

April 15, 2024

Comments from Wolters Kluwer on the
United States Core Data for Interoperability, Version 5

Below are Wolters Kluwer's comments to the Office of the National Coordinator for Health Information Technology (ONC) on draft Version 5 of the United States Core Data for Interoperability (USCDI or Version 5). Thanks for allowing us to provide our views.

As way of background, Wolters Kluwer is a leading global provider of clinical technology and evidence-based solutions that drive effective decision-making and outcomes across the healthcare continuum. Key solutions include UpToDate®, UpToDate® Lexidrug™, UpToDate® Patient Engagement, Medi-Span®, Sentri7®, Lippincott® Solutions, Ovid®, and Health Language®. Wolters Kluwer had annual revenue in 2023 of €5.5 billion.

Our comments below address some of the new data elements formally proposed for Version 5 and also reiterate recommendations we previously made to the ONC on earlier versions of the USCDI. The data elements for which we continue to advocate for addition to USCDI represent critical information essential to patient care, and are already widely used in various settings across the care continuum.

Collectively, these proposed elements also address several of the prioritization criteria ONC has defined for the USCDI build-out, including healthcare disparities and inequities, underserved communities, and public health. Moreover, because most of the data elements we are recommending are already at a Level 2 adoption level and/or supported by FHIR/US Core, they represent a modest implementation burden for stakeholders. More details are below.

Proposed New Data Classes for Version 5

New Data Class – Observations – We support the addition of a new *Observations* data class to USCDI.

New Data Class – Orders – We support the addition of a new *Orders* data class to USCDI, but request clarification on the proposed *Order* data element, which does not appear to have an accompanying vocabulary standard. Is ONC actually proposing the Level 2 data element *Types of Orders for Medical Care/Services*? If so, we request clarification if the type refers just to a class of orders (e.g. lab tests, radiology, referrals), or the actual order (e.g. cholesterol test, chest x-ray).

We also believe the new *Orders* data class would have greater utility for end users if it also had data elements for *Order Code*, *Order Status* and *Order Date/Time*. *Order Code* is particularly important to identify the specific order if the *Types of Order* data element only refers to class. As for the latter two data elements, we understand it may be some time before they can be added to USCDI as neither are Level 2, but both are still vitally important.

New Data Elements for Version 5

Encounter Information Class – We continue to recommend the *Encounter Class* data element be added to the *Encounter Information* data class.

Clinical Notes Class – We agree with the Interoperability Standards Work Group that the *Maternal Social Determinants of Health Note* data element be added to this class, and that the addition of other data elements related to maternal health be given priority in future versions of USCDI.

Laboratory Data Class – We agree there is utility in adding *Lab Test Unique Device Identifier* as a new data element, but believe capturing the date and time of the lab test is more important. As such, we reiterate our recommendation that *Laboratory Results: Date and Time Stamps* and *Laboratory Test Performed Date* be added to Version 5. Understanding when a laboratory test was given can be a valuable data point in a public health emergency, as well as in the context of caring for a member of an underserved community, who may not be able to consistently access care and have test results in their record that are out of date. Both the elements recommended above are also Level 2 because of their widespread adoption, and therefore represent minimal implementation burden to providers and developers.

For Version 5, we also recommend re-naming the *Tests* data element to *Laboratory Test/Panel Code* to help clinicians better differentiate between the various panels of tests available. We note in the Level 2 *Rationale for Separate Consideration* for the *Laboratory Test/Panel Code* data element, the Centers for Disease Control and Prevention (CDC) observed that “(t)he current element of ‘Tests’ does not specifically state that this is used to capture the code or name of the laboratory test performed. Suggest renaming the current element of ‘Tests’ to ‘Laboratory Test/Panel Code.’” We agree with this rationale and the change in name.

Immunizations Data Class – Here again, we have no issue adding *Lot Number* as a new data element, but believe other Level 2 data elements should take priority. We therefore reiterate our recommendation to add *Vaccine Administration Date*, *Immunization Code* and *Immunization Status* to Version 5. And with due respect to the Interoperability Standards Work Group, we believe these data elements have more utility than *Vaccination Event Record Type*, which they included in their recent report to the Health Information Technology Advisory Committee.

Medications Data Class – We support adding *Route* as a new data element, but continue to urge ONC to be more aggressive in building out the *Medications* data class. Like labs, it is critical to provide attending clinicians with granular data on their patient’s medications, not only to facilitate smooth continuity of care but to safeguard patient safety. The *Medications* data class is also foundational to ONC’s efforts to improve public health, health equity and the care rendered to underserved communities. As such, we believe the data elements listed below provide additional vital information to providers on their patients’ medications:

- *Medication Date Administered*
- *Medication Date Prescribed*
- *Medication Administered Code*
- *Medication Administration Dose*

We note these four data elements have been considered Level 2 in past versions of the USCDI, but now have been relegated to Level 0. We find this perplexing as there is significant support, implementation and use of these elements in real-world clinical workstreams, particularly by the CDC. We believe prior categorization of these elements as Level 2 is a more accurate reflection of their adoption, and given ONC's strong interest in enhancing the public health data infrastructure, we strongly urge their addition to Version 5.

Vital Signs Data Class – Consistent with our other comments that emphasize the importance of data elements that address date and timing, and our position that *Performance Time* in the *Procedures* data class is not multi-purpose, we recommend *Vital Sign Results: Date and Timestamps* be added to the *Vital Signs* data class.

Finally, as we have previously commented, we urge ONC to be more ambitious in building out the USCDI, particularly if the expansion includes data elements also supported by FHIR/US Core. Several of the data elements we recommend above are not only considered Level 2, but are also supported by US Core STU 3.1.1, which, as ONC is aware, is the implementation specification for the FHIR Release 4 standard. Specifically, *Laboratory Test/Panel Code*, *Vaccine Administration Date*, *Immunization Code*, *Immunization Status*, *Vital Sign Date and Time*, and *Medication Date Prescribed* are all data elements required by US Core. *Laboratory Test Performed Date* is considered “must support” by US Core if available.

Thanks again for the opportunity to share our views. If you have questions or want to discuss our response in more detail, please contact Bob Hussey at bob@bobhussey.com or (612) 281-8741 who can connect you with the appropriate staff at Wolters Kluwer.