National Committee on Vital and Health Statistics

Comments Received in Response to the ICD-11 RFI Published October 16, 2023

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January 12, 2024

Rebecca Hines
Executive Secretary
National Center for Health Statistics
Centers for Disease Control and Prevention
3311 Toledo Road
Hyattsville, MD 20782

Re: Request for information on addressing the potential use of ICD-11 for morbidity coding in the United States

Dear Executive Secretary Hines:

On behalf of the nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on your request for information (RFI) addressing the potential use of ICD-11 for morbidity coding in the U.S.

The International Classification of Diseases (ICD) is the global standard for health data, clinical documentation and statistical aggregation. It provides a common language for recording, reporting and monitoring diseases, allowing the world to consistently compare and share data among providers, including hospitals, as well as across regions and countries. The AHA appreciates the opportunity to share our perspective on the implications of the transition to ICD-11 on health data, statistics, privacy and national health information policy with the National Committee on Vital and Health Statistics' (NCVHS) ICD-11 Timely and Strategic Action to Inform ICD-11 Policy Workgroup as they consider recommendations regarding implementation to the Secretary of Health and Human Services (HHS).

The AHA supports NCVHS in its effort to promote the transition to ICD-11 and educate industry stakeholders on its potential to offer enhanced data reportability and consistency. However, before NCHVS finalizes a recommendation for an ICD-11 transition and implementation, the AHA encourages the NCVHS to:

- In collaboration with the Centers for Medicare & Medicaid Services (CMS), create and publish robust and meaningful case scenarios comparing side-by-side dual-coded acute care, post-acute care, outpatient and physician office cases (ICD-10 versus ICD-11) for industry stakeholder review.
- In collaboration with CMS, provide an in-depth analysis that specifies the reporting differences, benefits and challenges specific to these case scenarios when comparing ICD-11 to ICD-10.
- Utilize these analyses to determine if the potential benefits of the ICD-11 transition outweigh the health care industry operational issues and factor its findings into its final recommendations on implementation to the secretary.

This analysis should consist of, but not be limited to:

- Provider documentation requirements noting similarities and differences.
- Coding application and coding guideline similarities and differences.
- Critical considerations for claim submissions (i.e., capture and reporting similarities and differences specific to the UB04 paper claim form, 837I electronic claim form, and the CMS 1500 claim form).
- Key concerns related to quality reporting initiatives and anticipated differences in data output, meaning and reporting agency system capabilities.

Access to this type of information through case scenarios and analysis will better position organizations to understand the impacts of an ICD-11 transition. For example, these case examples will provide insight into individual and organizational considerations related to technology, systems, vendors, education and internal assessments. As such, they would help inform responses to the questions posed in this RFI. Specifically, organizations will gain insight to address several of the RFI questions, including:

- What enhancements in ICD-11 classification content would be most helpful in addressing requirements specific to the U.S.?
- What financial, educational or human resources will be needed to implement, manage and maintain ICD-11?
- What standards, systems, workforce and processes must change to accommodate ICD-11 in individual organizations?

In response to the RFI question related to the administrative burden, health care organizations will need access to a testing sandbox to fully respond. Early and often access to a testing sandbox would enable health care organizations to better understand the benefits of a transition to ICD-11 and gain insight into reduced burden potential and the capability to improve quality and accuracy through the greater automation that the ICD-11 online classification system may offer.

Reducing administrative burden in conjunction with the evolving artificial intelligence (AI) capabilities will be a critical factor in health care organizations' ability to fully assess the

costs and impacts of a change from ICD-10 to ICD-11, something that was not as prevalent with the transition to ICD-10 from ICD-9. A recent survey published by NORC at the University of Chicago and the American Health Information Management Association addressed challenges within the health information workforce.[1] The survey results noted that nearly half of respondents reported that their organization uses AI or machine learning (ML) tools for coding, documentation or other health information related workflows (primarily in urban/suburban areas). Improved productivity was among the top benefits cited for all AI and ML tools included in the survey, followed by reduced administrative burden. More than half of respondents reported that their organization plans to increase the use of AI or ML over the next 12 months. Just under half of the respondents plan to maintain the utilization of current AI or MI capabilities, indicating that the role of emerging technologies in health information will continue to accelerate.

The AHA recognizes that health care applications of AI may pose novel challenges related to provider documentation. NCVHS should provide in their recommendations to the Secretary any regulatory and systematic framework updates, ICD coding application and guideline revisions, and timelines for these updates and modifications to address challenges that arise considering AI capabilities and use.

The AHA appreciates the opportunity to provide comments in response to this RFI. We look forward to collaborating with you as NCHVS prepares recommendations to inform the Secretary regarding the decision for an industry transition to ICD-11. Please contact me if you have any questions or feel free to have a member of your team contact Tammy Love, AHA's director of policy, at tlove@aha.org or 202-626-2364.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development

[1] Health Information Workforce Shortages Persist as AI Shows Promise: AHIMA Survey Reveals | AHIMA

MARTING LAW

January 12, 2024

Via Electronic Mail to NCVHSmail@cdc.gov

RE: Request for Information on Implementation of ICD-11

To Whom it May Concern:

This letter is submitted on behalf of the Arizona, Colorado, Illinois, Kansas, Missouri, Nebraska, and Oregon Component State Associations of the American Health Information Management Association (CSAs), in response to the Department of Health and Human Services National Committee on Vital and Health Statistics October 16, 2023 Notice of Request for Information (RFI) on the potential use of ICD–11 for morbidity coding in the U.S. We appreciate the opportunity to submit comments for the agency's consideration.

The seven (7) CSAs, on whose behalf this comment is submitted, represent more than 8,400 health information management professionals. A workgroup of the boards for these CSAs convened to discuss the RFI and prepare their responses.

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

The CSAs collectively support enhancements to the ability to capture social determinant of health (SDoH) data in ICD-11-CM content. In particular, the need for codes to identify challenges with access to care, food, and medications and housing instability were consistently suggested as an enhancement need. Members discussed the Healthcare Effectiveness Data and Information Set (HEDIS) reporting and running into difficulties being able to fully report accurately because social determinates of health data is missing or uncaptured.

B. Coding to measure health care quality and patient safety

Members support the enhancement of diagnostic and procedural codes to measure and report health care quality and patient safety. We suggest the cooperating parties coordinate with CMS, the National Quality Forum, Joint Commission, and similar entities to develop codes that align with and support quality and safety metrics used in widespread provider/payor programs.

2. **What is the potential to reduce burdens and improve quality/accuracy through the greater automation offered by the ICD–11 online classification systems?**

Members unanimously supported access to an online classification system and emphasized the utility of periods of dual coding during the transition from ICD-9-CM to ICD-10-CM as a beneficial practice supporting the quality and accuracy of ICD-10-CM code assignment. Members encouraged the cooperating parties to make available similar online, automated crosswalk systems for any transition from ICD-10-CM to ICD-11-CM.

Members support leveraging artificial intelligence to improve efficiencies and accuracies in the development and use of ICD-11 codes. Examples of how such AI could be used to improve code capture included identifying patterns likely to increase risk for SDoH. For example, identifying that a patient lives in an area that is a hot spot for diabetes, food access, or access to care challenges. This could help with prospective gaps and care management by more quickly being able to apply proper interventions.

3. **What standards, systems, workforce, and processes must change to accommodate ICD–11?**

Accommodating ICD-11 may require changes to the standards and data elements for paper and electronic claims. Whenever changes to the standard claim forms are made, widespread information system changes such as clearinghouses, payer claims processing systems, electronic medical records, provider billing systems, data dictionaries, data mapping tools, encoder tools, and utilization management software among others are necessary as well. These information system accommodations consume extensive resources even with annual updates to current code sets. Sufficient time, budgeting of financial impact, and assistance for small or low income provider types should be planned to ensure a successful transition.

Our membership expresses concern with the extremely high cost and resources to undergo a classification system conversion on the heels of the pandemic and widespread financial impact to healthcare providers. HIM professionals caution the cooperating parties about the potential disparate impact such a conversion would have on rural providers.

Workforce readiness is an ongoing concern. Shortages of clinical and administrative workforce and professionals in the HIM profession with expertise to facilitate the transition to a new code set have the potential add strain to providers and facilities that may detract from resources needed to maintain clinical care.

Members expressed the need for compliance dates for payors to align with, or precede, those of healthcare providers. Experience from the transition to ICD-10-CM revealed third party payers were often unready to accept and process claims using ICD-10 codes successfully. The resulting delay in providers' payments added further, unnecessary strain.

We encourage the cooperating parties to re-evaluate the financial impact estimates of the conversion from ICD-9 to ICD-10 retrospectively to help better estimate the projected impact of a transition to ICD-11. Membership consistently shared both the hours estimates and the rate

estimates in final rulemaking for ICD-10 were grossly unrealistic, and vastly underestimated the actual costs of implementation.

A. How would your organization assess the cost and impact of these changes?

Many costs can be assessed as an expression of vendor fees for the update of information systems to accommodate a new code set. We caution the agencies that these vendors are in a unique position to have the ability to recover their costs of the conversion to a new code set and even profit from it, while payers and providers are generally absorbing the extensive costs. We encourage the agencies to consider creative solutions to help spread the cost more evenly among stakeholders.

Staffing costs are difficult to project and almost always exceed projections due to unanticipated circumstances. Lack of payer readiness, for example, creates considerable hardship on providers and forces them to incur unanticipated costs and resource expenditures to address circumstances beyond their control.

Education needs must be sufficiently considered. Nearly everyone in healthcare organization plays a role in either capturing information that will translate to code assignment, translating documentation into codes, analyzing codes, or using codes for operations purposes. Clinicians, administrative teams, information technology, financial and revenue cycle, information management, and leadership all need education about the code set transition and its impacts. This education requires substantial investments in time, money, and other resources to complete appropriately.

There should be a well thought out communication campaign of the potential benefits of a new code set, including how providers may stand to gain revenue improvements through better data capture.

4. What are the most important considerations and requirements for a U.S. governing body for ICD–11?

An ICD-11 governing body should be comprised of experts in fields of public health, data quality, SDoH, clinical quality, medicine, and allied health professions to ensure the terminology is consistent with current clinical practice, meets the needs of the industry's data capture, data reporting, and measurement initiatives, and includes appropriately clear and defined standards for effective, consistent application.

We appreciate your consideration of our membership's comments and feedback.

Sincerely,

Richelle Marting

JD, MHSA, RHIA, CPC, CEMC, CPMA, CPC-I

January 11, 2024

National Center for Health Statistics
Centers for Disease Control and Prevention
3311 Toledo Road
Hyattsville, Maryland 20782

Submitted electronically to NCVHSmail@cdc.gov

RE: Request for Information on Potential Use of ICD-11 for Morbidity Coding in the U.S.—AHIP Comments

On behalf of AHIP, the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day, thank you for the opportunity to provide comments on the National Committee on Vital and Health Statistics' (NCVHS) request for information (RFI) on the International Classification of Diseases (ICD).

AHIP commends NCVHS' efforts in support of ICD-11 adoption and implementation. The new architecture of the ICD-11 code set allows for more granularity that AHIP believes will afford an opportunity to drive greater accuracy in diagnostic coding for clinical and administrative use. We also appreciate NCVHS' engagement of stakeholders and solicitation of industry input as it develops recommendations to the Secretary of the Department of Health and Human Services (HHS).

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?

It may be premature to presume the U.S. will require its own adapted version of ICD-11, as has been done with prior ICD code sets. Given the fundamentally different structure of ICD-11 vis-à-vis ICD-10 and lack of experience with the World Health Organization (WHO) process for receiving new or revised code requests and making determinations, the health insurance industry does not yet have enough information to determine if a unique U.S. version is necessary. Notwithstanding this qualification, if a U.S. version is ultimately deemed necessary, we provide essential considerations below.

The WHO could remain the primary source for collecting and effectuating code changes, while the U.S. could serve as a source strictly for emergency codes on an as-needed basis. This would permit an expedited process for the U.S. to make coding updates in limited, exigent circumstances that merit rapid clinical response and coding updates. Examples could include a

U.S.-based outbreak, epidemic, environmental catastrophe, or terrorist attack. We are concerned that the WHO process may not be nimble enough to meet the needs of the U.S. health care system in these instances and that establishing a governance model and U.S. infrastructure for making codes updates could better meet our needs in these limited circumstances.

