Request for Information Preliminary Results

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12 Questions

1. What would be the benefits of implementing ICD–11 for morbidity in your setting or organization?

2. What information or research will your organization need in order to inform assessments of cost, benefits, implementation approaches, communications, and outreach regarding the transition to ICD–11?

3. What considerations affect the impact of ICD–11 on clinical documentation, payment processes including risk adjustment, public health, population health, or research?

4. What unique U.S. coding or terminology considerations are essential? For example, coding or terminology related to community health, social determinants of health, essential human needs, sexual orientation, gender identity and expression, obesity, external cause of injury, and information about mental, behavioral, or neurodevelopmental disorders including alignment with DSM–5?

5. How should HHS implement ICD–11 in the U.S. for morbidity coding?

6. WHO recommends establishing a national center for ICD–11 implementation. What entity should be responsible for coordinating overall national implementation of ICD–11 for morbidity coding, and how should the implementation be managed?

7. ICD–11 uses an open process in which WHO encourages requests for updates and changes, thus eliminating the main drivers of national clinical modifications. What entity should be responsible for coordinating U.S. requests for updates or changes to ICD–11? How should this process be managed?

8. What resources, tools, or support will your organization need for implementation?

9. What kinds of technical resources, guidance, or tools should the U.S. Federal Government make available?

10. What workforce, workforce planning, or training will your organization need to support implementation?

11. What are your organization’s requirements for ICD–11 mapping to other coding systems and terminologies, including value sets?

12. What other operational impacts of ICD–11 adoption and implementation should HHS consider?

What would be the benefits of implementing ICD–11 for morbidity in your setting or organization?

- Enhanced alignment and integration with EHR systems and with richer clinical terminology and vocabulary standards, such as SNOMED CT (“universal translator of local data into a language that can facilitate digital data exchange”).
- Increased ability to describe health conditions in greater detail through the combination of codes, facilitating research collaborations, clinical decision-making, accurate reimbursement, risk-adjusted quality measure reporting, value-based care and payment, and efforts to improve equity by addressing social determinants of health.
- The transition to ICD-11 is likely to be more impactful [than the transition to ICD-10] by shifting emphasis and capability to post-coordination (i.e., adding and joining codes to express detail across conceptual dimensions) and thereby introducing new flexibility and clinical precision.
- ICD-11 provides the flexibility and underlying structure to capture new discoveries in medicine, helping to streamline the code update process, support future expansions, and improve timely availability of data for all use cases

What information or research will your organization need in order to inform assessments of cost, benefits, implementation approaches, communications, and outreach regarding the transition to ICD–11?

- Decision on whether a U.S. clinical modification of ICD-11 will be developed and if not, how will U.S.-specific coding needs be handled (i.e., U.S. linearization within the WHO Foundation framework?)
- A comprehensive understanding of the structural and content differences between ICD-10-CM and ICD-11.
- Information regarding whether HHS plans to provide publicly available mapping software that links its linearization/clinical modification of ICD-11 to ICD-10-CM/PCS.
- More detailed information about the nature and scope of the changes; the pathway and transition between versions; requirements, if any, for EHR vendors' implementation of ICD-11.
- A detailed timeline with milestones and achievable benchmarks
- Clarity around changes in governance processes, including US deviation from WHO.
- Research ("comprehensive cost-benefit") around the benefits and costs of adopting ICD-11, including the impact on payment, reimbursement, and new payment models such as value-based care.
- Understand impacts of ICD-11 implementation on other adopted code sets, such as the Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), SNOMED-CT, and LOINC.
- Expected changes to administrative transactions and workflows, current data storage and transmission, etc.
- Expected software changes to accommodate ICD-11 in the electronic health record (EHR) and practice management systems, and estimated vendor implementation timelines and costs.
- Expected costs for staff training and expected changes to data collection and reporting, including quality measures, value-based programs, clinical research, and other clinical programs.
- Results from case studies of pioneering ICD-11 installations.

What considerations affect the impact of ICD–11 on clinical documentation, payment processes including risk adjustment, public health, population health, or research?

- Need to relate ICD-11 stem and extension codes directly to fields in EHRs, allowing users to add combinations of stem and extension codes to track the detailed course of a patient's health status, relate changes to diagnostic and therapeutic interventions, assess comparative risk-adjusted clinical outcomes, and guide healthcare quality improvement initiatives.
- Updates to a version of the mandated X12 transactions ("lengthy, burdensome process") that support ICD-11 must be in place prior to the ICD-11 implementation, along with updates to applicable operating rules.
- Evaluation of whether the level of granularity in ICD-11 matches clinical, public health or administrative needs or whether additional modifications are needed.
- Consider extent to which ICD-11 coordinates with non-clinical national and state mandated information interoperability content standards (e.g., coding used for social services coordination, public health case or surveillance reporting, or quality measures or health equity assessments).
- All ICD-11 coding specifications related to compliant and complete code generation, display, reporting, and billing will be needed to identify tools and platform needs.
- Need upgraded capabilities to efficiently generate the content creation and to provide the end user an optimal experience with ICD-11.
- ICD-11 must be implemented properly to better meet various needs, which means adopting and mandating a U.S. version ("linearization") that is more capable than the WHO's MMS alone.
- All systems and processes leveraging ICD-10-CM codes will need to be evaluated for impact on transitioning to ICD-11: payment systems, public health, social service entities, population health and research.
- Will there be consistency across payers in the definitions as to a complete code? What level of post-coordination is necessary to adjudicate a claim?

What unique U.S. coding or terminology considerations are essential?

