March 15, 2018

Don Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, DC 20201

Dear Dr. Rucker:

The National Committee on Vital and Health Statistics (NCVHS) welcomes the opportunity to make comments and recommendations to the Office of the National Coordinator (ONC) on the proposed U.S. Core Data for Interoperability (USCDI) expansion process, Version 1, and candidate/emerging data classes under consideration.

1. NCVHS fully supports ONC’s approach to advancing interoperability through core data content standards. This approach has the potential to advance interoperability in three ways:

   • It provides semantic standards for the data to be exchanged so they can be accurately captured, accessed, exchanged, understood, and used.
   • It carefully limits the data set to a predetermined core making it feasible for stakeholders to accomplish the exchange.
   • The core data set can be expanded in the future.

2. The Committee commends ONC for laying out a proposed expansion process and for building on content standards adopted as part of Meaningful Use. NCVHS is currently formulating recommendations for a clear roadmap for administrative standards adoption. This type of clarity is something that all stakeholders including providers, payers and technology companies have been asking for.

   The Committee does question whether ONC’s goal of expanding USCDI on an annual basis is realistic from the outset. Like the flywheel metaphor often used to describe the accelerating effect of incremental improvements, it may take a few cycles before the industry is routinely capable of incorporating candidate and emerging elements in an annual cycle. NCVHS advises ONC to ask HITAC to recommend a cadence for the expansion cycle that includes time to disseminate “teachings” from early adopters and orchestration of technology and operational changes.
3. The USCDI data classes do not stand alone. They are most often based on a named health terminology and vocabulary (e.g., ICD, SNOMED, LOINC, CPT, etc.) and these source systems each have their own cycle for updates. In fact, the NCVHS is also currently studying the process for development and maintenance of health terminologies and vocabularies with a goal of formulating recommendations to ensure smoother uptake and improved coordination. There will need to be a mechanism for ensuring alignment between the USCDI expansion process and the inherent core data set definitions with evolving terminology and vocabulary standards.

4. In addition, the clinical and administrative workflows, supported by EHR technology, need to capture the USCDI data classes accurately at the source to achieve the potential to advance interoperability. Otherwise, while data may be exchanged, its accuracy and meaning will remain unclear.

NCVHS recommends that ONC limit USCDI Version 1 to data classes with well tested semantic standards that are widely implemented in EHR technology, with workflows that have been shown to capture data classes accurately at the source. The Committee recommends that ONC ask HITAC to recommend a threshold for accurate capture at the source as one of the criteria for advancing a data class from candidate status. Regulating data collection and exchange across enterprises before that data class is sufficiently well defined and tested could result in data inaccuracies that could jeopardize patient treatment and safety. It could also increase administrative costs.

5. We note and agree with ONC’s stated commitment to industry consensus in the advancement of categories from candidate status. Consensus, however, must be supported by objective evidence through EHR certification compliance and field testing.

6. With regard to Draft USCDI Version 1 Data Classes, the Committee offers the following comments:

V1 (2018)

- Laboratory values/results should probably be removed from V1 as it has no associated standard and is notoriously variable from lab vendor to lab vendor and from system to system.
- V1 should probably be limited to data classes that are well tested and that meet the criteria for accurate capture at the source as noted above.
- While we support inclusion of Birth Sex, we note that many legacy systems may not be able to specify whether its sex code represents true birth sex or may, in fact, represent sex as reported by the individual or sex as captured by an employer’s human resources system, or sex as reported on an insurance application, for example.
V2 (2019):
- FHIR is a V3 Standard for Trial Use from HL7 developed specifically to support interoperability of health information. The Committee was briefed on FHIR (January 10, 2018) and understands that it is an important new tool. Nonetheless, to suggest that it will be the basis for a 2019 (V2) standard seems unrealistic, particularly for several data classes that are otherwise not highly standardized nor accompanied by workflow integration lessons learned.
- Cognitive status, family health history, and functional status are not highly standardized.
- Reason for hospital admission is another notoriously problematic data field.

V3 (2020):
- Includes individual goals and priorities, responsible practitioner, provider goals, all of which are highly problematic.

Providing a clear roadmap is essential, however, the Committee believes that this timetable may be unrealistic in terms of the speed with which the data collection stakeholders and the technology companies that support them can add and standardize new data classes. The source systems need to be modified and system users need to be trained on the updates in order to capture the new data accurately and consistently. Standards don’t exist or are not part of the named code set standards used in the U.S. for several of the proposed data classes. The Committee supports the overall vision, but believes the timetable needs to be realistic. To go from where we are in early 2018 to reliable interoperability in 2019 or even 2020 does not seem feasible. Limiting the scope of the USCDI would improve the odds of success, which could then be built on in the future.

We presented an overview of NCVHS and our work plan to HITAC at its February 21 meeting. The comments from HITAC members indicated an interest in understanding and leveraging our work on predictability roadmap and in collaboration between the FACAs, especially around data harmonization. There was also interest in the next generation vital standards.

We look forward to collaborating with HITAC and ONC going forward.

Sincerely,

William W. Stead, M.D., Chair
National Committee on Vital and Health Statistics

cc: Alex M. Azar, J.D., HHS Secretary
    Jon White, M.D., ONC