Beyond limited situations, any substantial customization of ICD-11 within the U.S. should entail careful consideration of its impacts on international research. Differing substantially from the WHO risks hindering reliable cross-country comparisons. An approach that allows for necessary customization like enhanced granularity for clinical, administrative, public health, societal, public policy, and research purposes could be narrowly scoped to match U.S. needs while still permitting reliable international comparison and analysis. Below we discuss some potential areas where U.S. customization may be beneficial.

Commitment to Equity

The move to ICD-11 brings the opportunity to advance health equity goals in the U.S. Collecting data on social determinants of health (SDOH) can foster a greater understanding of a patient's needs, in turn empowering action and intervention to mitigate the impact of social risks, drive quality improvements, and engage patients. Structured code sets enable more standardized collection of SDOH data compared to unstructured narrative notes in electronic health records, but limitations of existing SDOH codes have hindered reliable identification and documentation of social risks. ICD-11 can help overcome these limitations by filling in existing gaps in social needs coding and evaluating existing code language for opportunities to reduce vagueness or ambiguity.[1]

As NCVHS considers whether a country-specific modification is necessary, it should evaluate whether ICD-11 as administered by WHO could accommodate U.S. cultural sensitivities that are evolving. Even the U.S. modification has not kept up with this evolution and requires revision of existing code descriptors that contain pejorative, dated, or stigmatizing language.[2]

Regardless of whether the U.S. develops a country-specific modification, we suggest establishing a periodic U.S. review process to assess codes for cultural sensitivity and to facilitate openness to social and cultural evolution. Reviews should include participation from language experts and individuals with diverse backgrounds.

[1] For example, ICD-10 codes that describe illiteracy and low literacy can result in inconsistent application since terminology like "low literacy" is prone to subjectivity, which in turn can compromise consistent data capture.

[2] For example, Z72.52 "High risk homosexual behavior" is stigmatizing.

AHIP recommends that ICD-11 strive to align with the coding and vocabulary standards identified by the consensus-driven Gravity Project[3] and in the USCDI Version 3 for SDOH Diagnosis. Including socioeconomic needs in the USCDI would allow for broader sharing of this data and improved interoperability across systems. We also recommend further discussion to determine opportunities to educate and incentivize provider use of not only ICD-11 in electronic and paper billing forms but also the new SDOH codes specifically.

Value-Based Payment Reform Across the U.S.

For over a decade, health insurance providers have been striving to scale and continually improve value-based payment arrangements based on experience, emerging best practices, technological updates, patient needs, and other factors. Complete, precise clinical data is crucial to continued improvement of these arrangements. ICD-11 presents an opportunity to document patient clinical and social profiles with greater precision, which, in turn, could assist HHS in meeting its goal of having all Medicare and Medicare Advantage beneficiaries in an accountable care arrangement by 2030.[4]

For example, more precise coding and data collection could increase the accuracy of risk adjustment and improve the ability of payers to account for patient complexity in value-based payment methodologies. This could help avoid inadvertently penalizing providers who treat patients with complex needs by adjusting payments to reflect increased resource use. Diagnostic granularity could potentially permit more meaningful analysis into the clinical drivers of high-cost conditions to prioritize and tailor care management and other interventions. Finally, additional granularity could also facilitate more robust quality measurement to drive higher quality of care and ultimately, better outcomes within these arrangements. To the extent that claims could capture more information, such as cancer staging, it could improve measurement and financial risk adjustment. It could also reduce provider burden by enabling more electronically derived measures without a need for chart review.

Again, these benefits are heavily contingent on provider adoption of not just ICD-11 generally, but use of precision coding and use of post-coordination to code diagnoses and social risks with greater specificity Thus, it is critical to ensure adequate education and training as well as to identify opportunities to incent ICD-11 adoption, including for the more specific purpose of value-based arrangements.

U.S.-Specific Implementation Needs

[3] https://thegravityproject.net/.

[4] https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper.

ICD codes are used throughout the U.S. health care system; they are pivotal in providing detailed information for purposes of claims adjudication and processing, clinical decision making, public health efforts, and research. Thus, migration to ICD-11 will have a major impact across the U.S. and will require significant financial and human resources for successful implementation. The planning process should devote significant consideration to how a transition period should be structured to minimize the disruption to patient's first and foremost, but also implementers.

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 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?

Computer-assisted coding technology has the potential to bring benefits to ICD-11 implementation by automating aspects of clinical documentation and coding. Natural language processing to extract codes from clinical notes, computer-assisted coding recommendations, and system logic to determine optimal codes could reduce the need for manual work. Deep learning models trained on large datasets may exceed human coder accuracy for diagnosis classification if tools are tailored to accommodate idiosyncrasies of medical language used in the U.S. and any other necessary U.S. health system attributes that could impact coding. However, we note that Human-in-the-Loop (HITL) standards should be developed and adhered to as uses of artificial intelligence (AI) within the context of ICD-11 proceed.

Transformative AI has rapidly proliferated over the past several years, making it one of the most salient topics across many different stakeholders, regulators, app developers, and businesses. Companies seeking business opportunities are developing new tools and capabilities every day to meet different needs. But not all tools are created equal. The industry is still grappling with how to address challenges of bias, security, safety, and governance. To the extent that any governing body considers use of AI in the context of ICD-11 implementation, we suggest leveraging recommendations AHIP recently offered on U.S. agency use of AI.[5]

With the proliferation of AI, there should also be a mechanism to assist with tracking of AI, such as for patient safety. Patient safety is just one example, but it is important to note the novelty and rapidly changing field of AI will create new, unknown variables that cannot be contemplated at the outset of implementation. Establishing a framework to track and document these unknown variables through code sets could help prepare the U.S. to respond to new emerging issues around AI.

[5] https://ahiporg-production.s3.amazonaws.com/AHIP-Comments-OMB-AI-Use-Draft-Policy_Final.pdf.

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?

The transition to ICD-11 will have a systemic, wide-reaching impact across the U.S. health care system. Just a few examples of the many anticipated actions include:

- Updating data processing algorithms and classification software that handle ICD codes.
- Modifying EHRs, claims forms, and databases will also need to accommodate the longer character lengths necessary to record and store ICD-11 codes.
- Training health care stakeholders including employees such as the coding, revenue cycle, and clinical staff.
- Respecifying quality measures.
- Updating standards transactions.

In particular, the new post-coordination feature of ICD-11 will be completely novel. Post-coordination will support combining, or linking, two or more codes into a cluster to describe a clinical concept with greater specificity and granularity compared to ICD-10. This new clustered code structure is comprised of a stem code with the option to include and combine post-coordination extension codes to capture more clinical data, like severity, disease stage, and anatomical details. This permits rich data and coding options, but also brings about new challenges. HHS should help prepare stakeholders for post-coordination by developing resources and engaging in extensive education campaigns.

ICD-11 will be fully digital and come with a set of software tools.[6] While a digital framework can enable enhanced functionality and eventually lead to burden reduction, AHIP emphasizes the need for robust and tested electronic tools to aid implementation. In particular, end users will need software, tools, and education to support implementation of post-coordination work given its novelty. Core capabilities of assistive software or tools should help guide post-coordination selection of relevant extension codes that match to the stem code and include validation support or rules that flag or prohibit misclassified or incorrect clusters. In general, validation functionality can help reduce variability and errors. ICD-11 versioning also needs to be understood to help with validation on the receiving end. In addition, clarity is needed around how bundled codes will be validated (e.g., will each code need to be validated separately or in a bundled fashion?). For example, if an individual code is validated against a single date of service

[6] ICD-11 Implementation or Transition Guide, Geneva: World Health Organization; 2019; License: CC BY-NC-SA 3.0 IGO.; https://icd.who.int/en/docs/ICD-11%20Implementation%20or%20Transition%20Guide_v105.pdf

that has far fewer permutations than a group of bundled codes being validated across a range of dates.

Costs

AHIP members report it is not feasible at this time to conduct an accurate estimation of the costs associated with ICD-11 implementation. The migration to ICD-11 code sets will have a major impact on business and administrative operations, and there are still too many unknown variables to begin to develop a comprehensive, accurate estimate. More detailed information is needed about the nature and scope of the changes; the pathway and transition between versions; requirements, if any, for how EHR vendors to implement ICD-11; timelines for implementation; and adoption by government, payers, regulators, and accrediting bodies will assist organizations in assessing and preparing for implementation costs.

While comprehensive or detailed estimates of costs and human resource needs are not feasible at this time, what we do know is that they will be substantial.

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 organization. c. Ongoing management and maintenance of U.S. ICD–11 and its use. d. Other requirements not named above?

AHIP believes the considerations enumerated in the RFI question are all important and offers recommendations for a U.S. governing body below.

Implementation Plan

The governing body, together with stakeholders and relevant federal agencies, should develop a detailed implementation plan that includes a roadmap toward full implementation.

This roadmap should include a testing period for the new code set, once necessary preparatory steps have been completed. Prior to any testing, the U.S. governing body should ensure required updates to standards transactions are in place to accommodate ICD-11 codes. There should also be a clear understanding of any necessary changes to claims adjudication policies. For example, adjudicating concepts like principal diagnosis and admitting diagnosis and whether those require clustering or a stem code and post coordination as this will affect the structure and rules associated with the claim forms and thus transaction standards.

Encouraging testing will allow the industry to understand how ICD-11 impacts claims processing and other core health system functions. The testing period should allow sufficient time

adjustments and identification of impacts. Ideally, real-world testing claims data sets should be developed and shared across payers, providers, and vendors. This will help individual stakeholders gain experience and identify pain points, as well as confirm vendor (e.g., EHR companies, clearinghouses) and all parties' ability to process claims with ICD-11 coding. It also enables validation of systems revisions, early detection of potential issues, mitigating disruption in revenue cycle management, and driving improved processing to minimize consumer inconveniences that could arise from claims processing issues.

In addition to a testing period, the implementation guide should include a dedicated transitional period where both ICD-10 and ICD-11 codes will be permitted. Throughout the testing and transitional periods, guidance and flexibility regarding reporting requirements will be critical to prevent confusion and unnecessary burden.

Stakeholder Engagement

Communication, outreach, and engagement with stakeholders by the governing body and the broader U.S. government will be paramount given the size of this endeavor both in terms of the number of organizations impacted and the scope of changes necessary within those organizations.

In addition to holding listening sessions and other direct engagement opportunities, the governing body should create a website and newsletter to use as a conduit for sharing educational resources and updates. The website should include the implementation plan along with all published guidance materials. It should also include FAQs, to be updated regularly on the website, and a portal where stakeholders can submit individual questions and issues. The website or other technology-based platform should also support bidirectional communication, where stakeholders can engage with the governing body virtually and receive a response.

Coordination

Implementation of ICD-11 will entail close coordination across government agencies and independent organizations that assist with functions like standardization. The governing body should work with standards development organizations that rely on ICD coding, such as the National Uniform Billing Committee (NUBC), National Uniform Claims Committee (NUCC), X12, HL7, as well as interested bodies like the National Association of Health Data Organizations (NAHDO).

In coordinating across U.S. government agencies, the governing body should facilitate information sharing, communication, and coordination around various agency activities that will impact stakeholders, such as plans for implementing new requirements or changes, to avoid creating situations where numerous policies are being concurrently implemented by numerous

agencies while the U.S. works to implement ICD-11. Overlapping implementation requirements across health care programs creates significant administrative burden, drives up costs, and can result in confusion when concurrent activities are connected but their nexus or cross-program impact is not sufficiently considered and accounted for.

The implementation roadmap noted above could help to mitigate these challenges and drive coordination across U.S. agencies by alerting them to the ICD-11 transition timeline preemptively.

Adoption Incentives

We encourage the governing body, together with HHS and with the input of stakeholders, to consider developing incentives for stakeholders to adopt ICD-11 within a reasonable timeframe. We also suggest taking this opportunity to think of ways to move the health care system completely away from paper claims processing given the digital nature of ICD-11 and that providers may use older versions of ICD on the paper claims We understand that some entities, such as solo practitioners or small practices, and those located in rural areas, may not have made the transition to electronic billing yet and that doing so may entail significant investments. We believe there are ways to encourage moving to electronic claims in an incremental manner and would support maintaining exceptions for situations in which paper claims could be used in exceptional circumstances.

