January 12, 2024

Mandy K. Cohen, D, MPH
Director
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road NE
Atlanta, GA 30333

Jacki Monson, JD
Chair
National Committee on Vital and Health Statistics (NCVHS)
Centers for Disease Control and Prevention (CDC)/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

 Cc:

Rebecca Hines, MHS
Executive Secretary
National Committee on Vital and Health Statistics (NCVHS)
Centers for Disease Control and Prevention (CDC)/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Submitted electronically to:
NCVHSmail@cdc.gov

RE: RFI Addressing the Potential Use of ICD–11 for Morbidity Coding in the U.S.

Dear CDC Director Cohen and NCVHS Chair Monson:

Health Level Seven (HL7) International welcomes the opportunity to provide feedback on the October 16, 2023 Request for Information (RFI) seeking input on addressing the potential use of the International Classification of Diseases, Eleventh Revision (ICD–11) for morbidity coding in the U.S. and broader implementation questions.

Progress on ICD-11 --in the United States and globally-- must be informed by input from both the public and private sectors. This RFI is an important step in advancing ICD-11 usage. HL7 notes the incredible potential ICD-11 possesses to improve health care quality, equity and coordination. As such, we are pro-actively working with relevant stakeholders and government regulators on effective implementation strategies. HL7's efforts in concert with the World Health Organization (WHO) to refine their use of the HL7 FHIR terminology services API and collaborative development of the guidance for use of ICD-11 in HL7 standards, are an important examples.

Our organization's perspectives on the RFI are below. As the global authority on health care interoperability and a critical leader and driver in the standards arena, we look forward to being part of a collective effort to progress ICD-11 thoughtfully, advancing global health care goals without providing undue burden to implementers. A critical part of the HL7 mission is to provide a comprehensive framework and related standards for electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7 also actively supports cross-community terminology and value set needs to further benefit data driven policy and operational needs. Each of these elements will be foundational to ICD-11's ultimate success and we stand ready to collaborate and help drive consensus.

Comments detailed in this RFI response reflect the combined perspectives of HL7's leadership, the Policy Advisory Committee and the Payer/Provider Information Exchange (PIE) and Patient Empowerment Work Groups. Should you have any questions about the attached document, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We look forward to continuing this discussion and offer our assistance to NCVHS and the CDC.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
HL7 International

Julia Skapik, MD, MPH
Board of Directors, Chair
HL7 International

HL7 RFI Comments

RFI Questions	HL7 Comments
Overarching	**ICD-11 and HL7 Standards:** HL7 recognizes that ICD-11 implementation will touch upon and impact many of its standards and product families such as HL7 Fast Healthcare Interoperability Resources (FHIR), HL7 Consolidated Clinical Document Architecture (C-CDA) and HL7 Version 2 (V2). Our organization is exploring the impacts of this currently to prepare for any future ICD-11 timeline and to work effectively with the U.S. government and other stakeholder partners.
	ICD-11 and Terminologies: HL7 recognizes that adoption of standard terminologies is complex. One of ICD-11's key innovations is the use of post-coordination. Structurally, this feature is well supported by HL7 standards. The foundational data types for representing terminology

	concepts in all of HL7's product families, support the use of post coordinated expressions, as well as conventional concept codes.
	For the major coding systems, HL7 works with the Terminology SDOs to develop specific guidance for implementers about how to use their terminologies in HL7 standards. We have published such guidance for use of SNOMED CT expressions. Regarding ICD-11 and terminology at a macro level, HL7 recommends that ICD-11 implementation take into account how terminology is used practically in real world scenarios.
	ICD-11 [HL7 and WHO]: HL7 has not yet developed our guidance for ICD-11. However, in Summer 2023, HL7 and WHO signed a collaboration agreement to refine WHO's use of the FHIR terminology services application programming interface (API) and will be collaboratively developing the guidance for use of ICD-11 in HL7 standards. These efforts will also address complex licensing and tooling issues related to ICD-11.
	ICD-11, Artificial Intelligence (AI) and Standards Development: The RFI questions inquire about AI, ICD-11 and our organization. HL7 highlights that we are undertaking an important assessment of Generative AI usage in the standards development arena. Findings and action steps related to this AI initiative could inform ICD-11 rollout and many other health care related efforts in the U.S. and internationally. HL7 is committed to sharing relevant results with NCVHS, CDC and other relevant government agencies as they become available.

