Cerner Corporation USCDI V2 Inquiries and Feedback

Link to CFS-3307 Ticket

General Feedback

As a general point of feedback on the adoption of USCDI V2, it appears that ONC has taken a path of using the new finalized USCDI V2 to include data elements that have not yet been profiled in key exchange standards (e.g., HL7® FHIR® US Core and HL7® CDA C-CDA) and using their adoption as a push to Standards Development Organizations (SDO) to profile them in their key exchange standards. While we understand and appreciate the desire to use USCDI to push the industry forward for supporting exchange of key data elements significant to high priority federal and industry needs, e.g., data elements focusing on health equity and for public health reporting during the pandemic, we are concerned that using the USCDI in this way will challenge the quality and value of data being exchanged. Until the necessary guidance is published and recognized the lack of consensus standards is likely to create inconsistency in the format and specifications used by various actors to exchange these key data elements and/or may delay adoption.

> **ONC Response –** A system's ability to capture and access new USCDI v2 data elements is the first component of the updates needed to implement USCDI v2. However, ONC appreciates the need for mature and updated US Core and C-CDA specifications that incorporate the new USCDI v2 data elements, as it is through these specifications that exchange of USCDI data elements are achieved. For this reason, ONC has delayed the Standards Version Advancement Process (SVAP) comment period by 7 months, to May 2, 2022, to allow the development of newer versions of these implementation guides so they also can be considered for SVAP Approved Standards for 2022.

The USCDI is rightfully considered the essential data set for supporting exchange, and, as new versions are released, healthcare providers want to ensure they maintain contemporary capability to support exchange. This is driven both by a genuine desire to advance standards-based interoperability for all electronic health information as well as to avoid a perceived compliance risk that accrues to not keeping up. While this is positive, it also raises the concern that exchange that is not supported by adopted standards may result in different formats and value sets being used by developers, providers, and others customizing ways to fit new data elements into adaptations of various exchange mechanisms (e.g., FHIR resources, C-CDA sections, HL7 v2 segments) in ways that are not necessarily appropriate or intended for it. Further, given the significance of certified HIT developer uptake in support of the new versions of USCDI in SVAP, taking this approach could dampen HIT developer willingness to take on support for data elements where consensus standards have not been identified or well adopted into use. Such developers may also be faced with eventual needs to prove out their support for new USCDI versions in Real World Testing, which, while downstream from new version adoption, still weighs heavily in the minds of developers.

> **ONC Response –** ONC works with standards developers at HL7 to ensure alignment of terminology and vocabulary bindings across all relevant standards, including USCDI v2, FHIR US Core, and C-CDA. ONC's engagement with SDOs and the recently announced SVAP delay is designed to allow for this alignment between these exchange standards and new versions of USCDI.

In our view, a better approach would be to develop a process for identifying high-level candidate data classes/elements ahead of issuing each annual USCDI draft version (e.g., an "ONC-endorsed" subset of Level 2 elements) that could be used as a trigger for SDOs to pursue profiling so that established specifications exist – at least for the key exchange standards of HL7® FHIR® US Core and HL7® CDA C-CDA – before a new data element is actually adopted in a final USCDI version. Additionally, we would minimally recommend that ONC take such an approach as it relates to approving new USCDI versions for the Standards Version Advancement Process (SVAP). In other words, new versions of USCDI should not be approved for voluntary certification until appropriate standard specifications for each new data class/element have been published. The corresponding versions of the applicable standards (presumably new versions of HL7® FHIR® US Core and HL7® CDA C-CDA) must also be linked with the approval of any new version.

ONC Response – The current process is designed to not only identify submitted data elements of sufficient maturity to make them potentially implementable (Level 2) but also to identify the criteria ONC uses to prioritize among those Level 2 data elements for consideration for future versions of USCDI. The Draft USCDI version published each January includes what ONC considers to be the right set of additional data elements for the next final version of USCDI, which ONC publishes each July. ONC engages with SDOs at each step of the process to signal ONC's intent in developing USCDI to allow sufficient time for planning and designing of future versions of implementation guides for exchange of new USCDI data elements.

General Inquiries

1. We have noticed that each newly adopted data element provides a link to the associated public submission that the element originated from. What is unclear is whether this is provided purely for referential purposes, or if the content of the submissions being referenced is somehow intended as normative or authoritative in some way. We are assuming the former as the submissions are not at a suitable level of formality to be cited as such but recommend ONC provide this clarity to avoid confusion for stakeholders.

   ONC Response– We maintain the original submission information to provide greater transparency into the process. Should a data element be considered for addition to future versions of USCDI, we will edit certain pieces of information, especially the data element name, definition, and applicable vocabular standards. This information will be prominently displayed on HealthIT.gov/USCDI and must be concise and may reflect a potentially broader use of the submitted data element.

