2800 Rockcreek Parkway
Kansas City, MO 64117
Direct: (816) 201-1024
Fax: (816) 474-1742

April 12, 2021

Micky Tripathi, Ph.D. M.P.P.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: *United States Core Data for Interoperability (USCDI) Version 2 Draft*

Dear Dr. Tripathi,

Cerner Corporation appreciates the opportunity to submit public comment on the draft USCDI Version 2. As a leading supplier of clinical and management information systems and a market leader in health information interoperability, we believe our experience provides us with valuable insight in this subject area and are grateful for the ability to share that insight.

Cerner supports and appreciates the hard work and dedication of you and your staff behind the creation of the USCDI and the ONC New Data Element and Class (ONDEC) submission system and process for ongoing annual expansion of the USCDI. Cerner strongly supports ONC's drive for interoperability across healthcare stakeholders and recognizes the valuable role that the USCDI plays in that endeavor.

If you have any questions or if we can provide any additional information, please do not hesitate to contact me at (816) 201-1465.

Sincerely,

John Travis
Vice President & Regulatory Strategy Executive
Cerner Corporation

General Comments

Overall, Cerner appreciates ONC's proposals for the version 2 (V2) draft, which reflect a modest yet valuable step forward adopting new data elements that are already well established within critical exchange standards, such as HL7 FHIR US Core and HL7 CDA C-CDA. While expanding the USCDI is critical to move the industry forward and achieve the goals of nationwide interoperability, it is also important to do so in a controlled and deliberate manner to avoid the problems that arise when data exchange occurs absent a supporting adopted standard and without consistency amongst actors (namely, the decreased value and usability of that data at the point of care). While we respect that part of ONC's role in curating the USCDI is to lead the industry forward, because the USCDI is itself a standard that HIT developers must eventually certify to and prove out support for in Real World Testing as to new versions even before they are required as a certification standard, expansion of the USCDI should be a grounded process. To ensure successful adoption of each new USCDI version by the industry, ONC should seek to provide more advanced notice of the data classes planned for future versions to allow the standards community appropriate opportunity to draft and test implementation guidance for them. In the current state, the "Level 2" data elements designation includes far too broad of a scope of potential new elements for the standards community to pursue implementation guidance on in any short order for next version use, so a more controlled list is needed well before the USCDI version draft releases each January. Well established standards for data elements are essential to successful USCDI version updates and should be considered prerequisite to any such updates.

As the USCDI does begin to expand, we are also starting to see the need for stratifying the USCDI to identify specific actors and/or interoperability use-cases for which the various data classes and elements are intended and/or required for support. We have already seen some data elements under version 1 highlight this need. Most conspicuously, the Pediatric Vital Signs elements under the Vital Signs data class, which, while important to include in the USCDI for the clear value they have for many in the industry, are irrelevant for some actors who are held to enable support for the whole of the USCDI but who are not significantly involved with pediatric populations (e.g. healthcare providers who care for strictly non-pediatric populations or health IT developers whose products are exclusively marketed for non-pediatric specialties and care settings). This will only increase as the USCDI expands. Further, in the deliberations of the USCDI Task Force of the Health Information Technology Advisory Committee (HITAC), CMS has sought addition of the Medicare Beneficiary ID as a patient identification data element and also discussion of adding subscriber ID which predicts the addition of financial data elements to the USCDI. Not all HIT able to otherwise be certified may support financial demographic elements of this kind due to their clinical nature. That should not deprive them of the ability to be certified. Likewise, the addition of some financial data may not comport sensibly with C-CDA, FHIR or other standards for providing a singular artifact that encompasses all USCDI required data elements. To require such is an artifice over time. Accordingly, we urge ONC to consider specific stratification of data classes and elements as a feature of future USCDI versions appropriate to the needs and characteristics of certain segments of the provider, payer, other sources of USCDI, and HIT developer industries.

