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Micky Tripathi, Ph.D., M.P.P.
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

Dear Dr. Tripathi,

On behalf of our 29 member companies, the HIMSS Electronic Health Record (EHR) Association is eager to initiate deeper conversations regarding our members' concerns about USCDI modeling. As the national trade association of EHR developers, our member companies play a pivotal role in serving the extensive network of healthcare providers – including hospitals, post-acute care facilities, specialty-specific clinics, and ambulatory healthcare providers – utilizing EHRs and other health IT solutions across the country.

As a follow-up to our discussions, the USCDI presents increasing challenges for all relevant health IT – specifically in the growing challenges arising from the increasing ambiguity of USCDI data classes. Additionally, in the case of specialized EHRs and other targeted health IT such as laboratory, radiology, and imaging systems, it can be difficult to support all necessary USCDI data classes due to many data types being inapplicable for the systems and their users.

As the USCDI and USCDI+ continue to expand into areas with less defined or mature standards, the ambiguity of vague definitions is creating increased challenges. This is of particular concern for certified health IT, as the gap is widening between what data is made available through adherence to defined HL7 FHIR US Core and HL7 CDA C-CDA specifications, and the ambiguity of USCDI. The lack of clarity risks missed expectations, unnecessary effort by the healthcare industry, and increased burden on provider systems to implement future USCDI classes in an overly complex and vague way. This ultimately decreases the effectiveness of standards-based interoperability, and conflicts with the stated prioritization criteria for USCDI expansion of ensuring only modest burden on health IT developers, standards developers, and healthcare providers as expressed in the July 2023 ONC Health IT Standards Bulletin.

We strongly urge the ONC to reduce ambiguity and increase clarity regarding the intended scope of USCDI data classes and elements. This would provide clarity for standards developers to address gaps necessary to support the next standard and/or implementation guide version and for the industry to

better understand available standards-based interoperability without having to understand all the details of the enabling standards and implementation guides.

The following provides examples of ambiguity that should be addressed.

1. We recently became aware that there are substantially different interpretations regarding whether Medication Administration is covered in USCDI. This became apparent in the context of addressing how to represent Medication Adherence (introduced in USCDI v4) as an example, although the discrepancy in interpretation apparently already existed in USCDI v3. According to a USCDI author, one could consider the combination of USCDI Medication and USCDI Procedure to indicate that Medication Administration is covered.

   Such an interpretation is quite different from one used in interoperability where a Medication Administration is not considered a Procedure and those terms are used for different concepts; in HL7 v2, HL7 CDA C-CDA, and HL7 FHIR, these are two separate and distinct data classes. The focus of a Medication Administration is on the drug codes, route, etc., and does not include the use of a CPT code for example, while the Procedure focuses on the activity being performed and does include CPT 4 codes.

   A similar disagreement has surfaced in USCDI v3 where feedback on dates/times for the Laboratory data class started to reference dates/times in the Procedure to already be present.

   The USCDI documentation does not clarify its intent, thus leading standards developers to spend excessive time attempting to interpret and identify the appropriate scope and boundaries, often arriving at conclusions that may be different from others' interpretations of USCDI. Thus, some expect in this example that Medication Administration is to be covered, yet certified capabilities do not include that.

2. In addition to scenarios similar to Medication Administration, which potentially require the use of two USCDI data classes to determine whether it is supported, we are concerned about USCDI data classes that are defined yet cannot exist on their own. For example, Facility Information has limited or no meaning without understanding the context in which a facility may be relevant and the level of detail of the facility. However, no indication of facility relevancy is included in USCDI. While the Encounter has an Encounter Location data element (which is a type of facility, although unclear at what level of granularity this would be of interest, e.g., hospital, building, clinic, room, or bed location), no other USCDI data classes provide even that minimum level of guidance. If the definition is taken literally, it is only a listing of facilities. But in the context of potential interpretations that require combining data classes to understand intent, it would not be clear which one(s) it should be associated with.

3. Data classes that represent a concept that is managed in workflows such as order entry, referral requests, and results reporting do not clearly indicate which aspect of the workflow the data class is meant to represent. There are distinct but similarly named data requirements whether one is ordering a laboratory test, medication, or procedure vs. resulting. Data critical to the

definition of the test, medication, or procedure is relevant, but ordering information is different than the recording of the actual results, administration, or performance. Considering the Laboratory data elements, the focus seems to be on the lab results, not the lab order. Yet the introduction of the Reason for Referral could cause one to infer that laboratory orders are covered by USCDI. That would make the values/results, result unit of measure, result reference range, result status, and result interpretation irrelevant, while the specimen type and (to a lesser extent) source site could be either and the specimen condition acceptability questionable. At the same time, critical ordering data would be missing.