2. The following newly adopted USCDI data elements are not provided with an explicit definition. While some of these elements may be considered self-explanatory, it is important to establish a definition to ensure a common understanding of the intent and scope of each data element. For example, the Care Team Member Identifier element seems to be intended to encompass unique identifiers for healthcare providers, such as an NPI. But without definition this could be understood as being something like the person's title at the organization (e.g., Registered Nurse). We ask that ONC publish definitions for these data elements and, where relevant, take into consideration the additional questions we've outlined below that merit response by ONC in development of those definitions (and associated guidance).
   a. Care Team Member Name
   b. Care Team Member Identifier
   c. Encounter Diagnosis
   d. Encounter Type

   ONC Response– Thank you for the input. It is ONC's intent to provide clear data class and element definitions where needed and will continue to improve on these through our Certification Companion Guides (CCGs) and future versions of USCDI.

Requests for Clarification

As our clarification requests to follow will outline, there is general ambiguity regarding the intent and scope of several new data classes and elements. As referenced above, not all data elements have a clear definition (or any definition at all) and seem to rely on the submission details, even though the submissions may not have been accepted in totality or needed further clarifications to be implementable. This highlights the need for clear and complete definitions and more focused guidance beyond the basic name for the data class/element where one is provided.

1. One of the concerns with the new Care Team data elements (most specifically the CareTeam Name, Care Team Member Location, and Care Team Member Telecom elements) is that there are instances where it may not be appropriate to expose personal information of care team members. For example, an organization may not wish to provide the full name or contact information of a nursing care team member, and there may even be instances in which doing so creates a risk of harassment for the care team member. Is it safe to assume that the intent is for entities to have full flexibility for choosing when or whether to expose such data elements about a care team member? Are there limitations with such flexibility (e.g., physician providers are expected to have all elements made available but other clinician

and non-clinician care team members are flexible)? Providing this guidance as part of the data elements in question would be beneficial for the industry.

ONC Response – The standards associated with USCDI data elements relate to building capabilities of health IT systems to capture and exchange data elements. Where standards and formats are not specified in USCDI or in the supporting exchange standards (FHIR US Core, C-CDA) there is flexibility to health IT developers and implementers to design these data elements that meet the needs of end users. This includes the extent to which each Care Team Member is represented in the record and exchange document and the amount of detail that is included.

2. Regarding the Care Team Member Location data element, the definition provided ("Physical location of provider or other care team member") lacks sufficient specificity to appropriately support the element. For example, is this simply intended to be the location where the patient received care (i.e., the facility of an encounter)? And if so, how would the concept of location apply to longitudinal clinical care team members for whom a single associated location may not be appropriate, or for non-clinical care team members (e.g., family members, clergy, etc.) who are not providing a service but who have a long term relationship to the patient of a non-clinical variety? On the other hand, is this intended to be more of a contact method (e.g., mailing address) for the care team member and not necessarily related to locations where care was directly provided? These are just some of the questions that the data element, as adopted, leaves unanswered which highlights the need for additional guidance on the intent and constraints of the data element.

   ONC Response – Care Team Member information is intended to capture details related to the episode of care. Thus, if a Care Team Member was a family member, Location would indicate that the family member was in the clinic, unless the intent was to indicate that a family member would provide care elsewhere, such as in the home. This flexibility is intentional and the way it is implemented is left to the developer and implementer.

3. Regarding the Care Team Member Telecom data element, generally "telecom" can refer to multiple types of electronic communication. For example, the contactPoint data type used for the Practitioner.telecom attribute in FHIR R4 can be a phone number, fax, e-mail, SMS, URL, or other types of contact methods. The submission cited as the source for this new data element also identifies options like a Direct address or FHIR endpoint as possibilities as those could be used to send electronic notifications in alignment with CMS Condition of Participation requirements (and also aligns with CMS requirements for electronic contact information in the National Plan & Provider Enumeration System (NPPES)). However, the standards adopted (ITU-T E.123, Series E & ITU-T E.164, Series E) suggest that this is intended exclusively to be a telephone number for the care team member. Was this truly the intent? If not (i.e., if the data element is intended to encompass a more expansive set of electronic contact methods), then it is critical that ONC remove those standards and specify in the definition (and/or within supporting guidance) the specific electronic contact methods allowable or intended as part of the data element.

   ONC Response – Care Team Member Telecom is defined as electronic contact information of a provider or other care team member, with the applicable vocabulary standards ITU-TE.123 and ITU-T E.164. These standards cover multiple forms of telecom, including telephone, email, and web address. We believe that this is compatible with the way in which FHIR US Core implements Patient.telecom.

4. Regarding the Clinical Tests data class, while the intent appears to have been for this to be a "catch-all" data class for any types of medical testing that would not fall into the Laboratory or Diagnostic Imaging data classes, the lack of specificity makes this one difficult to apply. Since

LOINC is adopted as the standard, a defined set of specific codes for this data class is needed for implementers to appropriately scope it. As an additional note, one of the specific examples provided is electrocardiogram (ECG) tests. We had previously understood this to qualify as diagnostic imaging and so would not present as a valid example of a Clinical Test, which illustrates the ambiguity with this data class.