As we consider the new data classes and elements proposed for V2 and the stated intent behind them (i.e., to adopt data elements that are already discretely supported in key exchange standards) it seems that the most obvious approach is to establish an appropriate baseline of adopting all data that are currently considered "must support" under HL7 FHIR US Core and subject to SHALL conformance in the HL7 CDA C-CDA R2.1 IG Companion Guide R2 (or otherwise mandatory for C-CDA criteria certification) as data elements under the USCDI V2, i.e., all data elements currently in scope of certification tests for the 2015 Certification Edition Cures Update. Since the USCDI establishes the floor for nationwide interoperability, there is no reason that those compelled to use standards for exchange (e.g., certified health IT developers and healthcare providers participating in Certified EHR Technology (CEHRT) programs) should be held to a higher bar than those not compelled to use standards (e.g., non-developers for information blocking).

By that same token, we ask ONC to consider developing a publicly-accessible matrix defining explicitly how the USCDI data elements are expected to be represented within key exchange standards – specifically, HL7 FHIR US Core and HL7 CDA C-CDA. We understand that the intent of the USCDI is not to define explicit exchange standards. However, having some common definition to reference is critical to dispel confusion amongst actors

regarding precisely how specific data should be exchanged for consistency's sake. At times, this is clear and obvious. However, as the USCDI expands, it is critical to have a common and consistent understanding of how all data shall be exchanged, at least for these most common exchange standards.

Finally, we understand there has been interest expressed in including the Diagnostic Studies data class in USCDI V2 although it was not included in the V2 draft (still a Level 2 data class). While we do see value in adding the data class in the future, it currently lacks clarity in scope and appropriate support in downstream exchange standards to be adopted in USCDI V2. We suggest it instead be considered for USCDI V3 and that ONC work in the meantime with the industry to define a reasonable set of studies for which to establish the necessary standards/guidance/profiles to implement as currently there is a wide variety of documentation approaches that need alignment.

Care Team Member(s) Data Class

In reference to both the proposed additions to the Care Team data class for USCDI V2 ("Provider Name" and "Provider Identifier"), we note that it is critical to amend the naming convention to remove the explicit reference to "Provider." This inappropriately implies that care team members are limited to healthcare practitioners whereas the care team concept across the industry is commonly thought to be more expansive to include non-clinical roles such as family members, general caretakers, transportation sources, and clergy. This perspective is reflected in both HL7 FHIR US Core, as well as HL7 CDA C-CDA via use of the Care Team Member Function (2.16.840.1.113762.1.4.1099.30) vocabulary standard. Accordingly, while we support that both proposed elements be adopted in USCDI V2, in addition to the separate recommendations laid out below, they should be adopted as "Care Team Member Name" and "Care Team Member Identifier."

In consideration of the adoption of the "Care Team Member Name" data element, it would be redundant to maintain the existence of the current "Care Team Member(s)" data element. Therefore, the "Care Team Member(s)" data element should be removed in alignment with the adoption of the "Care Team Member Name" data element.

Regarding the proposed "Provider Identifier" element, in addition to our recommendation that this element be amended to be adopted as "Care Team Member Identifier" it is also appropriate to adopt the National Provider Identifier (NPI) as a standard for the data element. NPIs are well established as the most common identifier for healthcare providers and are also leveraged in both HL7 FHIR US Core as well as HL7 CDA C-CDA. The caveat is that, considering our comment on the more expansive definition of care team members (i.e., not isolated to only healthcare providers), it is important to set realistic boundaries and expectations for following the standard. Although it is technically feasible for non-healthcare providers/organizations to obtain an NPI, this is not a common practice and it would be inappropriate to establish an expectation that NPIs be obtained and exchanged for non-healthcare provider care team members. Therefore, we recommend adopting the NPI standard with a specific clarification that it only applies for care team members who qualify as a health care provider as defined under 42 U.S.C 300jj (https://www.law.cornell.edu/uscode/text/42/300jj). Finally, we note that as other identifier types may be used for different care team members, we recommend to also include identifier type. While in some of the HITAC USCDI Taskforce discussions the notion of an identifier version was raised, we submit that the identifier type is more relevant while a version would be reflected in the type where necessary.

