April 15, 2021

Mickey Tripathi, PhD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health IT
U.S. Department of Health and Human Services
330 C Street, SW
Washington, DC 20201

Dear Dr. Tripathi,

On behalf of Medical Information Technology, Inc. (MEDITECH), I am pleased to offer comments on the United States Core Data for Interoperability (USCDI) Version 2. In our comments below, you will find the elements we support, suggestions for improvement, and elements that would benefit from additional clarification. We also want to bring to your attention the data elements we believe should not wait until Version 3 (or beyond) but be added to Version 2.

V2 Data Elements:

Elements We Support

In general, we fully support and encourage the implementation of any data element that is already part of FHIR R4. We encourage and support using the same naming conventions as FHIR R4 as well. Specifically, we support the Provider Name and Provider Identifier data elements as well as the Date of Diagnosis and Date of Resolution data elements. We agree that Diagnostic Imaging should have its own data class. We applaud the alignment with the US Core IG on the Diagnostic Imaging Report data element and the alignment with R4 for Encounter Type data element.

Suggestions for Improving V2 Elements

We want to encourage ONC to review the data elements that will be added to future versions of the USCDI and align the naming conventions and data classes with FHIR and US Core IG for more streamlined standards.

Specifically, we have some suggestions to improve the following elements.

- Encounter Diagnosis - We believe this would be better suited under the Problems data class. We also would encourage ONC to choose one word to describe this element, either problem or diagnosis.

- Encounter Time - We support this data element. However, We would encourage ONC to change the name to Encounter Date Range or Encounter Period for more clarity if this element captures visit duration rather than the time of an appointment or admission.

- Laboratory Report Narrative and Pathology Report Narrative (Both moved from Clinical Notes) - We encourage ONC to create a data class for all reports which would follow the DiagnosticReport FHR R4 standards.

V2 Elements that need Further Clarification

We would encourage ONC to provide further clarification on the following data elements.

- Diagnostic Imaging Narrative - We ask that ONC provided further clarification on what a narrative is. If the word narrative is different from report, we would also appreciate a clear definition of both. If a narrative is a report, we would ask ONC to consider changing the term to report to be more precise.

- Diagnostic Imaging Order - The definition for this data element is "The request by a clinician for an imaging procedure to be performed for a particular patient." We would encourage ONC to review the terminology used for this data class. If this is considered a procedure, this data element should be left in the Procedure data class. If this element is deemed an order, then use that terminology in the definition and data class. The hybrid causes confusion and issues when relating it to FHIR standards. We encourage ONC to review the FHIR standard before deciding to remove this element from the procedure class.

- Procedure - We agree with the comment on this data element. "A note to clarify what is meant by procedures would be helpful here because everything, lab tests, radiology studies, etc., could be considered procedures in some sense of the meaning. FHIR used "procedure" to mean surgical and similar invasive processes. It is messy because CPT, for example, considers tests of all kinds as procedures, so some distinctions would be helpful."

Level 2 Data Elements

Elements to Add to V2

We strongly support and advocate that ONC add the following data elements to the USCDI v2.

- Sexual Orientation and Gender Identity - There is no reason to wait to add these to the USCDI. This information is already being captured and should be shared. Sharing these data elements aligns with this administration's goals ([Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government](#) and [Section 1557 of the Patient Protection and Affordable Care Act](#).)

- Allergies and Intolerance - It is vital to share data elements that will keep patients safe. Allergies can be life-threatening; adding the food and non-medication data elements to v2 would assist in the safety of consumers.

- Encounter Status, Encounter Disposition, and Encounter Location should all be part of v2. These are elements that are already being captured and easily shareable.

Elements We Support for Future Versions

We support all of the following data classes for future versions of the USCDI.

- Travel Information

- Unique Device Identifiers for a patient's implantable devices

- Family History

We support all of the following data elements for future versions of the USCDI.

- BMI

- Vital Sign Results: Date and Timestamps

- Problems, defined by ICD-10-CM terminology standards
  - As always, we encourage ONC to be consistent with standards.

- Medicare Patient Identifier
  - We believe that ACOs will benefit from this data being shared.

Suggestions for Improving Level 2 Elements

- Laboratory Test Performed Date - We strongly encourage ONC to evaluate the name of this data element. It currently is not clear. Is this the date and time the specimen was collected or obtained?

- Author (Provenance) - We would encourage ONC only to add authors with NPI numbers. For many years we have heard from Healthcare Organizations that adding nursing staff full names to patient's documents could cause a privacy or security risk to those individuals. We understand the need for this element but would encourage ONC to evaluate only adding those clinicians with NPI numbers to this data element.

- Facility Level - We support this data class but encourage ONC to review the classification that HL7 has designed. HL7 uses the term organization instead of facility.

- We would recommend a separate data class for Pediatrics. Birth Time and Multiple Birth Order are data elements that could fall into a Pediatric data class. We also encourage ONC to evaluate only allowing for the capture of birth time at the time of birth for accuracy purposes.

- Mother's maiden name - This element is used very frequently for security questions. Having this data available via a data class could cause security concerns.

Level 2 Elements that Need Further Clarification

We are looking for additional clarification on these data elements.

- Provider Locations - We encourage ONC to provide a more detailed definition of this element. Is this element where the provider cared for the patient or all of the places where they provide care? This element could become very large if a provider practices in multiple locations.

- Medication, all of the administered data - If a patient is in the hospital for an extended time, this will become an extensive data set. We also encourage ONC to review use cases and determine if this information is truly valuable to be shared in all circumstances.

- Observations - We are looking for clarification on why labs and observations are being separated. We would encourage ONC to review the [HL7 observation guidelines](#) and aline with the FHIR standards.

- Types of orders for medical care/services - We recommend ONC provide more guidance on why an order or referral status would not satisfy this use case. In addition, the definition of the element does not provide a clear distinction between a referral and this type of "request." We would encourage ONC to redefine this element to be more precise and clarify the difference between an order's status and this data element. If a new data element is needed, we would encourage ONC not to separate this data element from the procedure data class.

- Average Blood Pressure - We suggest that if we are to capture an average, there is also a need to obtain the specified time period, according to a specified algorithm or protocol, which will provide more context on the average.

- Vaccination vs. Immunization - Does ONC feel that these terms are interchangeable? We ask that ONC provide more clarification on the definitions.

- SNODENT - We are looking for ONC to provide guidance on how restrictive they believe this data element will be.

Thank you for your time and consideration. We look forward to the continued review and additions to the USCDI.