ONC Response – ONC provided a small list of examples in the definition but appreciate the recommendation to provide a more extensive list of applicable clinical tests. Such a list was recommended by the HITAC and will be considered as a "starter value set" in future Certification Companion Guides, as well as future versions of USCDI.

5. Regarding the Encounter Diagnosis data element, the adoption of SNOMED-CT and ICD- 10-CM as standards seems to imply that this is only intended as coded diagnoses as opposed to the free text reason for visit generally captured as a patient-stated reason for the encounter. Additionally, it is unclear whether this element is intended to encompass any particular "type" of encounter-level diagnosis (e.g., admission vs. working vs. discharge vs billing, etc.) or simply all types of coded diagnoses for an encounter. Providing this clarity would enable standards developers and implementers to determine how best to support this data element within downstream exchange specifications.

   ONC Response – The intent and definition of this data element is to capture the coded diagnosis associated with an encounter. Additional details are not included to allow for flexibility to use this code for different purposes while maintaining the ability to capture and exchange coded diagnoses.

6. Regarding the Encounter Location data element, it is unclear whether the intent is to represent the actual physical location at which care took place, or the facility/organization that was responsible for the provision of care. The distinction is a subtle yet important one, especially in cases such as a home care visit or where the specific performing site is one of several within the same practice or facility and bears a difference for the purpose at hand. Ultimately, the distinction dictates how this data element would be represented in FHIR – if the former, the Encounter.location.location attribute would be leveraged; if the latter, the Encounter.serviceProvider attribute would be leveraged.

   ONC Response – This data element is defined as the "physical location of facility which delivered a person's health care or related services". While the location could be the same location as the facility or organization providing that care, it was intended to capture the location of the care.

7. Regarding the Date of Diagnosis element, the definition provided stating the "date of first determination by a qualified professional" is problematic as it does not conform well to concepts supported in EHRs. As we expressed in our submitted comments on the draft USCDI V2, there are four possible date/time aspects to consider for problems: *Onset Date*, *Asserted Date*, *Recorded Date (original)*, and *Record Date (local system)*. We've used the below example scenario to define each of those four.

   - A patient schedules an appointment with Dr. Jones to discuss issues they have been having with breathing difficulty since January 2021.
     - This would be the *Onset Date* since it is when the condition first appeared independent of an actual diagnosis or recording in the record
   - After assessing the patient, Dr. Jones diagnoses them with asthma on February 15, 2021 at 11:00 am.
     - This would be the *Asserted Date* since it is when the provider determined the

diagnosis

- Dr. Jones' nurse then records the asthma entry to the patient's problem list later that same day at 12:30 pm.
  - This would be the *Recorded Date (original)* as it is the first time the diagnosis has been entered into the patient's record in any EHR system (it would also represent the Recorded Date (local system) for Dr. Jones' EHR exclusively)
- Following the visit, Dr. Jones refers the patient to a pulmonologist, Dr. Smith, and sends a summary of care record. Before the patient's appointment, Dr. Smith reconciles the asthma problem into her EHR system on March 1, 2021 at 9:00 am.
  - This would be the *Recorded Date (local system)* for Dr. Smith's EHR (each subsequent system that the problem is reconciled/recorded into would have its own unique Recorded Date (local system) observation).

As defined, the Date of Diagnosis element seems to align most closely with the *Asserted Date*, but this is not a concept currently supported in common exchange standards (the HL7® FHIR® US Core Condition Profile does not include it as an attribute although it is technically available as an extension on the base HL7® FHIR® Condition resource). We suggest ONC consider amending the adopted element in one of two ways: (1) specify it explicitly as the *Onset Date* and align definition accordingly, or (2) specify it explicitly as the *Recorded Date* and align definition accordingly.

ONC Response – ONC maintains the current definition of Date of Diagnosis and have communicated that with the working groups responsible for updating appropriate exchange standards FHIR US Core and C-CDA to insure accurate representation of this data element in future versions of these standards.

8. Regarding the newly adopted Date of Diagnosis and Date of Resolution data elements under the Problems data class, since these are distinct elements from both the preexisting Problems data element and newly adopted SDoH Problems/Health Concerns data element, it is unclear whether those elements apply to both SDoH and non-SDoH problems or only the latter. In other words, are Date of Diagnosis and Date of Resolution expected to be supported for SDoH problems?

   ONC Response – It is ONC's intent that these data elements apply, as needed and as appropriate to all "problems" including SDOH Problems/Health Concerns. This should be reflected in appropriate test data and certification companion guides.

As these examples clarify, absent clear definitions in USCDI and agreed to guidance on how to implement these data classes and elements in the applicable standards (particularly HL7® CDA® C- CDA and HL7® FHIR® US Core as the recognized implementation guides for USCDI), implementations may be divergent and delayed, thus missing the expectations set under the 21st Century Cures Act to enable nationwide interoperability without special effort.