1. Related to ICD-11 content and addressing U.S. -specific needs, which enhancements in classification content would be most useful?
   a. Coding to assess and address population health equity, social, behavioral, and community health
   b. Coding to measure health care quality and patient safety
   c. Coding for rare diseases
   d. Content on other topics?
	Social Determinants of Health (SDOH): Regarding question 1a, health equity and SDOH are increasingly measured and integrated into U.S. health care practice. HL7's Gravity Project has been key in this effort. Coding to assess and address population health equity, social, behavioral, and community health is a critically useful and an important ICD-11 classification content enhancement. HL7 and its Gravity Project stand ready to provide needed expertise and perspective.
	
	ICD-11 Content on Other Topics: Regarding question 1c, the full spectrum of health care services should be addressed. An example highlighted by the HL7 Patient Empowerment Work Group is that patient advocacy groups are asking for codes to track de-transition and other complications that arise from gender affirming procedures.

2. **What is the potential to reduce burdens and improve quality/accuracy through the greater automation offered by the ICD-11 online classification systems?**
    a. How might automation reduce burdens of clinical documentation and coding for reimbursement, risk adjustment, clinical registry, and public health reporting?
    b. What might be the role of artificial intelligence (AI) for your organization?
    c. What might be the role of standardized cross-maps to other coding systems?
    d. What other potential features could promote burden reduction?
	ICD-10 and ICD-11 Crosswalks: Overall, HL7 notes that extensive coding mapping and crosswalks between ICD-10 and ICD-11 will be needed. They will serve as an essential resource to support efficient ICD-11 adoption and reduce implementer burden while promoting data interoperability and interpretation reliability.
	
	Longitudinal Records: Regarding question 2c, HL7 observes that aliasing and cross-mappings would be very useful for symptom clustering in longitudinal records.

3. **What standards, systems, workforce, and processes must change to accommodate ICD-11?**
    a. How would your organization assess the cost and impact of these changes?
    b. How might technical changes such as clustered (post-coordinated) coding be implemented in your environment?
    c. What other changes are related?
	Implementation Insight: Regarding question 3a, HL7 recommends examining the implementation time and costs in the transition from ICD-9 to ICD-10 as a point of reference to include an additional factor related to the significant coding system redesign between ICD-10 and ICD-11.

4. **What are the most important considerations and requirements for a U.S. governing body for ICD-11?**
    a. Developing and managing implementation plans and programs for ICD-11 in the U.S.
    b. Developing regulations or guidance for ICD-11 applicable to your
	Incentivizing ICD-11 Uptake: Regarding question 4a, HL7 recommends considering ICD-11 incorporation into relevant existing programs to incentivize health care provider uptake.
	
	Critical Regulatory or Other Guidance: Regarding question 4b, HL7 believes important considerations include:
	• Timely release of implementation strategies and policy guidance;
	• Development of ICD-11 FAQs;
	• Stakeholder educational sessions that are targeted by role such as business, technical, clinician, coders; and

organization.
   c. Ongoing management and maintenance of U.S. ICD-11 and its use.
   d. Other requirements not named above?
	• Testing period for health plans, providers, vendors, state entities and other applicable bodies.

5. What financial, educational, or human resources will be needed for:
   a. Implementing ICD-11 in your organization.
   b. Managing and maintaining U.S. ICD-11 in your organization.
   c. Meeting the needs of smaller, less resourced, or less externally supported entities.
   d. What other resources not listed here may be needed
	Stakeholder Expenses and Incentives: Overall, related to the financial, educational and human resources costs associated with ICD-11, HL7 recommends appropriate stakeholder incentives, expense recording and offset. An example of this is including ICD-11 implementation costs in the Medical Loss Ratio (MLR) calculation for health plans.
	
	Additional ICD-11 Resources: Regarding question 5d, HL7 notes the following additional resources may be needed:
	• Support for standards development organizations (SDO) to work with industry stakeholders in order to create ICD-11 materials, crosswalks, and recommendations. These include information on how to manage ICD-10 and 11 overlaps and the methods for incorporating ICD-11 into existing standards, such as HL7 FHIR documents. HL7 notes that implementation resources and needs will vary across entities.
	• Crosswalks from ICD-10 to ICD-11 would be needed.
	• Education on ICD-11 from US SDO's (webinars, presentations at conferences).