Finally, while it has not been formally proposed as part of the draft USCDI V2, a data element for "Care Team Member Role" is key to the Care Team data class and should be adopted as part of USCDI V2 (there is a current Level 2 data element for "Provider Role"). Even above the need for exchanging a reliable identifier for care team members, it is critical to positively identify the role that those members play within the particular care team. This is especially true given the fact that care team members, as discussed above, consist of a wide range of actors not limited to healthcare providers.

It is appropriate to move forward with adopting this data element as part of the Care Team data class for USCDI V2 even though it was not included in the V2 draft given its current adoption in both HL7 FHIR US Core and HL7 CDA C-CDA. Both standards specifically reference the Care Team Member Function vocabulary

standard for defining member roles within the care team, thus we also recommend that this be adopted as the vocabulary standard for the "Care Team Member Role" data element. To that point, it is also critical that this data element be explicitly defined as the specific responsibility of the individual within the care team, which aligns with HL7 FHIR US Core's CareTeam.participant.role attribute, as opposed to the role that a practitioner may perform at an organization independent of their role within the care team, which would align with HL7 FHIR US Core's CareTeam.particpant.member attribute when referencing PractitionerRole Profile. This is important because the role or job that the individual performs at an organization may not always be relevant to the actual role they are playing for the patient's care team. In context of the Care Team data class, the member's explicit role within the patient's care team must be the priority and focus.

Diagnostic Imaging Data Class

Cerner appreciates and supports the proposal to add the new Diagnostic Imaging data class in the USCDI V2. The exchange of diagnostic imaging data is important to facilitate the best possible patient care and is mature enough within the industry for inclusion in the USCDI. However, we believe there are some important changes that must be made to the underlying data element proposals before adopting.

First and foremost, while we agree that the Diagnostic Imaging Narrative data element should be removed from the Clinical Notes data class as the content does not fit the intent of that data class, it represents a duplication of the newly proposed Diagnostic Imaging Report data element. As defined, the Diagnostic Imaging Report data element would actually encompass the Diagnostic Imaging Narrative (i.e., the narrative interpretation of the image). Furthermore, the standalone Diagnostic Imaging Narrative is limited in its value and usability without the additional supporting information from the full imaging report. Therefore, the Diagnostic Imaging Narrative data element should be eliminated from the Diagnostic Imaging data class in favor of the more complete Diagnostic Imaging Report data element.

Regarding the Diagnostic Imaging Report data element, there needs to be more clarity on the specific scope of a report. Most importantly, clarification is needed that the report does not include the diagnostic image itself. While in some cases the full report may contain replications or components of the diagnostic image (e.g., a .PDF report containing references to the image pointing out particular components for the interpretation), the diagnostic image itself is independent. Additionally, HL7 FHIR US Core does not currently provide a Profile supporting diagnostic images (only the reports), so it would be inconsistent with ONC's stated intent with the USCDI V2 to include the actual diagnostic image in scope.

The proposal to adopt LOINC as the standard for the Diagnostic Imaging Report data element also appears problematic considering that the full report would consist of both structured and unstructured components. We would recommend that the standard be clarified as specific to distinct components of the full report to be clear that unstructured content is not expected to be codified by LOINC. Additionally, we note that if the re-classification and replacement of the Diagnostic Imaging Narrative data element is finalized in USCDI V2, ONC should include the same changes in USCDI V1 via an errata adoption. This is important for consistency as HIT developers and healthcare providers are currently working to align with USCDI V1. If changes other than additions are made for USCDI V2 it may create inconsistencies for exchange of the same data between those versions.