- Refine and augment existing social drivers of health (SDoH) and social needs codes to gather data in a standardized way across payers and providers, aligning when possible with the Gravity Project (for SDoH) and US Core Data for Interoperability.
- Consider concepts such as loneliness, lack of social support, military deployment, digital literacy, lack of internet access, IPV
- Current ICD-11 codes may be insufficient for osteopathic and chiropractic providers.
- Consider requirements and timelines of other mandated regulatory changes and updates, including interoperability standards, No Surprises Act, Health Insurance Portability and Accountability Act (HIPAA) standards and operating rules, and Trusted Exchange Framework and Common Agreement (TEFCA), etc.
- Updated versions of the mandated X12 transactions will be needed to accommodate all coding/terminology considerations.
- If the U.S. has unique ICD coding requirements that require either an extension or modification, will the U.S. create its own type of URI to align to the WHO's foundation/MMS?
- Consider need for increased specificity in the area of rare diseases and genetic conditions.
- Consider governance model to coordinate coding solutions and consolidate terminologies used in clinical practice in US (e.g., stages of disease)

How should HHS implement ICD–11 in the U.S. for morbidity coding?

- SLOWLY AND CAREFULLY – time frames from 2 years to 10 years.
- ICD-11 should be implemented only after a clear return on investment is established to show that there is value in using the updated code set for morbidity, and that it outweighs the implementation costs.
- Develop a detailed roadmap and transition plan, with a phased approach.
- Coordination across all agencies and stakeholder groups is essential
- Collaborate with key stakeholders (e.g., providers, payers, public health, EHR/health information technology vendors, professional associations) to develop tailored implementation guidance and materials.
- Provide a comprehensive set of crosswalks (mappings) with ICD-10-CM, SNOMED CT, etc.
- Consider lessons from ICD-10-CM implementation, but what are they?
    - Some advocate a “hard cut” from ICD-10 to ICD-11 based on date of service
    - Others advocate a “transition period” during which both code sets could be used.
- The mandated version of ICD-11 in the U.S. should facilitate access to all “Entities” (clinical concepts) available in the ICD-11 Foundation.
- National implementation must consideration which linearization will be leveraged; private efforts are underway to develop a US-tailored linearization building on MMS but other linearizations may be useful for specific specialties or settings (i.e., mental health).

What entity should be responsible for coordinating overall national implementation of ICD–11 for morbidity coding?
What entity should be responsible for coordinating U.S. requests for updates or changes to ICD–11? How should this process be managed?

- Commenters expressed differing views.
- Some advocate traditional approach, relying on the National Center for Health Statistics (NCHS), with input from the Cooperating Parties, Office of National Coordinator (ONC), National Library of Medicine (NLM), CMS, etc.
- Some advocate enhanced role for National Library of Medicine's (NLM) Office of Health Data Standards and Terminologies (HDST), leveraging its role as National Release Center for SNOMED CT (but with input from other agencies and stakeholders).
- Some advocate enhanced role for Centers for Medicare & Medicaid Services, leveraging its role as primary regulator and user of coded data
- Consider the creation of a national steering committee or task force with representatives from key stakeholders, including government agencies, professional associations, healthcare organizations, and academia, to oversee the implementation process and address challenges, ensuring effective collaboration and representation of diverse perspectives.
- Structured and transparent process will be needed to align requests with global updates and support timely and clear versioning.

What resources, tools, or support will your organization need for implementation? What kinds of technical resources, guidance, or tools should the U.S. Federal Government make available?

- Timely release of policy guidance.
- Develop a specific ICD-11 FAQ section on the CMS website, along with other guidance and public and private sector resources.
- Stakeholder-specific educational webinars (live and on demand), computer-based training, toolkits, training conferences, publications.
- Regular review of industry readiness, with an ICD-11 ombudsman at DHHS to address concerns
- Include an ICD-11 support component into ONC's electronic health record certification program.
- Work collaboratively with industry organizations to develop and disseminate resources.
- U.S.-specific browser, especially if the U.S. defines specific requirements of ICD-11 coding, such as for extension reporting.
- Standards or coding guidelines around how specific features of ICD-11 should be used to ensure consistency, such as the use of extension codes.
- ICD-10-CM to ICD-11 and ICD-11 to ICD-10-CM maps, with NLM's HDST responsible for developing and disseminating the mappings.
- Consider special needs of physician practices, rural hospitals, Medicaid providers and plans

What other operational impacts of ICD–11 adoption and implementation should HHS consider?

- The wide-scale upheaval and significant cost that will occur with the implementation of ICD-11 needs to be closely considered along with expected benefits.
- HHS should consider other legislative and regulatory requirements and deadlines that will overlap with the implementation period for ICD-11.
- Healthcare providers have limited resources for updating their EHR and practice management systems, training staff, changing administrative workflows, and sustaining the loss of productivity through an implementation of this large scale.
- Careful coordination of various regulatory deadlines with changes requiring extensive data and/or IT updates should be considered.
- Implementing an updated version of the mandated X12 transactions to a version that supports ICD-11 needs to happen before the implementation of ICD-11.
- Look at lessons learned from the ICD-10 implementation to identify best practices for use with ICD-11.
- HHS should consider the impact the adoption of ICD-11 would have on the pharmacy industry, clinical laboratories, physician practices, rural hospitals, small health plans, etc., and provide support to ease the transition and ensure workforce readiness.
- Testing, testing, testing – requires support, dissemination, learning and feedback

Concluding thoughts

- The RFI published in the Federal Register launched robust discussion among key stakeholders and helped set the agenda for today.
- The number and detail provided in comments was limited by the timeline for response.
- The general tenor of responses suggests cautious enthusiasm, with a need for careful attention to many critical challenges.
- Learning from ICD-10 implementation, more planning, research, testing, and evaluation are needed, with involvement of all stakeholders
- Another RFI cycle may be launched after this meeting, with refined questions and a longer opportunity for response, to engage more stakeholders.