

September 20, 2023

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's (ONC) to help inform the development of version 5 of the United States Core Data for Interoperability (USCDI). Thanks for allowing us to provide this preliminary feedback.

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®, Medi-Span®, Lexicomp®, Sentri7®, Lippincott® Solutions, Ovid®, Health Language®, and Emmi®. Wolters Kluwer had annual revenue in 2022 of €5.4 billion.

Our comments reiterate several of the recommendations we previously made to the ONC on earlier versions of the USCDI. These recommendations address data elements that 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 Elements for Version 5

Encounter Information Class – In previous comments sent to ONC on earlier versions of the USCDI, we advocated for renaming the *Encounter Type* data element to *Encounter Class* to ensure accurate alignment when USCDI is translated to the Fast Healthcare Interoperability Resource (FHIR) standard, and to adopt the HL7 v3 Value Set ActEncounterCode to improve interoperability.

It appears now that the USCDI definition of *Encounter Type* may have changed to align with FHIR. In USCDI v4 ONC defines *Encounter Type* as the category of health care service, such as office visit, telephone assessment and home visit. FHIR R4 gives examples for Encounter.type such as email consultation, surgical day care, skilled nursing and rehabilitation. These definitions appear to be aligned, but it would be helpful if ONC provided clarification that this is the case. We also note that US Core 6.1.0 binds Encounter.Class to the ActEncounterCode value set, which addresses our previous recommendation on this issue.

While both developments appear to satisfy our concerns, we still recommend the *Encounter Class* data element be added to the *Encounter Information* data class.

Laboratory Data Class – Though *Performance Time* was added to USCDI v. 4 in the *Procedures* data class, we agree with the Interoperability Standards Work Group and other stakeholders who believe this new data element is insufficient to provide important timing information related to lab tests. As such, we recommend 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.

In v. 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 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 – Though the COVID Public Health Emergency is officially behind us, the FDA's recent approval of the next version of the COVID vaccines is a stark reminder that the public health system must remain vigilant for new outbreaks and pandemics. As such, it is vital that ONC give priority to building out the *Immunizations* class of constituent elements. Here again, we do not believe the new *Performance Time* data element in the *Procedures* data class can be extended to cover immunizations, and therefore recommend adding Level 2 data elements related to *Vaccine Administration Date*, *Immunization Code* and *Immunization Status*.

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. We were pleased ONC commenced a modest build-out of the data elements of the *Medications* data class in Versions 3 and 4, and believe the Level 2 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*
- *Medication Prescribed Code*
- *Medication Prescribed Dose*

Given the critical importance of the *Medication Prescribed Dose* data element, we also recommend the eventual adoption of the more granular *Medication Prescribed Dose Units*. Admittedly, the *Units* data element is still in an early adoption stage and will likely be added at some later version of USCDI after the above Level 2 elements have already been adopted.

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*, *Medication Date Prescribed* and *Medication Prescribed Code* 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.