Finally, while we also support inclusion of the Diagnostic Imaging Order element to represent the service request from which the Diagnostic Imaging Report originated, there is a need to ensure that the definition sufficiently distinguishes the data element from a procedure that may also be associated with the Diagnostic Imaging Report.

Encounter Information Data Class

Cerner appreciates ONC's proposal to add the Encounter Information data class and supports its inclusion in USCDI V2. We agree that encounter information for the elements proposed is commonly recorded and exchanged today using consensus standards and the data is of sufficient importance to clinical care to warrant

immediate adoption. However, there are some critical points of clarity needed to ensure a clear, consistent understanding of the scope and intent of its constituent data elements for the industry.

This is especially true of the proposed Encounter Diagnosis data element. The current description of "Represents the primary reason for a healthcare encounter and associated diagnoses, represented by a diagnosis code" (https://www.healthit.gov/isa/uscdi-data/encounter-diagnosis) appears to consolidate multiple concepts that should be represented as distinct data elements in USCDI. Specifically, the "primary reason for a healthcare encounter" portion of the description appears to align most closely with the concept of a "reason for visit," which is normally either patient-stated or a general observation from the clinical care team for why the patient sought care and may often be a free text/narrative entry that is rarely codified. This concept would align most closely with the reasonCode attribute of the Encounter Profile in HL7 FHIR US Core, and with the Reason for Visit and/or Chief Complaint section in HL7 CDA C-CDA. It is also distinct from the actual coded diagnoses on the encounter for clinical or billing purposes, which would align with the diagnosis attribute of the Encounter Profile in HL7 FHIR US Core (i.e., the "list of diagnosis relevant to this encounter") and the Encounter Diagnosis (V3) entry in HL7 CDA C-CDA. The distinction between these concepts is an important one and should be accommodated in USCDI.

Accordingly, we highly recommend that the Encounter Diagnosis data element be explicitly defined as encompassing the list of all coded diagnoses for the encounter whether for clinical, billing, or administrative purposes. In line with that definition, the data element should also be specifically named as "Encounter Diagnoses" to directly support the fact it may be comprised of a list of relevant diagnoses and not a singular diagnosis. It is sensible that this element encompasses multiple types of coded diagnoses given that HL7 FHIR US Core features an Encounter.diagnosis.use attribute that defines the role of the diagnosis (e.g., admission, discharge, billing, etc.) to the encounter. This means that consumers of the Encounter Diagnosis data element still have the ability to isolate to the specific type of coded diagnoses relevant for their use-case. Further, HL7 CDA C-CDA Encounter Diagnosis (V3) entry also supports multiple diagnoses with priority ranking. Limiting the types of coded diagnoses that could qualify under the data element (e.g., only diagnoses used for billing) would be unnecessarily restrictive and potentially limit the utility of the data element for reference in various downstream use-cases. Lastly, ICD-10-CM and SNOMED-CT should be adopted as the applicable standards for the data element.

With this recommendation, given that the Encounter Diagnoses data element would specifically consist of the full scope of coded diagnoses for the encounter, it will also be necessary to adopt an independent data element for the primary reason for the healthcare encounter as stated by the patient or observed by the clinical care team. We recommend moving forward with adopting that separate concept as the "Reason for Visit" data element under the Encounter Information data class. Since it is generally not a coded observation, it should be adopted without any associated standard. Adopting these independent data elements will achieve multiple purposes including covering the full range of relevant contextual diagnosis information for the encounter, ensuring clarity and sensibility in the types of diagnoses that may be present for an encounter that needs to be supported in these data elements, and aligning with downstream exchange standards.

