



The Sequoia Project
8300 Boone Blvd,
Suite 500
Vienna, VA 22182

Don Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator
U.S. Department of Health and Human Services
330 C ST SW: Mary Switzer Building; Office 7009A
Washington, D.C. 20201



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Re: U.S. Core Data for Interoperability (USCDI)

Submitted electronically to exchangeframework@hhs.gov

Dear Dr. Rucker:

The Sequoia Project is pleased to submit comments on the Office of the National Coordinator (ONC) U.S. Core Data for Interoperability (USCDI). We appreciate the careful consideration that ONC is giving to development of the USCDI and to the comments from stakeholders.

The Sequoia Project is the non-profit, 501(c)(3) organization that houses several independently governed health IT interoperability initiatives, including the eHealth Exchange network and Carequality. Our comments on the proposed USCDI are based on our organization's significant experience supporting large-scale, nationwide health data sharing initiatives. Through these initiatives, we serve as an experienced, transparent and neutral convener of public and private-sector stakeholders to address and resolve practical challenges to interoperability, including in-depth development and implementation of trust frameworks and common agreements. This work extends to several crosscutting projects, including patient matching, improving the quality of clinical documents exchanged, and other matters prioritized by these stakeholders.

Our team's decades of combined experience implementing national-level health IT interoperability, including our track record of supporting and operationalizing federal government interoperability initiatives, such as our sponsorship of the eHealth Exchange, provide a unique perspective on various aspects of the USCDI.

The Sequoia Project comments, based on our deep experience in developing and implementing such agreements, are aimed at helping ONC strengthen the final USCDI and successfully carry out its implementation. Our shared overall aim is to improve the health and health care of patients, consumers, and our nation through more seamless access to health information.

Overview

The Sequoia Project applauds ONC for using the USCDI model to implement the 21st Century Cures (Cures Act) definition of interoperability as including exchange of “all electronically accessible health information” in a prudent and stepwise fashion. We agree with ONC’s approach of starting with the requirements from the current Common Clinical Data Set (CCDS) and providing a multi-year roadmap for expansion. We also agree with ONC’s three-category approach to potential and final USCDI data classes and its recognition that the field will require significant time before and after a data class is added to the USCDI and that the time needed to move through the stages will be variable.

The Draft USCDI (p. 3) states: “*The USCDI and its expansion process are intended to be collaborative vehicles around which ONC and the industry can coalesce to identify the critical data needed to enable interoperability and achieve the goals outlined in the Cures Act, we invite stakeholders to submit feedback on the proposed process and initial assignment of the data classes.*” We agree with and appreciate this approach and want to emphasize that The Sequoia Project has multiple mechanisms in place to work with industry stakeholders to achieve goals outlined in the Cures Act and will continue to provide feedback to ONC as the proposed processes are solidified.

We do believe that the *annual* update tempo illustrated in Graphic 1 (p. 5) is too rapid given the technical work required to prepare a data class for USCDI adoption and necessary work by the industry to adopt new data classes, as well as other burdens of workflow changes faced by clinicians and exchange partners. We suggest that *ONC not finalize an annual update process*, which would seemingly require annual expansions in data classes supported by participants in programs that reference the USCDI, such as the Trusted Exchange Framework and Common Agreement (TEFCA). It is unclear how the existing [Interoperability Standards Advisory \(ISA\)](#) will fit into the new Trusted Exchange Framework and Common Agreement (TEFCA) linkage to the USCDI, but coordination of the release for both the USCDI and the ISA will be imperative.

The Draft USCDI states that “[o]nce a data class has been proposed by the industry, it will follow a gradual process where it will be promoted to emerging status, then candidate status and ultimately, included in the USCDI.” (p. 4) We note that the Sequoia Project would be well positioned to communicate with our members and align with content testing requirements and implement these with appropriate tools following a formal change management process. We have experience with such formal change management processes that are open and transparent, allowing our initiatives to be self-governing. We also appreciate that ONC states that “[t]he timing by which a data class moves from candidate status to USCDI will ultimately depend on the industry as a whole.” (p. 5)

We suggest that the first USCDI edition should be targeted for 2019 as that is the initial year of planned TEFCA implementation. We also believe that TEFCA participants should have up to 18 months (rather than the 12 months proposed in the Draft TEFCA) to add classes added to the USCDI from the CCDS and that subsequently. Overall, we believe that timelines should be set and agreed to by industry. For the TEFCA, the Recognized Coordinating Entity (RCE) could set such timelines through its process. We note that The Sequoia Project’s pilot and workgroup processes have determined that changes to content exchanged among the eHealth Exchange stakeholders would require *18 months* to correct outstanding issues once they are identified by

vendors and their customers. We also emphasize that inclusion in the USCDI (and hence when this implementation clock starts) should be based on the existence of finalized standards and tested and robust implementation guides.