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?

Health insurance providers report the need for various materials to prepare for and engage in implementation efforts. Common themes of resource needs include those that describe differences between ICD-10 and ICD-11, vendor capabilities, mapping, and a request for an open channel for communication. In general, we recommend HHS collaborate with standards development organizations and industry stakeholders on the creation of materials, crosswalks, and recommendations.

We encourage HHS to strive for timely release of policy and operational guidance and to continually engage with the industry, both directly and via the ICD-11 governing body, through interactive education opportunities, including collaborative meetings and partnerships with payers, providers, and others.

Specific resource needs could include:

- A detailed roadmap describing the U.S.'s transition plan.
- Templates for health care organizations to prepare, plan, transition, and fully implement the new coding standard.
- Whitepapers outlining the difference between ICD-10 and ICD-11.
- Plan for managing mapping overlap.
- Plan on how ICD-11 SNOMED codes would be integrated into the Fast Healthcare Interoperability Resource (FHIR®) and standard transaction Implementation Guides (IGs).
- Resources to understand alignment with state mandates.
- Understanding of clearing house and vendors ability to accept new ICD-11.
- Extensive coding mapping between ICD-10 and ICD-11.
- Comprehensive crosswalks between the various coding standards, including ICD-11, ICD-10, CPT, SNOMED, LOINC, and HCPCS.
- Where applicable, resources should include standard terminologies and other classifications that provide the common medical language necessary for interoperability.
- Testing tools.
- Troubleshooting guides.
- Multi-modal training programs with resources like guidelines, fact sheets, webinars, training sessions, online courses with assessments to gauge learning.
- Lessons learned from early adopters.
- An industry portal to submit issues and questions.

Ultimately, resource needs will vary across entities, but active engagement and partnerships with stakeholders can help the governing body anticipate needs.

Conclusion

Thank you for the opportunity to provide input on these important issues. If you have any questions, please contact Danielle Lloyd at (202) 778-3246 or at dlloyd@ahip.org.

Sincerely,

Danielle A. Lloyd
Senior Vice President, Private Market Innovations & Quality Initiatives

AMERICAN CLINICAL LABORATORY ASSOCIATION

January 12, 2024

Ms. Jacki Monson, JD, Chair
National Committee on Vital and Health Statistics
National Center for Health Statistics
Centers for Disease Control and Prevention
3311 Toledo Road
Hyattsville, Maryland 20782-2002

Submitted electronically to: NCVHSmail@cdc.gov

RE: Request for Information (RFI) on the Potential Use of ICD-11 for Morbidity Coding in the U.S.

Dear Ms. Monson,

Please accept the comments of the American Clinical Laboratory Association (ACLA) on the above-referenced RFI.[1] ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care. We appreciate that the National Committee on Vital and Health Statistics (NCVHS) is seeking input from stakeholders who will be affected by implementation of ICD-11 in the United States.

ACLA submitted comments on the RFI that was published in the Federal Register on June 13, 2023.[2] We expressed our expectation that implementation of ICD-11 in the U.S. will be a complex and costly undertaking and urged NCVHS to draw on the lessons learned in the transition from ICD-9 to ICD-10. Our comments focused on the following:

- All stakeholders in the U.S. healthcare system – regulators, providers, payors, clearinghouses, and electronic health record vendors – need **adequate lead time** to plan for the transition, educate their employees and trading partners about ICD-11, reprogram multiple information systems, and conduct end-to-end testing.

- **The federal government has a vital role to play** in the implementation, ensuring that its own information systems are prepared for a smooth transition to ICD-11, developing informational resources for a variety of stakeholders and widely publicizing their availability, educating stakeholders about key aspects of the transition to ICD-11, and monitoring the implementation and providing flexibility

[1] National Committee on Vital and Health Statistics; Notice of meeting (virtual); notice of request for information (RFI), 88 Fed. Reg. 71369 (Oct. 16, 2023).
[2] 88 Fed. Reg. 38519 (Jun. 13, 2023).

to stakeholders, as warranted.

- Like in the transition from ICD-9 to ICD-10, stakeholders will **have to expend significant monetary and human resources** to transition to ICD-11, and many are still recovering from the COVID-19 pandemic and have limited financial reserves to allocate to such an all-encompassing project.

Our responses to the questions in the current RFI are below, and they build upon our previous comments.

RFI Questions

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

For laboratories, among these options, coding for rare diseases would be most useful as an enhancement to classification content. However, we believe that ICD-10 already could accommodate additional coding to address any of these classification categories.

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 the clustered (post-coordinated) coding be implemented in your environment?
c. What other changes are related?

ICD codes are essential to many aspects of the lifecycle of a laboratory test, including coverage by health plans, marketing and education about the test, ordering by clinicians, results reporting, claims preparation and submission, and appeal of denials. A laboratory must plan for and implement changes from ICD-10 to ICD-11 for each of these steps in the test's lifecycle. Virtually every step will require education, training, programming, testing, and oftentimes reprogramming in order to ensure that the codes included in ICD-11 are reflected everywhere that ICD codes are required or used. Also, laboratories will have to determine how to integrate new features and concepts into their workflows that have not been part of ICD-10 but are a part of ICD-11, such as the new Foundation content model and clustered coding (which might describe not just the presence of a cancer but also its histology, anatomic site, stage, and extent in a single ICD-11 code).

Many health plans include in their coverage policies for laboratory tests the diagnosis codes for which they consider a test reasonable and medically necessary. Oftentimes the diagnoses for

which a test is covered and/or indicated are included in a laboratory's test menu, and laboratories' representatives educate ordering clinicians generally about their test menus and how to order tests, including the ICD codes that are in major health plans' coverage policies (although laboratories are not permitted to suggest to the ordering clinician specific ICD codes for a particular test order). A laboratory's test requisition form – whether electronic or paper – usually asks an ordering clinician to provide one or more ICD codes to support the medical necessity of the test and to provide critical information about the appropriate reference ranges for the results that are reported to the ordering clinician. ICD codes also are used in claims preparation and submission and to support the reasonableness and medical necessity of a test if a claim is denied. Further, "prior authorization" requirements for claims for laboratory tests are increasingly common and increasingly automated: if the correct ICD-to-CPT code pair is present on a request for prior authorization, it may be approved, and if the correct code pair is not present, it may be denied and/or require additional time to correct and resubmit.

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 organization**
- **c. Ongoing management and maintenance of U.S. ICD-11 and its use**
- **d. Other requirements not named above?**

"Developing and managing implementation plans and programs for ICD-11 in the U.S." is foundational to everything else that a governing body must do, including developing guidance and managing ICD-11 and its use. The governing body's implementation plans should anticipate the types of regulations and guidance that will be necessary to implement ICD-11 successfully across all sectors of the health care industry and in each context in which it is used, and it must communicate early on with the entities that are empowered to issue and/or implement the regulations. The implementation plans also should anticipate the types of maintenance that will be required, estimate the resources required to perform the maintenance, and plan for obtaining those resources. As we mentioned in our previous comments, we would expect the governing body to collaborate and coordinate with partners such as ACLA, the American Medical Association, the American Health Information Management Association, and the American Hospital Association on aspects of development and implementation coordination.

ACLA recommends a multi-year preparation and transition period so that the governing body may solicit stakeholder feedback prior to implementation and involve stakeholders in the preparation steps. The plan for the preparation period should include a reasonable timeline with measurable goals so that the governing body can determine whether or not the healthcare system as a whole is prepared to implement ICD-11 or whether a delay in implementation is required.

Once ICD-11 is implemented, there should be a reasonable transition period during which it is acceptable to use either ICD-10 codes or ICD-11 codes, and a period of enforcement discretion during which health plans do not deny claims solely because the most specific ICD-11 code were not used. This type of flexibility was afforded to health care providers by CMS after the transition

from ICD-9 to ICD-10, and in the transition from ICD-10 to ICD-11 – which has four times as many codes – it will be needed again.

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?

ACLA member laboratories anticipate having to hire additional certified professional coders, information technology programmers, customer service representatives, and billing experts, and to shift existing employees from their current responsibilities to focus on these functions in preparation for and deployment of ICD-11. Those performing services in these areas will need the most training on ICD-11, how it differs from ICD-10, and the laboratory's internal plans for implementation, but virtually all employees throughout ACLA member laboratories will need some training.

Additionally, ACLA member laboratories will need the following resources, tools, and support for implementation:

- Education on the structure of ICD-11 and on the differences between ICD-10 and ICD-11
- Educational resources to share with trading partners (*e.g.*, ordering clinicians, payors, referring laboratories, IT vendors, clearinghouses)
- General equivalency mapping/crosswalks between ICD-10 and ICD-11
- Publicly available resource of entities that are ready to test implementation readiness

  Central portal to which laboratories can submit questions and receive answers and support (and speak with a subject matter expert) and where a laboratory can notify NCHS about issues and problems with implementation

ICD Official Guidelines for Coding and Reporting "Excludes Notes"

When ICD-11 is implemented, the Official Guidelines for Coding and Reporting "Excludes Notes" should not be applicable to independent clinical laboratory providers that do not interface with a patient and that do not themselves select ICD coding. Application of the "Excludes 1" code pairs too often results in claims denials for laboratories that furnish medically necessary services ordered by health care practitioners who select ICD codes. The laboratories have no responsibility for having selected the ICD codes, yet they are penalized when claims include more than one of the codes. One ACLA member laboratory reported approximately *six thousand* ICD-10 code pair combinations that were impacted by the Excludes 1 notes in one month. This led to a significant number of claim denials and administrative burden on the laboratory and ordering provider because it required the laboratory to re-submit the claims, despite both of the tests being medically necessary for two conditions that occurred together.

An example of such a code combination is Z00.00 (Encounter for general adult medical exam without abnormal findings) paired with Z01.419 (Encounter for gynecological examination (general) (routine) without abnormal findings). A woman may have a primary care visit during which she has a gynecological exam. The health care practitioner may order a comprehensive metabolic panel, lipid panel, pap smear, and human papilloma virus test or infectious disease panel, and inclusion of both ICD codes supports the full range of laboratory tests ordered (which one or the other may not support). Despite the laboratory testing meeting coverage requirements and being medically necessary under the policies of these payors, some payors have edits in place that deny claims that bear both of these ICD codes, even though it is not the case that the "two conditions cannot occur together" and they are not analogous to a condition being both congenital and acquired.[3]

Since independent clinical laboratory providers are not in a position to select two or more ICD codes that will appear on a claim, they should not be penalized for submitting such a claim. ICD-11 Official Guidelines for Coding and Reporting should except claims submitted by independent clinical laboratory providers (place of service 81) from application of "Excludes 1" edits.

* * * * *

Thank you for accepting ACLA's comments on the ICD-11 RFI. Please do not hesitate to reach out to me if you would like to discuss any of ACLA's comments.

Sincerely,

Joan Kegerize, JD MS CPC CPMA
Vice President, Reimbursement and Scientific Affairs
American Clinical Laboratory Association

[3] ICD-10-CM Official Guidelines for Coding and Reporting FY 2023 at 9, *available at* https://www.cms.gov/files/document/fy-2023-icd-10-cm-coding-guidelines-updated-01/11/2023.pdf.

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

January 11, 2024

Jackie Monson, JD
Chair, National Committee on Vital and Health Statistics
Centers for Disease Control and Prevention
3311 Toledo Road
Hyattsville, MD 20782-2002

Submitted via email to: NCVHSmail@cdc.gov

RE: Response from ACOG regarding ICD–11 RFI

Dear Ms. Monson,

On behalf of the American College of Obstetricians and Gynecologists (ACOG), representing more than 62,000 physicians and partners in women's health, I am pleased to offer the following comments in response to the National Committee on Vital and Health Statistics (NCVHS) Request for Information (RFI) for potential use of the International Classification of Diseases, Version 11 (ICD–11) for morbidity coding in the U.S. As physicians dedicated to providing quality care to those seeking obstetric and gynecologic services supported by data and evidence, ACOG supports the appropriate and correct use of standardized medical coding systems, such as the ICD-11.