Understanding these differences is critical to understanding what constructs to include in HL7 FHIR US Core and HL7 CDA C-CDA, even if only currently used in query context.

4. Many of the vocabulary references indicate the overall code system only, not a particular branch. For example, when referencing LOINC, SNOMED, ICD, and CPT, the codesets are so large that they do not convey the scope sufficiently. Additionally, these may be used in different data classes with different subsets of codes. Specifying codes or sets of codes would reduce this ambiguity.

5. As a consequence of referencing LOINC codes as document types, Clinical Notes are defined in a manner that could cause them to be considered document types rather than more focused narrative note types. As a result, the same LOINC code is now used for a document type that can include a narrative note and structured data, while the narrative note as implemented in FHIR US Core focuses on the narrative note.

6. A USCDI data class may not be clear in its scope as to whether it includes a patient-expressed or clinician-expressed concept. For example, allergies and intolerances may be documented as expressed by a patient and include statements that indicate the patient does not know whether they are still allergic in the case of a previously recorded allergy. Meanwhile, an allergy documented as expressed by a clinician may have a more definitive expression, although it still may be as believed rather than as tested.

   The perspective of the documenter is not sufficiently identified which leads some standards developers to scope it with a focus on the clinician, while others may interpret USCDI and have an expectation that both the patient's and clinician’s perspectives are included.

7. There are also numerous data elements with a general ambiguity in the overall intended scope and definition that leave far too much room for variable interpretations and applications. The most obvious example of this is the Health Status Assessments data class which includes elements such as Functional Status, Disability Status, Mental/Cognitive Status, Alcohol Use, Substance Use, and Physical Activity which are woefully under-defined. All of the named elements cite LOINC as a vocabulary standard but lack any specificity on distinct assessments or instruments that should be coalesced around as an industry for representing and exchanging the data (at least as an initial minimum starter set). This inherently leads to inconsistency in real-world application which waters down the value and purposes of standardizing these concepts for exchange in the first place.

8. As these challenges arise, one would consider the submission to better understand what may be intended. However, that could yield a different scope than what the definition seems to state. For example, references to an implementation guide do not mean that the entire guide is to be included, but do not clarify which subset may apply.

   Examples include the USCDI Coverage Type for which the submission seems to provide more clarity. However, concluding that the entire submission would apply would be inappropriate, which leaves questions as to the intended scope. Another example is the introduction of Clinical Experience Preference or Treatment Intervention Preference, which could have multiple interpretations based on the submission – the definitions are excessively broad such that it is unclear as to whether they are to be expressed by the patient or the provider. Therefore, the choice of what to use in the standards can be unclear. Similarly, the proposed vocabulary is excessively broad as well, particularly in determining whether it is intended to focus on the question, the answer, or both.

   See HL7's Response Letter to the USCDI v5, which also addresses many of these concerns.

As USCDI and USCDI+ advance to encompass electronic health information (EHI), standards-based interoperability will be driven for all EHI. With the addition of new data elements in future versions, these ambiguities will further hinder the interpretation and alignment of expectations regarding what can be reasonably advanced in a 12 to 24-month cycle.

In consideration of the current modeling methodology's lack of the needed clarity, the EHR Association strongly urges ONC to consider the following enhancements:

1. Utilize multiple tools to decrease ambiguity. Consider tools such as working with HL7 to name specific FHIR resources and resource categories, define very specific inclusion and exclusion criteria, and provide more in-depth definitions with clear examples of what is or is not in scope for a given data class.

2. Provide more specific bindings beyond a general reference to a code system. In some instances, this may include defining specific minimum sets of values or instruments to support where implementers still have the flexibility to go above and beyond where needed.

3. Reposition the links to the submission and add further clarifications, including:

   a. Submission documentation is not part of the definition and scope of the USCDI data class or data element, but rather for background information and context only.

   b. Future USCDI versions may incorporate other aspects raised in the submission.

4. Express the perspective of the data class explicitly. For example, whether it is intended to represent the definition of, the request for, the performance of, and/or the results of the data class. Splitting these perspectives is generally far more clear than combining them, as data element requirements may vary depending on context.

We appreciate your ongoing partnership and your consideration of these improvement opportunities. If needed, we will be happy to discuss them in an upcoming meeting for further context and clarification.

Sincerely,

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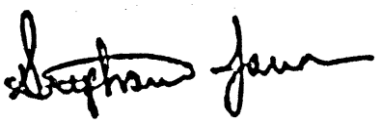

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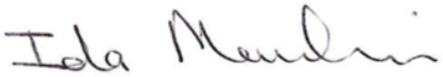

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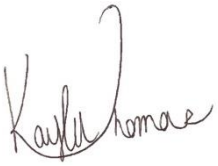

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Established in 2004, the Electronic Health Record (EHR) Association is comprised of 29 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

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