Regarding the Encounter Type data element, while we support its adoption, we note that there is a need to simplify the definition. We suggest adopting a definition close to that of the US Core Encounter Type value set used for the HL7 FHIR US Core Encounter.type attribute of "a specific code indicating type of service provided" (http://hl7.org/fhir/us/core/ValueSet-us-core-encounter-type.html). Additionally, CPT-4 and SNOMED-CT should be adopted as standards for the Encounter Type data element. Use of these code set systems to represent encounter types is sufficiently mature across the healthcare industry and also aligns with the standards leveraged for both HL7 FHIR US Core within the aforementioned US Core Encounter Type value set, as well as HL7 CDA C-CDA via the EncounterTypeCode value set (2.16.840.1.113883.3.88.12.80.32) leveraged for the Encounter Activity (V3) entry template.

Laboratory Data Class

Cerner supports the proposal to re-classify the Laboratory Report Narrative and Pathology Report Narrative data elements from the Clinical Notes data class to the Laboratory data class. As with the Diagnostic Imaging

Narrative data elements (for which we provide recommendations in the Diagnostic Imaging data class section of this comment letter), the data elements do not fit within the intended scope of Clinical Notes and are better classified in a more distinctive data class. That said, there is still significant ambiguity as to the intended definition of those data elements, even with their reclassification. Additionally, we note that if these re-classifications are finalized in USCDI V2, ONC should include the same changes in USCDI V1 via an errata adoption. This is important for consistency as HIT developers and healthcare providers are currently working to align with USCDI V1. If changes other than additions are made for USCDI V2 it may create inconsistencies for exchange of the same data between those versions.

Our first recommendation is to remove "narrative" from the data elements' naming and adopt them simply as "Pathology Report" and "Laboratory Report." Including "narrative" in the naming is misleading because it implies the whole of the content is narrative. However, freetext narrative content would be only one component of a full report, which consists of both coded and freetext/narrative data, as well as quantitative and/or qualitative observations. In the case of Laboratory Report, a narrative component may not even be relevant as even textual results are generally encoded as a discrete observation with a specific result "type" classification (e.g., "string"). We recommend accounting for this in adopting the formal definition of the data elements and ensuring that the scope of data to be contained within each is clear so that health IT developers and healthcare providers have a consistent understanding of precisely what is required or expected to be exchanged for the data class.

Additionally, regarding the Laboratory Report data element, we note that there are already well-defined standards established by the regulations of the Clinical Laboratory Improvement Amendments (CLIA) that define what constitutes a laboratory report. This is explicitly the data elements listed below, which are adopted in the CFR at 42 CFR 493.1291(c)(1) through (7).
CLIA laboratory report elements:

- For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.
- The name and address of the laboratory location where the test was performed.
- The test report date.
- The test performed.
- Specimen source, when appropriate.
- The test result and, if applicable, the units of measurement or interpretation, or both.
- Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

Furthermore, supporting the ability to represent a laboratory report is already a requirement as part of the ONC's Health IT Certification Program under the 170.315(e)(1) View, Download, and Transmit to 3rd Party criterion. Guidance in the 170.315(e)(1) Certification Companion Guide states that the laboratory report should be represented with a HL7 CDA C-CDA Result Observation entry template, which HL7 has published examples of (see here). This has similarly been a requirement of past certification of laboratory results reporting in prior editions of ONC's certification criteria.

Given the precedence for both the established definition of what constitutes a laboratory report and how it should be represented for purposes of ONC Health IT Certification (at least in HL7 CDA C-CDA), the most sensible approach would be to adopt the Laboratory Report data element with a definition aligned with that of CLIA regulations defined above, inclusive of any relevant narrative notes. Following this recommended approach will maintain consistency with long-held industry principles and ensure a common understanding of the scope of the data element.

As a final note, the Laboratory data class is a fitting example for our recommendation under the General Comments section of this comment letter that ONC seek to stratify the USCDI to specify the actors for whom various data classes and/or elements are intended (or required). This is because specific interoperability use-cases for laboratory data may not call for all elements of a CLIA laboratory report to be present.

Problems Data Class

Regarding the proposed addition of the "Date of Diagnosis" element to the Problems data class, the element necessitates further specificity as to which date/time aspects are potentially relevant to the Problems data class. There are four different date/time aspects for problems to consider: 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.
    - January 2021 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.
    - February 15, 2021 at 11:00 am 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.
    - February 15, 2021 at 12:30 pm 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.
    - March 1, 2021 at 9:00 am 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).