For context, the International Classification of Diseases (ICD), provides the world with a standardized coding system to collect, share and compare data on health-related conditions and diseases in the U.S, for epidemiological studies and health insurance claims adjudication.[i] In October of 2015, the U.S. transitioned from ICD-9 to ICD-10, radically changing the structure and nomenclature of how physicians and providers classify diseases.[ii] The transition was delayed for many years for electronic health records (EHR) and the health care community to successfully adopt the new system.[iii] In recent years ACOG has worked closely with NCVHS to create new code sets for endometriosis and fetal anomalies and has provided consultation on codes proposed by the public for other obstetric and gynecologic conditions.

ACOG is dedicated to promoting diverse voices and perspectives, educating physicians and medical professionals, and raising awareness about health inequities and ways they can be addressed. ACOG recommends that obstetrician-gynecologists and other health care providers inquire and document health related social needs (HRSN) such as access to stable housing, food, safe drinking water, utility needs, safety in the home and community, immigration status and employment conditions and maximize referrals to social services to help improve patients' abilities to meet these needs.[iv,v] These factors are responsible for a large proportion of health inequities that exist in the U.S. and affect many conditions treated by obstetrician-gynecologists, including pre-term birth, unintended pregnancy, infertility, cervical cancer, breast cancer, and maternal mortality.[vi,vii] Despite recommendations to document and code HRSN, many coders and physicians may not be aware there are some ICD-10 codes, and several ICD-11 codes,

that may be available. Education is imperative for accurate coding of HRSN, and ICD-11 may provide better options and an opportunity to educate, capture and collect data.

Maternal mortality and morbidity are on the rise in the US, and the nation's experts predict that the current US maternal mortality crisis will only worsen now that there is no federal protection for abortion care.[viii] The U.S. currently has the highest morbidity rate of all developed nations, with a rate of 32.9 deaths per 100,000 live births in 2021.[ix] In addition, tracking gynecological disease like endometriosis, which impacts more than 11 percent of American women between the ages of 15 and 44, is critical for better understanding the impact of the disease on women in the U.S. and subsequently allocating the appropriate resources.[x] Moreover, obstetrician–gynecologists provide care for people across lifespan, and periodic well visits are appropriate and necessary for both perimenopausal individuals and postmenopausal individuals.[xi] In fact, an obstetrician–gynecologist is often the only doctor a woman sees on a regular basis.[xii] It is therefore critical that physicians are aware of the importance of social determinants of health (SDOH) across the lifespan and in this way, they can address any HRSN during the visit.

Overall, ACOG supports a transition from ICD-10 to ICD-11; however, we strongly caution NCVHS to first:

- Perform an analysis, in collaboration with the ACOG and other medical specialty societies, to ensure that ICD-11-CM will meet the needs of the U.S health system;
- Evaluate the cost, resources and impact of the transition from ICD-9 to ICD-10 and determine the return on investment for transitioning from ICD-10 to ICD-11; and,
- If the decision is to transition to ICD-11, develop a realistic timeline that includes lessons learned from the ICD-9 to ICD-10 transition.

It is with this evidence, experience, and expertise in mind that we offer the following recommendations.

Related to ICD-11 content and addressing US-specific needs

a. Coding to assess and address population health equity, social, behavioral, and community Health

ICD-10 has proved to have a slow uptake of SDOH coding. This is partly due to the barrier in standardized coding across the country, but also the availability of Z-codes.[xiii] In 2019, United Healthcare (UHC) submitted a request to the ICD-10 Coordination and Maintenance Committee Meeting requesting new codes for employment, income and social environment. However, the codes were not finalized.[xiv] Additionally, while many payers recommend and provide guidance for using Z-codes on claims to report SDOH, according to Medicare data compiled in 2017, only 1% of Medicare Fee-for-Service patients were coded using Z-codes.[xv] ICD -11 is known to be more precise with higher specificity on disease diagnosis, and it is possible using.[xvi] Also, it is reported that coding in ICD-11 will enable detailed research into specific diseases and the disparities based on racial, ethnic group, sex, disability, and other socioeconomic factors. **However, a comprehensive analysis on the current use of ICD-10 and the appropriateness of ICD-11 should be performed before initiating any transition.**

b. Coding to measure health care quality and patient safety

Regarding how ICD-11 content can be used to address and measure health care quality and patient safety, consideration should be taken into how ICD-10 coding structures have been integrated into current quality measurement efforts. As quality measures have been developed with focused efforts on addressing quality

of care and outcomes, ICD-10 diagnosis codes have become foundational to determining a patient or measurable entities applicability for a specific measure. As we prepare through the process of establishing and implementing ICD-11, the intersection and integration of ICD-10 diagnosis codes into existing quality measures should be taken into serious consideration. Any transition should be made to ensure smooth transition of ICD-9 and ICD-10 coding structures in quality measurement data element specifications to direct comparisons in the ICD-11 coding set. A large effort will need to be made by measure developers and stewards to ensure the appropriate ICD-11 diagnosis codes are integrated into existing and future quality measure specifications to avoid any miscalculations or misappropriations in quality measurement evaluation and performance. This further underscores the need for detailed and comprehensive crosswalks of the new ICD-11 codes and previous ICD sets.

Additionally, thought should be given on the needs of future quality measurement initiatives and how ICD-11 can meet these needs. For example, health equity measurement is becoming an important focus of quality measurement development in many settings. This is exemplified by the inclusion of the *Screening for Social Drivers of Health*, *Screen Positive Rate for Social Drivers of Health,* and *Hospital Commitment to Health Equity* measures developed by the Centers for Medicare and Medicaid Services (CMS) in the Medicare Merit Based Incentive Payment System (MIPS) and Hospital Inpatient Quality Reporting (IQR) programs. Each of these measures focuses on aspects of patient health that are non-clinical in nature or are directly impacted by HRSN of an individual patient. Fortunately, the specifications for these measures do not rely on ICD-10 Z-codes to capture SDOH. As previously mentioned, existing ICD-10 Z-codes tangentially related to SDOH are available, but there has yet to be widespread uptake or utilization of these codes in practice. **As work is done to finalize and implement ICD-11, further consideration must be taken to allow measure updates without increasing the administrative burden around documentation already faced by physicians.**

c. Coding for rare diseases

There are thousands of rare diseases that are underrepresented in ICD-10 coding, which makes it difficult to understand the history of the diseases, track patients with rare diseases, and their epidemiology. Both ICD-9 and ICD-10 resulted in clinically underreported diseases and failed to capture clinical content.[xvii] In addition, the clinical modifications are critical for billing and reimbursement.[xviii] Regarding using ICD - 11 for coding rare diseases, there will be a need to increase rare disease representation in ICD-11 through accurate documentation, as this will facilitate increase in the number of specific codes. Also, having codes for each rare disease would help acquire a better knowledge of healthcare pathways and their impact on overall patient health quality and safety. ICD-11 offers tracking and coding for 5,500 unique rare diseases unlike ICD 10 where many rare diseases are not mentioned, leaving coders to find the most appropriate rare disease representation through the interpretation of ICD-10.[xix] According to the World Health Organization, every rare disease is identified in the ICD-11 foundation by a unique identifier, the Uniform Resource Identifier (URI). Therefore, having a Uniform Resource Identifier (URI) and rare Disease Registries for ICD 11 will provide researchers access to detailed epidemiological data. [xx] **To use ICD-11 correctly and accurately for rare diseases, US clinical experts should be consulted for the ICD-10 to ICD-11 crosswalk and on clear definitions of any new codes.**

d. Content on other topics

In the wake of the Supreme Court decision in *Dobbs v. Jackson Women's Health Organization*, millions of individuals' access to abortion care has been put in jeopardy. As of late, 14 states have banned abortion completely with many more imposing restrictions, and providers and patients are subject to criminalization for seeking, receiving or offering medically necessary services.[xxi] Additionally, for sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected, and fulfilled. Using ICD-11 codes to capture reproductive health data and report health statistics would help in improving patients' access to reproductive health care. Unlike ICD-10 which has most chapters organized by body or organ system such as "Diseases of the genitourinary system", there is a proposal on the creation and inclusion of a new chapter on sexual health in ICD-11. **NCVSH, along with the Department of Health and Human Services, should ensure a chapter is designated in the ICD-11 that would help providers and coders to accurately document and capture conditions related to reproductive or sexual health** as this would help health policy makers to develop programs that support reproductive health. [xxii] **Additionally, NCVSH should carefully consider, and work with experts, to ensure the language describing conditions of reproductive sexual health is both accurate and respectful.**

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?

Clinical documentation plays an essential role in communicating the reason for the patient visit, physician assessment, and treatment recommended and provided. As the demand for health care quality reporting and value-based payment increases, physicians spend much of their time documenting while providing direct care. On the other hand, medical coders go through a rigorous process of extracting pertinent medical information from patient's medical record and translating them into codes which can be used for submitting claims, in statistical analysis of risk adjustment, clinical registry and reporting of public health issues. Efforts to reduce the burden of clinical documentation and coding for risk adjustment, clinical registry and public health reporting can be achieved by embracing automated Artificial intelligence (AI) speech to text dictation tools that is embedded into the EHR workflow. Using this technology enables the physician's documentation to be integrated with coding and other practice management workflow, thus reducing retrospective documentation queries, decreasing administrative burden and possibility of errors.

Many existing documentation requirements were crafted with paper-based systems with acute or chronic single-system medical problems in mind. At the same time, health IT solutions have not adequately addressed a range of administrative processes health care providers face; for example, prior authorization processes, where effective electronic automation could significantly reduce physician and organizational burden. This misalignment between administrative health care processes and the health IT tools clinicians have at their disposal adds to overall frustration with the increasing amount of time health care providers must devote to paperwork, at the expense of time and resources that could be better directed to patient care. Utilizing automated AI speech to text tools enable clinicians to document more accurately within a short period of time, giving them opportunity to improve the quality of care provided to their patient. As medical coders work under strict deadlines or quota to review and extract pertinent data from the medical record, incomplete or inaccurate clinical documentation can prevent accurate coding and billing which automatically impact reimbursement.

The Center for Medicare and Medicaid Services (CMS) assign a *Risk Adjustment Factor (RAF) score* to each Medicare patient to estimate future medical expenditures for Medicare beneficiaries, using the *Hierarchical Condition Category (HCC) model*. Conditions extracted from clinical documentation are coded to provide a more comprehensive overview of patient health and risk. Therefore, embracing automated AI for coding risk adjustment is a significant factor for identifying and capturing risk adjustable comorbid diagnoses, improve coding accuracy and reduce medical chart review time. In addition, utilizing a machine learning Natural Language Processing enables automated coding of key elements of clinical registry such as site, histology, behavior, laterality, and grade from large volumes of pathology reports to improve the efficiency of registry abstracting, coding, and reporting.

NCVSH, along with the Department of Health and Human Services, should investigate the potential use of AI to ensure accuracy of the tool and easy availability to all providers and medical coders. This work does not need to be accomplished dependent on a transition from ICD-10 to ICD-11.

b. What might be the role of artificial intelligence for your organization?

ACOG is exploring the potential of AI in the practice of medicine that will reduce the obstetrician and gynecologists' administrative burden of clinical documentation by integrating AI-powered dictation tools into the EHR workflows. Adopting AI will have profound impacts on the accuracy of the clinician's documentation resulting in improved health care quality and better patient health outcomes. Also, it will improve the accuracy, efficiency, and consistency of medical coding, thus minimizing error, and improving reimbursement. Adopting AI in ACOG will help us better educate our members on how to incorporate it into their research or pilot studies in such a way that it will improve precision in clinical diagnoses and treatment plans.

c. What might be the role of standardized cross-maps to other coding system

Having a standardized mapping to other coding system links one classification, nomenclature, or reference terminology scheme to another. Mapping allows the capture of data in the EHR with terminology appropriate for the documenters' need while making the data useful for multiple purposes. Standardized cross-mapping to other coding systems facilitates interoperability among international terminologies, classification and provides a meaningful way to report on the data that is being entered into the EHR. In addition, standardized cross-mapping maintains the value of the data when migrating to newer formats and schemas. Consequently, standardized cross-mapping supports the development of physician specialty subsets and new clinical reporting policies.