We appreciate the specific references in the USCDI to FHIR (STU3) and C-CDA (v.2.1). We do note that these standards and associated specifications/implementation guides will evolve over time and the USCDI will need to be updated accordingly. It will also be important for the USCDI to point precisely to *specific* implementations and specifications and we suggest that a technical appendix of the USCDI point to the templates, fields, or resources in these standards to which a data class applies. Such precision will be essential to enable effective implementation and testing. In addition, it will be important, in this regard, that ONC establish streamlined procedures effective for identification and processing of errata as issue and errors in the specifications are found to allow industry to leverage lessons learned quickly.

The draft USCDI notes that the current CCDS includes new and updated vocabulary and content standards for clinical data exchange. We would like to point out, relative to the pace at which content updates can be implemented, that only 98 value sets are in the National Library of Medicine (NLM) Value Set Authority Center (VSAC) for the HL7 C-CDA R2.1 Implementation Guides; this set of 98 is still incomplete with 12 value sets missing. Although we understand that a few value sets may never be published, such as postal codes, the lack of complete and appropriate resources could cause delays for adoption until all information is made available to the industry for implementation. The availability of value sets and similar artifacts should be a critical factor in assessing the readiness for inclusion of a data class in the USCDI.

Finally, the draft USCDI states that Qualified Health Information Networks (QHINs) and their Participants will be required to be able to exchange all USCDI data classes for which electronically accessible data is available (i.e. if a participant or QHIN does not capture or have access to a specific data class, they are not expected to be able to exchange that data class). To avoid confusion and ensure more efficient implementation, it will be important for ONC to address the extent to which users of the USCDI will (or will not) be required or able to indicate that a data class is unavailable for exchange. In this regard, we urge ONC to address the extent to which specifications or implementation guides will address whether and how to communicate the appropriate NULL value, with guidance for the industry on how to communicate such a status.

Comments on Specific Data Classes

- 2018: Provenance (p. 6) – We believe that provenance, although a very important data class, may not be appropriate for inclusion in the 2018 USCDI. The low levels of maturity and adoption for this data classes in the ONC 2018 Interoperability Standards Advisory (ISA) reinforce our concerns, both for the C-CDA and especially FHIR.
- 2018: Clinical Notes (p. 6) – We support inclusion of Clinical Notes in the USCDI, but believe that inclusion in the 2019 USCDI would probably be more appropriate, with an initial focus on priority note types as identified by the clinician and patient communities. Also, regarding Clinical Notes, Sequoia is well positioned to support notes within the enhanced content testing program launched February 5, 2018 and feel the industry has more awareness of the need to support notes.

- 2020: Diagnostic Image Reports (DIRs) (p. 9) – We agree with the desire to add Diagnostic Image Reports (DIRs) to the USCDI. DIRs are clearly a high value component of the electronic health record and are still too often inaccessible to patients and clinicians. In order to make DIRs available and usable to clinicians, however, there is still important work to be completed in developing and implementing standards and specifications and the required workflows. In particular, although the Draft USCDI indicates that both C-CDA and FHIR are available as standards to support the interoperability of DIRs, in fact these standards are not currently widely used to structure and encode DIRs and in their current state are not sufficiently mature to do so effectively. The scope of the work remaining to achieve the needed maturity is significant and inclusion to meet the stated 2020 deadline seems overly ambitious.
- 2021: (1) Reason for Referral and (2) Referring or Transitioning Provider’s Name and Contact Information. Given the importance of care coordination and the role of health data exchange in addressing this use case, we suggest that these two data classes be considered for earlier implementation.

Emerging Status: We urge ONC to take careful heed of comments received on its proposed emerging data classes, focusing especially on the standards maturity and ability to be integrated effectively into clinician workflow.

Conclusions

The Sequoia Project supports congressional intent and ONC’s goals to use the USCDI to enhance the extent of data exchange through interoperable networks and other models. We stand ready to work with ONC to refine and implement the USCDI. The years of experience of The Sequoia Project and our initiatives provide a unique vantage point and set of capabilities and involved public and private sector stakeholders. We are eager to make these resources available to ONC and submit these comments in that spirit.

Most respectfully,



Mariann Yeager
CEO, The Sequoia Project

CC:

John Fleming, M.D., Deputy Assistant Secretary for Health Technology Reform
Genevieve Morris, Principal Deputy National Coordinator for Health Information Technology
Elise Sweeney Anthony, J.D., Director, Office of Policy
Steven Posnack, MS, MHS, Director, Office of Standards and Technology