We note that two date/time concepts were in consideration for the USCDI v2 Draft: Date of Diagnosis and Date of Onset. The suggested definitions of both concepts appear to reflect the same aspect of Onset Date as we described. The proposed USCDI data element Date of Diagnosis seems to align more closely with the Asserted Date aspect if just looking at the name, but when considering the suggested definition, it would align more with the Onset Date aspect.

If the intent was to reflect the Asserted Date, based on ONC's stated goal with USCDI V2 to adopt elements that are "already supported by current versions of the C-CDA and FHIR US Core implementation guide" (https://www.healthit.gov/isa/sites/isa/files/2021-01/Draft-USCDI-Version-2-January-2021-Final.pdf), this element should not be adopted with USCDI V2 because it is not currently supported in the HL7 FHIR US Core IG Condition Profile, nor in the underlying standard. This Profile currently supports date/time observation concepts for onset (which would align with our Onset Date observation concept) and recordedDate (which would align most closely with our Recorded Date (local system) observation concept) in addition to the abatement attribute, which would align with the separately proposed Date of Resolution element. Furthermore, from a clinical perspective the distinction between the Asserted Date and the Recorded Date would be insignificant.

Accordingly, we recommend that ONC withdraw the Date of Diagnosis element from USCDI V2 and wait to introduce that concept until applicable standards (such as HL7 FHIR US Core and HL7 CDA C-CDA) have discretely accounted for it (if at all, given the lack of apparent clinical significance in comparison to the Recorded Date). Instead, we recommend adopting the following elements with USCDI V2 given the alignment with current supported elements in HL7 FHIR US Core and HL7 CDA C-CDA:

- Onset Date – this should be explicitly defined as the approximate date that the condition began for the patient (independent of when it may have been diagnosed or recorded to the record) and must also be clarified as having flexibility to be a "fuzzy" date given the reality of the concept (e.g., could be a specific calendar month or year, or a date range as opposed to needing to be a hard date). This element is already supported in both HL7 FHIR US Core (via the onset attribute), and also HL7 CDA C-CDA (via the Problem Observation (V3) entry template effectiveTime low observation).
- Recorded Date – this should be explicitly defined as the date the problem is recorded in the local system, which would be a unique date/time for each system. This is distinct from the original Recorded Date, which would be the very first time it was recorded in any system (a difficult observation to effectively/accurately trace). This element is already supported in both HL7 FHIR US Core (via the recordedDate attribute), and also HL7 CDA C-CDA (via the Problem Concern Act (V3) entry template effectiveTime low observation and/or Author Participation entry template time observation).

Regarding the proposed "Date of Resolution" element, we support its inclusion in USCDI V2. Unlike the "Date of Diagnosis" element, this element is clearer and more definite as to its intent. It is also already supported by both HL7 FHIR US Core (via the abatement attribute) and HL7 CDA C-CDA (via the Problem Observation (V3) entry template effectiveTime high observation).

Additionally, there is a need for further clarity on the intended scope of the Problems data class generally. It is currently defined very broadly as "Information about a condition, diagnosis, or other event, situation, issue, or clinical concept that is documented." Considering there is a separate "Encounter Diagnosis" data element proposed for adoption in USCDI V2 under the Encounter Information data class, the Problems data class should be focused on ongoing conditions that warrant long term management or tracking that are identified by a clinician, independent of encounters. This would distinguish the data class from Encounter Diagnoses data element, which, as we've recommended elsewhere in this comment letter, should be the list of coded diagnoses for a single visit and may or may not also qualify separately as Problems. It would also distinguish it from Health Concerns data class, which is broader and inclusive of concerns from the patient or family members that may not be clinical in nature or necessarily a concern of a clinician.