The role of standardized cross-mapping to other coding systems would have to undergo more analysis. For example, there are a few points that must be put into consideration when cross-mapping from ICD-10 to ICD-11, such as: What type of map is being used? Who is the target audience? Are procedural codes included? A very good terminology that can provide a standardized cross-mapping to other coding system is the Systematized Nomenclature of Medicine Clinical Terms (SNOMED-CT), which facilitate the reuse of clinical data for reporting statistical and management data using terminologies, classification, and code systems. **Effort should be made to ensure standardized cross-mapping to other coding systems is understandable, meets its intended purpose, and has a clear set of rules and guidelines.**

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?

A transition from ICD-10 -CM to ICD -11 for any organization will require large investments of time and resources, as the cost of implementation will include staff training and education; tools, documents, and resource development; internal analysis of contracting and documentation; and IT system upgrades. **Therefore, it is necessary for NCVHS to have a timeline and a comprehensive implementation plan in place to assist all stakeholders in analyzing the associated costs that will come with this implementation and understand the most effective way to budget for these expenses**. Lessons should be collected from the transitions from ICD-9 to ICD-10, including the costs from that transition.

What are the most important considerations and requirements for a U.S. governing body for ICD11?

a. Developing and managing implementation plans and programs for ICD-11 in the U.S

With strategic planning, the U.S. could manage implementation plans and programs for ICD-11 with optimal success. In general, ACOG recommends the NCVHS prioritize:

- Engaging all stakeholders at the national level and potential end users throughout the U.S. healthcare system to explore the use cases of ICD-11 will help create awareness across all organizations.
- Establishing a project management team that will set the vision and formulate strategy.
- Developing a national plan to transition from ICD-10 to ICD-11, with analysis and review of the health information system, specifying the opportunities and challenges associated with an implementation process.
- Integrating and piloting ICD -11 transition tools, like crosswalk mapping files, translation software and coded dataset into the software applications, with development of comprehensive training.

What financial, educational, or human resources will be needed for: a. Implementing ICD-11 in your organization?

a. Implementing ICD-11 in your organization

As the leading organization for obstetrician-gynecologists, implementing ICD-11 means collaborating with NCVHS, CMS and payers to create tools, resources, and education for our members. This will require sufficient notice and time, and **we strongly encourage NCVHS to release an implementation timeline that provides adequate notice for all stakeholders**.

b. Managing and maintaining U.S. ICD-11 in your organization

As all coding classification systems require routine maintenance and updating to meet user's need in content and terminology, managing and maintaining ICD-11 in ACOG will require that all stakeholders, physicians, and the coding staff continue to stay abreast of the revisions to ICD-11 by developing standards or guidelines on the usage of ICD -11 specific feature to ensure consistency in coding. ACOG must also ensure they provide continuous education and training to their staff and members on how to effectively document and code to the highest level of specificity using ICD-11 code set. Finally, ACOG will monitor feedback from obstetrician-gynecologists and work with NCVHS to provide updates and recommendations, as we do currently.

We appreciate the time taken to consider our comments. If you have any questions or wish to discuss these points further, please reach out to Kehinde Taiwo, Manager, Coding Policy (Ktaiwo@acog.org).

Sincerely,

Lisa Satterfield, MS, MPH, CAE, CPH
Senior Director, Health, and Payment Policy

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January 9, 2024

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RE: ICD-11 Request for Information (10/16/2023)

Dear Ms. Monson:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer a response to the National Committee on Vital and Health Statistics' (NCVHS) second Request for Information (RFI), dated October 16, 2023, on the International Classification of Diseases, Eleventh Revision (ICD-11). We appreciate the opportunity to provide the physicians' perspective on this important topic.

The AMA strongly supports the use of standard code sets and terminologies and participates in many cross-industry, multi-stakeholder efforts to advance standards and health information technology (health IT). We do, however, have significant concerns about moving to ICD-11 at this time. This RFI assumes that ICD-11 will be adopted in the U.S. We believe that it is far too soon to make this presumption since there has not been a thorough analysis of whether ICD-11 will meet physicians' needs for the various use cases in which they use the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). It is also unknown what ICD-11 code set is being proposed for adoption, i.e., the most current World Health Organization (WHO) version as is, a subset of ICD-11 stem codes, ICD-11 with post-coordination, or another ICD-11 version. Without a definitive ICD-11 code set to evaluate, responses to the questions in this RFI about implementation and necessary resources are limited at best.

Careful deliberation must be made before moving forward with any replacement to ICD-10-CM, as it will be extremely costly, cause wide-scale upheaval, and add significant burden to the health care system and to its diverse stakeholders. The growing evidence linking practice burdens to professional burnout for physicians underscores the importance of only implementing changes that are critical for health care and provide a measurable return on investment (ROI).[1,2] **We call on NCVHS to proceed deliberatively in evaluating the various needs for diagnosis coding and what will best meet those requirements.**

Below are our responses to the RFI questions:

[1] Rao SK et al. The impact of administrative burden on academic physicians: results of a hospital-wide physician survey. *Acad Med*. 2017;92:237-243.
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RFI Questions

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?**

This question assumes that an evaluation of ICD-11 has been completed for each U.S.-specific need and enhancements have been identified. If this work has been completed, then it needs to be shared with the relevant stakeholders so organizations can review these evaluations and complete their own analyses of proposed enhancements. It is critical for stakeholders to understand any current gaps in ICD-10-CM, the specific data needs for each use case, and to what extent ICD-11 will address them. Until we see the specifics of the ICD-11 structure and content, we will not understand how useful it may be compared to ICD-10-CM.

Additional information is needed to respond to the RFI questions more substantially, including:

- Data demonstrating the expected benefits and advantages of ICD-11, including specifics about how ICD-11 would reduce physician burdens.
- Findings from pilot testing within the U.S.
- Findings that depict the robustness of WHO's ICD-11 electronic coding resources for various use cases.
- Research and analysis about the technical, organizational, and system challenges, and costs of ICD-11 implementation.
- Information on the extent to which ICD-10-CM codes or concepts have been incorporated into ICD-11.
- Processes with the WHO's maintenance of ICD-11 that ensure the U.S. needs for ICD-11 codes can and will be incorporated adequately.

The essential function of ICD-11 will be to accurately identify the patient's diagnosis and any additional relevant factors. More specific needs for ICD-11 coding will vary based on the use case. For example, the coding needs, i.e., level of granularity or approach to aggregation, for rare diseases will differ from the coding needs for quality measurement, which will differ from the coding needs for population health. Identifying which proposed ICD-11 enhancements will be most useful depends on the use cases and the users. Decisions will need to be made about how to prioritize the enhancements and use cases.

It is unlikely, although unclear at this time, that the data coding and reporting needs for all use cases will align. For example, those using ICD-10-CM for billing and payment may not need the changes that are in ICD-11, but those using ICD-10-CM for health equity, social, or community health needs may find benefits in ICD-11. It is unclear how to assess the U.S. needs without knowing the ICD-11 content and whether it offers the specificity needed for our various use cases. Making available broad analysis of ICD-11 and how it better serves the various use cases will help convince physicians of the need to implement it.

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 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?**

The potential to reduce burdens with ICD-11 is completely unknown at this time, given the lack of information available on how ICD-11 will be implemented in the U.S. Physicians need more information to understand the changes associated with implementing ICD-11 before they can begin to assess the potential for automation to reduce burden or improve data quality or data accuracy. Additionally, the concept of automation reducing burden of clinical documentation is flawed because administrative and reporting burdens are not confined to the coding system itself. Despite the availability of various products and tools that automate ICD-10-CM coding, significant clinical documentation and coding burdens remain. The burden of clinical documentation spans various activities that are subject to regulatory and payer requirements, including prior authorization, claims payment, quality improvement, medical necessity, and clinical decision support. Certainly, implementing ICD-11 will impose an enormous burden on stakeholders over many years.

We question if the costs and burdens associated with ICD-11 implementation represent the best use of stakeholders' health IT dollars; this is particularly true for under-resourced physician practices in historically marginalized or rural communities. Indeed, physicians will likely not view investment in ICD-11 as a high priority for their limited health IT resources when viable technology solutions are desperately needed for pressing administrative simplification challenges. For example, the Centers for Medicare & Medicaid Services (CMS) is expected to release a finalized Advancing Interoperability and Improving Prior Authorization Processes Rule in the near future.[3] While we anticipate that, if finalized, this regulation will streamline the prior authorization process, improve efficiency, and prevent patient care delays, stakeholders, including physicians, will need to devote substantial resources and time to meeting its technological requirements.

Most physician practices rely on their practice management system and electronic health record (EHR) vendors for any automation programming or artificial/augmented intelligence (AI) solutions for clinical documentation and coding. The use of automation and AI in physician practices, both in clinical and administrative functions, is in the early stages. Despite predictions, it is unclear exactly what the benefits and ROI will be from AI tools and technology, and even more unclear what the effect could be on the implementation and use of ICD-11.

There will be a need to compare data longitudinally making a standardized and "official" crosswalk between ICD-10-CM and ICD-11 necessary. During the ICD-10-CM implementation, the naming of a single crosswalk came too late in the process and many organizations had already developed their own proprietary crosswalks. An official (source of truth) standardized crosswalk between ICD-10-CM and ICD-11 is needed as part of the ICD-11 assessment and early in the planning and implementation processes.

[3] Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule CMS-0057-P. Available at: https://www.federalregister.gov/public-inspection/2022-26479/medicare-and-medicaid-programs-advancinginteroperability-and-improving-prior-authorization.

Another area of coding that may reduce burden on physicians is greater transparency in the level of specificity needed for coding for the various use cases. This will allow practices to adjust the level of coding they do and report to various users, reducing burden on coding to a level of detail that is not used by the end user. Greater transparency is also needed for the types of coding that will be used by the end user. For example, if a payer will not process more than a set number of diagnosis codes, practices can reduce their burden by not reporting more than that amount.

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?**

More information is needed to understand ICD-11 and assess the standards, systems, processes, and workforce changes necessary for implementation. We also need to understand how current coding, data analysis, and quality and cost measures with ICD-10-CM will change under ICD-11 to better analyze any related changes that will be needed, e.g., the level of coding specificity for end users.

Assessing the costs and impacts of implementing ICD-11 is difficult to do. Physician practices rely heavily on their EHR and practice management system vendors for software and system changes. Costs for these updates will come from the vendors and be passed to physicians. Overall, physicians anticipate that the costs for implementing ICD-11 to include the following:

- Practice management system and EHR records changes, including updates to a new version of the administrative transactions.
- Software changes to accommodate ICD-11 in the practice management system and EHR, including data field length, code validation, and editing.
- Data and system conversions.
- Changes to current data management and governance, i.e., data storage, mapping, etc.
- Changes to data collection and reporting, including prior authorization, medical necessity, billing, quality measures, patient portals, public health reporting, value-based programs, clinical research, and clinical registries.
- Updates to any paper-based and manual workflows to support electronic administrative transactions.
- Initial and ongoing ICD-11 training for physician, clinical staff, and administrative staff, as well as training for associated changes to the practice management system and EHR.
- Any necessary information, technical, and educational resources to support ICD-11 coding.
- Loss of productivity during the training and transition to ICD-11, as was experienced during the transition to ICD-10-CM.

More information is needed to understand technical changes related to anticipated post-coordinated coding in ICD-11. We expect that significant changes will be necessary for the practice management system and EHR to accommodate the new format of ICD-11 codes. Other manual processes and paperwork will also need to be updated to support ICD-11 coding.

Accommodations will need to be considered for quality reporting during any transition, whether that will require preparing for coding with ICD-11 immediately, or dual-reporting with ICD-10-CM until the measures are calibrated to be used with 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 organization.**
    c. **Ongoing management and maintenance of U.S. ICD–11 and its use.**
    d. **Other requirements not named above?**

The most important function of a U.S. governing body for ICD-11 will be management and maintenance of the code set. Once users begin to review ICD-11 and assess whether it will meet their needs, there will likely be an influx of requests for new codes and modifications that will need to be adjudicated. In addition to managing and coordinating code requests from within the U.S., a U.S. governing body would also have the added responsibility to represent U.S. interests in areas where there is a need to potentially coordinate ICD-11 code changes across different world geographies.

Major actions are required to help ensure that all U.S. stakeholders can successfully transition to ICD-11, including:

- Robust ICD-11 implementation and transition plans and processes allowing for required rulemaking, systems updates and configurations, training, workforce development, and education, including major milestones, timeline, and deliverables.
- Development of resources to support nationwide general and targeted ICD-11 outreach, education, and testing.
- Mechanisms to help ensure that physicians and other stakeholders learn about ICD-11 and prepare for the transition.
- Rigorous and comprehensive testing to ensure that payer systems can accept and adjudicate claims with ICD-11 codes.

