specific to the Laboratory and Diagnostic Imaging data classes will provide clarity and context to USCDI implementers and users about the availability of order data based on the use case, in addition to the core order dataset. This approach also allows for greater specificity in definitions and vocabulary standards. For instance, lab orders could be coded using LOINC or SNOMED, procedure orders using CPT codes, and medication orders using RXNorm.

Regarding Do Not Resuscitate (DNR) orders, we suggest that it is premature to add this type of order as the standards and implementation guidance necessary to document this type of order have not been finalized. Once established, we suggest this would similarly be related to the Advance Healthcare Directives data class to provide further context and data beyond the core order data set.

Finally, the EHR Association requests clarification in the USCDI definition of “Orders” to indicate that while the data reflects order information, it does not imply a comprehensive ordering workflow management. Currently, neither HL7 FHIR US Core nor HL7 CDA C-CDA standards provide the necessary implementation guidance to support complete ordering workflow management. While HL7 FHIR US Core may evolve to support this functionality, HL7 CDA C-CDA is not suited for workflow management tasks.

Patient Demographics/Information

Name to Use

The EHR Association supports the inclusion of the “Name to Use” data element. To align with industry terminology, we recommend renaming this element to "Preferred Name" or "Patient Preferred Name."

Additionally, we propose the introduction of a "Legal Name" data element or an explicit clarification that existing fields for first, last, and middle names should be utilized for legal name purposes. This distinction is crucial for ensuring clarity regarding which names should be supplied for patient demographics.

Pronoun

The EHR Association supports the inclusion of the “Pronoun” data element.

Interpreter Needed

The EHR Association supports the inclusion of an “Interpreter Needed” data element and recommends augmenting it with additional details to specify the language for which interpretation is required, such as "Spanish to English."

Provenance

Author

The EHR Association suggests engaging in further standards discussions before adding the "Author" data element. There needs to be clarity on representing authorship across various workflows, including those

involving multiple authors (e.g., co-signed orders, multi-disciplinary care planning, shared notes, or differing authors for preliminary and finalized results).

Moreover, author information should only be expected when data has been documented in the system of record by an individual user. For data received from other systems (such as via interface) or converted from historical records, which may lack detailed author information, it should be permissible to omit this detail or attribute the data at a broader level, such as to an organization.

We also advise setting clear expectations regarding the applicability of different types of authors to various data types. For instance, while a patient might document a home blood pressure reading, it would be unreasonable to expect a scenario where a patient is the author of a medication prescription.

Author Role

Similar to our feedback on the "Author" data element above, we urge further discussions before incorporating the "Author Role" data element into USCDI due to potential misinterpretations without clearer definitions. The combination of "Author" and "Author Role" could lead to varied interpretations, such as identifying the individual who documented the data, the source of the information, the requester of the data element, or the person who reconciled the data.

The complexity of defining "Author" and "Author Role" is highlighted by the following scenarios, illustrating the need for greater industry maturity and dialogue before these elements are finalized in a USCDI data class:

- If an attending physician asks a resident to place an order on their behalf, who is considered the author? Is it the requesting physician or the resident who executed the order?
- When a patient informs their primary care physician (PCP) of a positive COVID test result, and the physician records this historical information, who is the author? The patient, as the source, or the physician who entered the data?
- For historical lab results transferred from a previous system, lacking specific clinician details or referencing a clinician by name who is no longer affiliated with the organization, how should "Author" and "Author Role" be determined?
- When a patient shares their Personally Generated Health Data (PGHD) and a clinician documents it in the EHR, who should be identified as the author? The patient providing the information, or the clinician who records it?

USCDI Level 2 Proposals

We offer the following considerations for various Level 2 proposals that are being considered for inclusion in USCDI v5.

Encounter Location

The EHR Association recommends adding the existing FHIR location.type coding system to the list of expected vocabularies. HL7.TERMINOLOGY\ServiceDeliveryLocationRoleType - FHIR v4.0.1

Clinical Notes - Maternal Social Determinants of Health Note

The EHR Association recommends collecting further provider feedback on which note types would be most valuable to add to the "Clinical Notes" data class. Prioritization is needed to ensure the most applicable and useful data elements are added to USCDI and in the appropriate order, based on priority.

Furthermore, for any new clinical note types considered for addition, we recommend the identification and assignment of LOINC codes to facilitate standardized implementation across health IT systems.

Health Insurance Information

The EHR Association recognizes the interest in including various Health Insurance Information data elements from Level 2 into USCDI v5, specifically:

- Coverage Period
- Medicare Patient Identifier
- Payer Name
- Plan Name
- Group Name

We support the inclusion of these elements as they are already incorporated in FHIR US Core and CDA C-CDA. However, we suggest renaming the Medicare Patient Identifier to Medicare Beneficiary Identifier to align with CMS terminology. Additionally, we recommend that the ONC collaborate with CMS and HL7 to enhance implementation guidance, particularly for consistently capturing the payer name and group name. Early implementation experiences reveal discrepancies between the information displayed on a typical insurance card versus the details preferred for real-time eligibility (RTE) queries with health plans. This disparity can diminish the value of sharing this information when different entities interpret the data differently.

The EHR Association does not, however, support suggestions to advance "Policy Number" and "Plan Identifier" from Level 2, as further clarity is needed on their use cases and the extent to which either data element is already covered by the FHIR US Core / CDA C-CDA plan number or other attributes. Following a thorough review, we suggest that ONC updates the Level 2 proposals for these fields accordingly, which may include updating the names, consolidating the proposals, or removing one or both elements to ensure clarity and relevance in their application.