While the U.S. governing body will have expertise that can assist with training needs, most other implementation activities and regulatory action will come from CMS, as it did with ICD-10-CM. Other resources, such as implementation plans, timelines, and guidance on implementation planning, will likely come from CMS and other organizations, such as the Workgroup for Electronic Data Interchange, American Health Information Management Association, and professional associations.

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?**

Physicians will require any and all financial resources to fully support the various aspects of implementing ICD-11 as listed above in question three. Because physicians have diverse needs based on

specialty, practice location, geography, and patient demographics, a variety of financial options must be made available. Options can include tax credits, grants, higher reimbursement rates, incentive payments, and advanced payments. Outreach must be made to physicians to determine which type of financial support will best meet their needs. Financial support cannot be a "one-size-fits-all" approach.

The cost to implement ICD-11, while not known at this time, will likely be expensive. Physicians are already facing rising costs to maintain their practices and decreased reimbursement. There is no margin under which practices can absorb the cost of the ICD-11 implementation. **The implementation of ICD-11 cannot be another unfunded mandate for physicians.**

Physicians must also be provided with realistic estimated costs for implementing ICD-11, and it is essential that messaging about the benefits of ICD-11 is transparent and forthright. There were many benefits of ICD-10-CM that were touted during its implementation, and physicians, in large part, were skeptical. They were frustrated by what they felt was disingenuous messaging and were not surprised when those benefits never came to fruition. It will be important to not push unrealistic or wishful benefits of ICD-11.

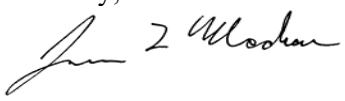
Summary

We recognize that the implementation of ICD-11 will be shaped, and possibly improved, by new tools that were unavailable for the implementation of ICD-10-CM, such as AI, natural language processing, and large language models. Physicians, however, require a sufficient level of analysis of the differences between ICD-10-CM and ICD-11 as well as an understanding of the training, education, and implementation plans in order to evaluate the benefits, costs, and ROI of moving to ICD-11. They cannot blindly accept the upheaval of implementing ICD-11 without a better understanding of how it will improve care delivery for patients.

We must stress again the current epidemic of physician burnout. The COVID-19 pandemic magnified long-standing issues that have accelerated this burnout rate, with physicians who identify as Black or two or more races reporting the highest rates of burnout.[4] Factors most associated with burnout include system inefficiencies, administrative burdens, and increased regulation and technology requirements. The fact that physicians and other clinical staff are retiring early or leaving the profession in large numbers cannot be overlooked. Large-scale change is necessary to address the physician burnout crisis.

Thank you for the opportunity to provide comments on ICD-11. We look forward to continuing our dialog with NCVHS on how health care can best leverage innovative technology to address unmet business needs without jeopardizing smoothly operating workflows or diverting limited health IT resources away from higher priority needs. If you have any questions regarding our comments, please contact Margaret Garikes, AMA's Director of Federal Affairs, at margaret.garikes@ama-assn.org or (202) 789-7409.

Sincerely,



James L. Madara, MD

[4] Experiences of minoritized, marginalized physicians in U.S. during COVID-19. Available at: https://www.ama-assn.org/delivering-care/public-health/experiences-minoritized-marginalized-physicians-us-during-covid-19.

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January 12, 20224

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Re: ICD-11 Request for Information

Dear Ms. Monson, Dr. Arnold, and Ms. Hines:

The American Osteopathic Association (AOA), on behalf of the more than 186,000 osteopathic physicians (DOs) and medical students we represent, appreciates the National Council on Vital Health Statistics (NCVHS) seeking stakeholder input on the adoption and implementation of the ICD-11 through this request for information (RFI). While the International Classification of Disease (ICD) maintained by the World Health Organization is the global standard for health data, clinical documentation, and statistical aggregation, it must be implemented in a manner that meets the distinct needs of the U.S. healthcare system. This includes accounting for differences in public health reporting systems, documentation and billing, monitoring care quality, and research, among a range of other essential functions that the ICD system is used for.

As osteopathic physicians, we are trained in a patient-centered, whole-person approach to care. Osteopathic physicians play a critical role in our healthcare system, often serving in rural and underserved settings, and practicing across all medical specialties. DOs are fully licensed physicians for the complete scope and practice of medicine and surgery in all 50 states. We are unique in that our education focuses on a whole-person approach to care, and we receive additional training in osteopathic manipulative treatment (OMT). OMT is a non-interventional, non-pharmacologic treatment modality that involves the therapeutic application of manually guided forces by an osteopathic physician to improve physiologic function. As the organization representing osteopathic physicians who practice across different geographic settings, practice settings, and specialties, we offer the following feedback regarding adoption and implementation of ICD-11 in the US.

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Question 1: Related to ICD–11 content and addressing U.S.-specific needs, which enhancements in classification content would be most useful?

d. Content on other topics?

Overall, the ICD-11 must be implemented in a manner that meets the distinct needs of the U.S. healthcare system. While some stakeholders have suggested that a full adoption of ICD-11 without modification may be possible, and studies of code mappings for specific disease areas suggest that a high match rate (above 95%) is possible, we are deeply concerned that there remain areas where complete mapping may not be possible without modifications.[1] This would have serious consequences for morbidity coding, billing, public health surveillance, and ultimately, overall patient care. As a result, while we appreciate the greater granularity ICD-11 affords in many areas, it is also essential that the codes available in ICD-11 reflect codes in ICD-10 as closely as possible.

In particular, the AOA is concerned about coding for "somatic dysfunction". The term "somatic dysfunction" is used to designate impaired or altered function of related components of the somatic (body framework) system, skeletal, arthrodial, and myofascial structures, and related vascular, lymphatic, and neural elements. A diagnosis of somatic dysfunction must include the appropriate body region where it is identified. While the ICD-10 had 10 separately billable codes to diagnose "segmental and somatic dysfunction" of various body regions, the ICD-11, as currently adopted by the WHO, collapses these into a single code. This will have harmful implications for documentation of patient conditions, reporting, billing, research, and other functions if implemented in the U.S.

When treating somatic dysfunction, physicians must report one of the 10 billable ICD-10 codes for segmental and somatic dysfunction (M99.00-M99.09) as a primary code, plus any other symptoms that the patient is exhibiting as secondary diagnoses that are not part of the usual disease course or are considered incidental. Documentation of the body regions affected and treated with OMT is necessary to justify the procedure code billed and the medical necessity of the service being performed, and to receive payment.

Additionally, the system of billing for OMT is based on the number of body regions treated. For the purpose of performing OMT, there are 10 body regions, with ICD-10 codes corresponding to the dysfunction of each region. The Common Procedural Terminology (CPT) codes for OMT (98925-98929) correspond to the total number of body regions treated, from 1 to 10. The collapsing of the segmental and somatic dysfunction codes to a single code (ME93.0) in the ICD-11 will have harmful consequences if implemented in the U.S. healthcare system, with implications across coding and payment systems. This change will hinder reporting of diagnoses in a uniform fashion, which will have implications for collecting data on morbidity and services performed, conducting OMT research, submitting appropriate documentation to payers, and receiving efficient claims review and payment. **When implementing ICD-11 in the US, HHS must ensure that 10 separate codes are adopted for identifying somatic dysfunction.**

[1] Fung KW, Xu J, McConnell-Lamptey S, Pickett D, Bodenreider O. A practical strategy to use the ICD-11 for morbidity coding in the United States without a clinical modification. J Am Med Inform Assoc. 2023 Sep 25;30(10):1614-1621.

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NCVHS should also work with stakeholders to identify other areas where post-coordination of ICD-11 codes would not enable a complete mapping to ICD-10. Ultimately, this assessment, development of necessary enhancements, the accompanying development of crosswalks and educational materials, and updating of corresponding technical standards will be an extensive process, and we urge HHS to allow for a multi-year transition timeframe for the adoption of ICD-11.

Question 4: What are the most important considerations and requirements for a U.S. governing body for ICD–11?

The U.S. governing body for ICD-11 will need to coordinate across a diverse range of stakeholders throughout the process of adopting, implementing, and maintaining the ICD-11 code set. The U.S. governing body for ICD-11 should be well positioned to:

1. Engage with Standards Developing Organizations (SDOs) that maintain code sets used in electronic transactions across our healthcare system (e.g. HL7, X12, NCPDP, etc.) to ensure appropriate updates to standards and comprehensive crosswalks between standards are developed;
2. Coordinate across federal agencies and within HHS to update and align regulation related to coding issues, including updating of standards that rely on ICD codes (e.g. Health Information Portability and Accountability Act transactions adopted by HHS Office of Civil Rights, Health IT certification standards adopted by the HHS Office of the National Coordinator for Health IT);
3. Convene stakeholders and engage in extensive outreach to identify coding needs and develop refinements to the code set.

The AOA has supported HHS' historical approach of maintaining a federal interdepartmental committee comprised of representatives from the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) to oversee implementation of the ICD and manage updates. This process has also provided a public forum for presentation and discussion of potentially relevant updates. We urge the agency to continue this approach that ensures public input. We agree with NCVHS that a single agency should be responsible for coordination with WHO on requests for updates to the ICD-11

Question 5: What financial, educational, or human resources will be needed for:
c. Meeting the needs of smaller, less resourced, or less externally supported entities.

Physician practices will have diverse resource needs based on a broad range of factors, including their geographic location, specialty, and primary patient population. Overall, as physician practices begin transitioning to ICD-11, nearly all practices will need to:

- Educate their clinical and office staff on the ICD-11 code set and proper coding, including cluster coding;
- Implement updated electronic medical records and practice management systems and educate staff on use of the updated technologies; and
- Understand changes impacting administrative transactions, including transactions with payers.

This entire process will have implications for:

- physician workflows during transition as processes may be slowed down;

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- how practices utilize technologies as they are updated;
- physician documentation in medical records;
- payment and potential payment denials during the transition period due to either provider or payer errors.

Each of these process changes, and accompanying challenges, will require significant financial, time, and staff investments, making the transition a costly process for small practices with limited resources. As practices prepare for the transition, the following resources, at a minimum, will be essential to support the best possible outcomes:

- A clear process and timeline for the transition to ICD-11;
- Comprehensive mappings and crosswalks of ICD-10-CM codes to ICD-11;
- Educational resources, including webinars, written materials, trainings, and open forums with federal agencies to facilitate the transition, ensure practices have the information they need, and provide opportunities for agency staff to answer questions;
- Timelines for updates to regulatory requirements to align with the transition, and educational material on any regulatory changes; and
- Educational resources on process and timeline for code set maintenance following initial implementation.

Small practices have limited resources and face an increasingly challenging environment to maintain operations due to declining Medicare payment rates. Financial support will be necessary to ensure that practices can make needed investments and do their part in achieving a timely transition across our health system.

Conclusion

The AOA appreciates the opportunity to comment on this ICD-11 RFI. Transition to ICD-11 presents a tremendous undertaking for all stakeholders across our healthcare system. While we appreciate NCVHS' recent efforts to solicit feedback from stakeholders in recent months, more time is needed to identify specific gaps in mapping ICD-10-CM to ICD-11, evaluate the technical changes that need to take place, and develop a longer-term transition plan. We strongly urge NCVHS, and HHS more broadly, to take a prudent approach to prevent unnecessary burden on stakeholders and allow ample time for stakeholders to prepare. The AOA looks forward to continuing to work with NCVHS on refining and implementing ICD-11 for the U.S. healthcare system. Should you have any questions regarding our comments or recommendations, please contact John-Michael Villarama, MA, AOA Vice President of Public Policy, at jvillarama@osteopathic.org.

Sincerely,

Ira P. Monka, DO, MHA, FACOFP
President, AOA

Kathleen Creason
Chief Executive Officer, AOA

Response from Betsy Humphreys regarding ICD-11 RFI January 12, 2024

My thanks to the NCVHS ICD-11 Workgroup on Timely and Strategic Action to Inform ICD-11 Policy for their Phase I Findings Report. The report does an excellent job of laying out many issues that must be considered in reaching policy and implementation decisions regarding use of ICD-11 for U.S. morbidity data.

I offer the following brief comments based on expertise and experience gained in directing the National Library of Medicine's (NLM) activities related to biomedical terminologies and coding systems (UMLS, SNOMED, LOINC, RxNorm and related tools and mappings) from 1986-2017. I retired from NLM in 2017. These comments are my personal views, not NLM's official position.

1. I agree with the Workgroup that "It will be possible for the U.S. to avoid a full clinical modification of ICD-11." In fact, I recommend that the NCVHS and HHS remove this option from further consideration and instead focus on what would be required to implement ICD-11 without producing a full clinical modification. In my view, none of the challenges associated with U.S. implementation of ICD-11 would be removed or likely minimized by creating a full clinical modification. On the contrary, development and maintenance of a full U.S. clinical modification would be expensive and time-consuming – both initially and over time – not just for the National Center for Health Statistics (NCHS), but also for other standards developers and the whole chain of implementers. The existence of a U.S. clinical modification would also hamper - rather than promote - international interoperability, aggregation, and analysis of health data.
2. I agree with the Workgroup that HHS should designate a single HHS coordinating entity for all governance and financing of all aspects of ICD-11 adoption. In my view, NLM (in its capacities as the designated HHS central coordinating body for clinical terminology standards and the U.S. Member of SNOMED International) should be a named liaison to this body, as should related standards development organizations, including HL7.
3. The World Health Organization (WHO) license for ICD-11 includes the following clause: "1.2.3.Mappings or crosswalks between other classifications and terminologies and ICD-11 and translations are not covered by the ICD-11 License and are subject to a separate written agreement from WHO." Such agreements will likely be required to enable inclusion of ICD-11 in the UMLS, creation of a crosswalk to ICD-10CM, and principled relationships to SNOMED International. As these and potentially other works covered by this clause will likely be critical to U.S. implementation, the HHS ICD-11 coordinating entity will have an interest in ensuring that the agreements made allow the range of uses necessary to facilitate U.S. ICD-11 implementation.

I commend the NCVHS for their leadership in addressing this complex and important matter.

Sincerely,

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Brandeis UNIVERSITY

January 11, 2024

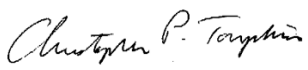
Dear Members of the NCVHS ICD-11 Workgroup:

We are pleased to provide comments in response to your RFI published on October 16, 2023, addressing the potential use of ICD-11 for morbidity coding in the U.S.

We provide answers to four of the five specific questions included in the RFI. However, our comments begin with an extended preamble that offers context and some preliminary thoughts regarding four major policy options that the U.S. could consider going forward and evaluation criteria to help select among the options.

In many ways, the field has seen much investment in transformation toward higher value. However, in our view, we need to replace the basic coding system and upgrade the administrative data that flow to programs and initiatives intended to make the healthcare system sustainable, efficient, and cost-effective.

Sincerely,



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Enclosure: Response to RFI in FR Doc. 2023–22753

Note: The views expressed in this document are solely those of the authors and do not necessarily reflect the views of Brandeis University or HCA or any of its affiliates.

The Coding System Hangs in the Balance

ICD-11 looms over the U.S. and other countries that implemented modified versions of ICD-10. The WHO ended support for ICD-10 and made available a multidimensional and comprehensive medical knowledge database (ICD-11 Foundation) coupled to a coding system linearization (MMS) optimized for calculating statistics on cause of death and condition prevalence in member countries. Although statistics are an important use case in public health, implementing ICD-11 is overkill for that and probably would not lead to benefits anywhere near the levels necessary to justify the implementation costs and burdens. With ongoing updating and revision, all the various national clinical modifications of ICD-10 would likely suffice for that use case, as well as for billing and administrative data analytics as currently implemented, for the foreseeable future. The countries that have invested in those clinical modifications will not see a need for ICD-11 MMS. The only reason to invest in ICD-11 would be to benefit from any novel use cases that it might provide.

Any novel use cases made possible in ICD-11 would result from some basic difference in ontology and architecture in ICD-11 compared to all previous implementations of the International Classification of Diseases. The ontology of ICD-10, including the expansion of ICD-10 used in the U.S. know as ICD-10-CM, relies heavily on precoordinated clinical codes – each code contains all relevant clinical information about a single specific medical concept, and all variations in that medical concept require their own separate precoordinated codes. The need to define an individual code for every variation of every disease meant that capturing granular clinical information including disease severity, acuity and clinical stage was prohibitive in all implementations of ICD-10.

The ontology of ICD-11, although still using some precoordinated codes, relies heavily on the process of post-coordination in which multiple codes can be linked to a single foundational stem code to fully describe all possible variations in a diagnosis or other clinical concept. Post-coordination allows for much increased specificity and detail in coding, without the need to create separate unique codes for each level of specificity and detail. Furthermore, ICD-11 has an architecture that is designed from the ground up, and optimized for, modern computer-driven data analytics. ICD-11 uses the combination of post-coordination and a modern data architecture to provide the possibility of novel use cases.

Need for a Formative Policy Analysis

At this juncture, there seem to be several overarching questions:

What novel use cases would ICD-11 provide to the healthcare environment?

How could ICD-11 be implemented to optimize any benefits from those use cases?

Would the benefits available from ICD-11 justify adoption?

The easiest, simplest, and least expensive implementation of ICD-11, if ICD-10 ever became truly obsolete, would be to adopt ICD-11 MMS just as the WHO released it. At this point, it is not known whether that would produce the best outcome for the U.S. This response to the RFI describes four policy options, including MMS, and major criteria for deciding among the available options.

Evaluation Criteria

To choose which option is best will require articulation of the evaluation criteria and information about how well each option rates against those criteria. Three generic categories of criteria by which the options can be evaluated, and which were included in a 2004 report sponsored by NCVHS to evaluate the anticipated transition from ICD-9 to ICD-10, are:[1] the preparation and transition costs; benefits that might be expected in the steady state or annual basis; and the costs and burdens in the steady state.

Preparation and transition costs.

Moving to ICD-11 will take preparation and time. ICD-10-CM is a large dictionary of precoordinated terms from which to choose to convey clinical concepts. The ICD-11 Foundation includes nearly all the individual clinical concepts that would be required to recreate the ICD-10-CM dictionary but goes beyond that to ate mpt a comprehensive repository of all diseases, injuries, etiologies, and signs and symptoms of illness, all definable by at ributes such as body site and laterality, organ system, and acuity and chronicity. However, the WHO's linearization of the Foundation elements to be used for mortality and morbidity (ICD-11 MMS) does not cover all the concepts in the Foundation or reproduce many of the precoordinated codes in ICD-10-CM. A pivotal issue for evaluating any potential move to ICD-11 is how the coding use cases required or demanded by U.S. stakeholders will be made available through the implementation of ICD-11. The alternative methods for doing so constitute the major policy options that will be considered in this response to the RFI.

There will likely be enormous costs incurred for education and system changes regardless of how ICD-11 is implemented. Coding is integral to the work of clinicians and delivery systems, which rely on a host of software vendors to construct and process patient records, and to produce derivative records for a multiple of purposes. CMS and other payers similarly must process patient records and make determinations based on the content in those records including diagnoses and other clinical concepts. Software must be writ en, adapted, tested, and implemented for each of the many steps to create records and to process their uses.

During the next few years, many organizations and vendors plan to invest heavily in changes involving AI and other automation features in EHRs and digital data repositories and exchanges. The preparations for ICD-11 must be forecasted for a period of dynamic changes already

[1] Libicki, M, and Brahmakulam, I, The Costs and Benefits of Moving to the ICD-10 Code Sets, TR-132-DHHS, March 2004.

underway. Significant capital expenditures will be allocated with uncertain ROI, which will compound the risk aversion and resistance to such a large undertaking as ICD-11.

Benefits in the steady state (annual).

A reasonable criterion for moving to ICD-11, and choosing the methods for doing so, is the expectation that the U.S. would reap benefits with greater value than other potential uses of the resources expended. Given the context of higher spending on healthcare in the U.S., by far, than in any other industrialized country without evidence of commensurate value, an essential question to answer is whether ICD-11 could enhance value in healthcare through higher quality with lower spending to achieve that quality.

Analogous hopes were raised in the 2004 report on the transition from ICD-9 to ICD-10:

- More Accurate Payments for New Procedures
- Fewer Miscoded, Rejected, and Improper Reimbursement Claims
- Bet er Understanding of the Value of New Procedures
- Improved Disease Management
- Bet er Understanding of Health Conditions and Health Care Outcomes
- Enhanced Ability to Evaluate Providers
- Timelier Intervention for Emergent Diseases

The 2004 report largely predicted success in each of those areas and concluded generally that the value of those benefits exceeded the aggregate costs of moving to ICD-10-CM. A common perception now seems to be that the transition to ICD 10-CM did not provide substantial benefits in many of those topics, much less justify the enormous costs and burdens incurred and remembered by many.

Some of the disappointing results probably relate to the coding conventions that developed in the use of ICD-10-CM, which tended to ignore or use unevenly the features available in ICD-10-CM. Because of the difficulty in coding granular clinical detail in ICD-10-CM, categories such as “not otherwise specified” were overused, while Z-codes for social and environmental factors affecting patients were underutilized. A general convention in ICD-10-CM was to code signs and symptoms only until a definitive diagnosis was reached, meaning that characteristics of illness that developed after the diagnosis was reached, as well as important at ributes such as acuity and severity, were largely ignored in the codes. Patient representations in ICD-10-CM have lacked modifiers to provide clinical nuance regarding clinical conditions or circumstances that might affect the patient as a whole, all of which has severely limited the use cases of ICD-10-CM.

Meanwhile, many of the reforms and programs initiated over the last decade to improve value in healthcare have depended on many of the specific benefits that were forecast to exist with the transition to ICD-10-CM, but that were not realized. These programs almost uniformly rely

on risk assessment and risk adjustment based on claims coded using ICD-10-CM, with the resulting gaps and limitations in the data leading to poor representations of patients' clinical status and relative risks of disease progression, acute exacerbation, complications, and need of costly services.

Could the prospects for those reforms and programs be reinvigorated with access to clearer and more granular representations of patients and their clinical conditions? ICD-11 can provide that additional nuance. A potentially huge advantage of ICD-11 is the expectation that post-coordination, with the appropriate use of extension codes, would provide crucial information about relative acuity and severity of conditions within claims data. That information would then invigorate risk adjustment and many of the tools and programs developed to measure and improve value in healthcare. Will that additional capability enable novel use cases enough to justify moving everyone onto a new classification system? Much will depend on the extent to which the full potential of ICD-11 becomes available to universal data exchanges such as the mandated Medicare claims forms and HIPAA standards.

Costs and burdens in the steady state (annual).

The benefits, such as they may be, must compare favorably to the expected ongoing costs of working under ICD-11 compared to staying with ICD-10-CM or waiting for a future offering besides ICD-11 and MMS in their current form. Costs can include ongoing computing costs such as higher fees to maintain EHRs, and the additional costs associated with running programs that become feasible or worthwhile because of the advantages of ICD-11. Costs also can include unintended consequences, such as payers denying authorization of services or reimbursement for claims because they raised the bar on what diagnostic and clinical details are required to document clinical care.

The Policy Options

This section describes four options for the U.S. regarding the coding for morbidity:[2] postpone adoption of ICD-11 indefinitely and continue to update ICD-10-CM; develop a U.S.-specific clinical modification of ICD-11; implement ICD-11 MMS; or seek modifications or alternatives to MMS.

1. **Postpone adoption of ICD-11 indefinitely and continue to update ICD-10-CM.** This has been the approach taken so far by the U.S.. Despite the urging of WHO, the U.S. and several other countries apparently are not yet convinced that ICD-11 will be worth the cost of implementation, particularly with a perceived risk of losing information content that already exists in their respective clinical modifications of ICD-10. Even still, simply emulating current code sets is hardly a strong argument for replacing the classification and coding systems in these countries at such a likely high cost. Therefore, The U.S. and other countries could postpone implementation of ICD 11 indefinitely until

[2] The U.S. is proceeding with ICD-11 for mortality as a signatory nation with possible implementation in 2028.

it becomes apparent that a modification or replacement of ICD 11 would likely optimize benefits in relation to costs.

2. **Develop a U.S.-specific clinical modification of ICD-11.**
   One way to rescue the content existing already in the clinical modifications and additions of ICD-10 would be to recreate or mimic their precoordinated codes in a similar clinical modification of ICD-11. This would involve adding many more precoordinated codes to the ICD 11 ontology.[3] Besides postponing adoption of a fully realized ICD 11 indefinitely, and losing access to whatever benefits a fully realized ICD-11 might offer, this option of nation-specific clinical modifications would work against the goal of the WHO to have comparable systems and statistics available from all member countries. It also has the downside of the considerable expense that would be needed to create such a clinical modification.

3. **Implement ICD-11 using the MMS taxonomy and coding rules.**
   This seems to be WHO's preference for the U.S. and all member countries. MMS is a linearization: a single hierarchy of stem codes extracted from the polyhierarchical ICD-11 Foundation along with a variety of (so-far) less-well organized extension codes used to modify the stem codes as appropriate. [4] While providing the ability to record and analyze mortality and morbidity, this implementation would be limited for clinical research and administrative data analytics.

4. **Implement ICD-11 using a modification of MMS.**
   The WHO has put a lot of time and resources into MMS. Many countries are implementing MMS for mortality and morbidity, and the U.S. will implement MMS at least for mortality. There would seem to be a practical argument for using MMS to advantage for morbidity as well, at least with sufficient expansion and modification.

   Keeping this option distinct from #2 above, which would add many precoordinated codes in an at empt to recapitulate ICD-10-CM, we describe two ways that ICD-11 MMS could be expanded to gain new use cases. One way would be to get WHO to modify the underlying ICD-11 Foundation by adding codes incrementally until there are enough new codes to reach a threshold of utility encompassing one or more new use cases. Another way would be to use the existing ICD-11 Foundation and then build a new linearization

[333] The ICD-11 Foundation includes some precoordinated codes, partly in deference to the legacy of previous versions. However, the expectation is to use post-coordination for most clinical representations. Millions of unique code clusters could be derived from the concepts in the Foundation, many more than the tens of thousands of precoordinated codes in ICD-10-CM.

[4] In a single hierarchy, each concept that is a subcategory of a larger concept (i.e., a "child" in the lineage) can have only one "parent" or larger category to which it belongs. Polyhierarchical relationships acknowledge that a concept can belong to more than one larger category (e.g., stomach cancer is a type of cancer and an abdominal illness).

that encompasses the MMS linearization but exploits an extensive use of post-coordination to create a new and comprehensive system useful for mortality and morbidity analysis but optimized for billing, research and data analytics use cases. We call this comprehensive linearization C-CLEAR (Comprehensive Clinical Linearization, Evolution and Response). Both options could be developed and compared, and they are described in the next section.

Comparing the Linearizations: MMS versus C-CLEAR

MMS is a limited linearization developed and made available by the WHO to collect data on cause of death and the incidence and prevalence of disease for longitudinal and cross-sectional mortality and morbidity statistics globally and across member nations. C-CLEAR is a comprehensive linearization that encompasses MMS, provides 1-to-1 matching with the codes in ICD-10-CM when needed, and expands on MMS to include every clinical concept available in the ICD-11 Foundation. The two linearizations have much in common, literally, because C-CLEAR assigns codes for all concepts in the ICD Foundation while keeping the MMS linearization intact as a subset.

Exhibit A compares MMS and C-CLEAR on several dimensions. C-CLEAR provides codes for all the concepts in the ICD-11 ICD Foundation by building onto the MMS structure, coding rules, and code set. Whereas MMS is optimized to support statistics, C-CLEAR is intended to support clinical care and a multitude of secondary data use cases. Both linearizations are available now for testing as non-proprietary tools that utilize the ICD-11 Foundation.

Both linearizations are expandable, which is important because the content in the Foundation is expected to expand greatly in the coming years. C-CLEAR coding logic is built to anticipate expansion with an infrastructure that includes additional levels that accommodate codes omit ed from MMS but without interfering with or overwriting codes assigned or added to MMS.

MMS adheres to a classic restriction in its taxonomy that prohibits any concept from having multiple parents. For example, salmonella pneumonia is considered in MMS to be an instance of infectious and parasitic disease. In C-CLEAR, the MMS taxonomy and lineage are assumed by default, but the coder can declare a different lineage and appeal to a different taxonomy supported in the Foundation. For example, an infectious disease specialist can describe the condition and patient based on the default MMS taxonomy while a pulmonologist seeing the same patient can indicate that he or she is describing the condition and the patient from the perspective of a respiratory disease.

Regardless of specialty, every clinician using C-CLEAR can access all the common concepts present in MMS, as well as less common clinical concepts with C-CLEAR codes, and can select and modify those codes within the hierarchy pertaining to the clinical perspective in mind. For example, the ID specialist might identify and track a patient with exposure to salmonella and

document the severity and spread of infection over time, including in some cases, salmonella pneumonia. The pulmonary specialist can track a patient from onset of symptoms to a diagnosis of pneumonia and then add additional detail that comes available, including in some cases, etiology due to salmonella. C-CLEAR allows for tracking of the same patients over time, from multiple perspectives, to support the clinical care and analysis of utilization pat erns and outcomes for similar patient cohorts. This purpose explains the part of its name: the evolution of a patient's status over time, and the response of the patient to healthcare interventions.

Extension codes are concepts available in the ICD-11 Foundation that modify stem codes. MMS makes simple use of extension codes. C-CLEAR organizes the extension codes systematically according to a set of rules including an alphabetical order, anatomical aspects of the clinical concepts, and a clinical logic that anticipates how clinicians would think about the relationships among the concepts. The comprehensive and organized code set in C-CLEAR should appear user-friendly to all clinicians regardless of specialty and can form computer-friendly code clusters representing the breadth and depth of clinical conditions.[5]

One of the biggest challenges in adopting any ICD-11 linearization is the movement to post-coordination of codes, in place of the strict reliance on precoordinated codes in ICD-10-CM. Such a challenge is a major argument for maintaining ICD-10-CM, even though the WHO has moved onto ICD-11, or to developing a clinical modification of ICD-11 that maintains that familiar pre-coordination coding convention. MMS provides structure to the post-coordination, using clear rules and strict limits in the use of codes. C-CLEAR provides more flexibility for coders through arranging the codes into unique clusters that conform to a reliable recording format. This facilitates the use of natural language processing as input, and interpretation of code clusters for natural language as output. C-CLEAR is user-friendly to humans and machines (i.e., data processing and analysis).

[5] What is user-friendly to humans is the comprehensive and rather intuitive coding experience in ICD-11, which is largely automated and can shield humans from having to know (or see) the actual esoteric code clusters. Machines can work more efficiently with reliable and standardized code clusters.

Exhibit A: Comparison of MMS and C-CLEAR

Descriptor/Criterion	MMS	C-CLEAR	Comments
All foundation entities coded	No	Yes. Maintains MMS intact as a subset	Can trim long CCL codes
Main purpose	Mortality and Morbidity	**Clinical care**	Detailed capture of the evolution of health status
Availability	Now	Now	Refine and pilot
Ownership	WHO	RADIUS Collaborative	**Not proprietary**
Taxonomy – stem codes	Single parent	Uses MMS taxonomy	Can access full ontology
Taxonomy – extension codes	None	Alphabetical / Anatomical / Logical	Organized as **user-friendly dictionary**. **Computer-friendly codes** support analytic tools.
Postcoordination	Highly structured	Supports more flexible use of codes which then are systematically arranged within clusters	Creates a **unique cluster** for each clinical concept. Supports two-way **natural language translation**.

Exhibit B illustrates this capability. At the top is a clinical note in natural language similar to what clinicians create every day. At the bot om is the natural language output using C-CLEAR, which takes the whole note as input, translates it into C-CLEAR code clusters, then reinterprets those code clusters back into natural language. The question for the writer (or speaker) of the note would be whether the output was faithful to the content in the original note or EHR extract. The clinician or coder could be a novice or an expert in ICD-11 codes *per se* and could still review, modify, or confirm the codes via the natural language outputs. The middle of the exhibit illustrates the output when the coding process is restricted to what is in MMS. Generating comparisons like these, and others as well, could be used to test and compare MMS and C-CLEAR for adoption in the U.S.

Exhibit B: Clinical Note Conveyed via Code Clusters in MMS and C-CLEAR

Source Clinical Note: A 67-year-old woman with a history of chronic obstructive lung disease and a one-second forced expiratory volume of 82 percent returns to clinic with acute, rapid onset, active nosocomial pneumonia. Her sputum culture was positive for salmonella bongori. Her chest X-ray revealed a patchy left lower lobe pulmonary infiltrate. Arterial oximetry revealed moderate hypoxemia. She is currently being treated with C:efalexin. Diagnosis: Moderately severe salmonella pneumonia.
TRANSCRIPTION BASED ON ICD-11 MMS CLU.S.TER: A patient presented with mild (GOLD 1) chronic obstructive pulmonary disease with nosocomial left-sided salmonella bongori pneumonia and associated asphyxia.
TRANSCRIPTION BASED ON C-CLEAR CLU.S.TER: A 65-to-80-year-old female seen for follow-up of pneumonia caused by salmonella bongori affecting the left lower lobe of the lung. The diagnosis was confirmed by culture and imaging. The pneumonia was nosocomial, with an acute, rapid onset. It currently is active, of moderate severity, and is being treated with Cefalexin. The patient currently has hypoxia, moderate, confirmed by laboratory examination. Related conditions include chronic obstructive pulmonary disease, mild (GOLD 1) with an FEV1≥80% predicted.

Preliminary Analysis of the Four Policy Options

This section considers the four policy options using the three categories of costs and benefits. Exhibit C illustrates a preliminary analysis of the four options. The horizontal axis shows the four policy options under consideration and their estimated impacts on the three criteria. The vertical axis quantifies those impacts with positive values meaning higher cost or benefit relative to the status quo and negative values meaning lower cost or burden than the status quo.

Continue ICD-10-CM. Updating the ICD-10-CM code dictionary to include additional codes would be minimally disruptive and still provide codes for recent concepts in medicine, genetics, and social determinants of health. That way, the U.S. could avoid the potentially enormous and disruptive movement to post-coordinated code clusters for which lit le rationale has to date been provided. Some local computing environments have been using SNOMED CT, which utilizes post-coordination, but generally claims data and widespread secondary data uses have been limited to pre-coordinated codes.[6]

Continuing the current conventions would have the least impact on costs and benefits. For the U.S. to continue with ICD-10-CM might mean incrementally higher costs due to the lack of support from the WHO. Also, presumably adding codes over time to keep pace with medicine

[6] It is advantageous that digital data exchange standards have been updated to support post-coordination because of its use in SNOMED CT.

would add incremental benefits to the coding system. Overall, this option is closest to a base case of “doing nothing.”

Clinical Modification of ICD-11. Another option for the U.S. would be to develop a clinical modification of ICD-11 that might suit our perceived needs bet er than the standard offerings from the WHO. This would follow precedent from past revisions of the ICD, and presumably would take several years of detailed review and modification by clinical societies and other stakeholders. Hence, the cost to the U.S. in time and resources to prepare this option is much greater than the others. It would include replacing the ICD-10 coding system with ICD-11, but likely add a large number of precoordinated codes and U.S.-specific codes to the basic dictionary, even though they would not be in the WHO’s Foundation. There would likely be significant benefits to building the revised code set on ICD-11 rather than continuing with ICD-10-CM because WHO will continue to provide new medical concepts in the Foundation, for example, from the burgeoning field of genetics. Once the new system is built, it is likely the annual cost in the steady-state would be similar to maintaining ICD-10-CM and would include adding new codes to keep pace with knowledge and identified gaps in the current set. A major downside of this option is that all of the current limitations in ICD-10-CM would be perpetuated in the ICD-11-CM.

ICD-11 MMS. From the WHO’s perspective, having all member nations implement ICD-11 MMS would appear optimal. MMS is ready to go and will be updated periodically based on input from all user nations and other contributors. Many nations have already embarked on the transition to ICD-11 using MMS presumably for its primary use case, i.e., to collect data for mortality and morbidity statistics. However, countries using clinical modifications of ICD-10 have balked at ICD-11 and MMS. One issue is that MMS truncates details in the Foundation by ending branches in the taxonomy with ‘Y’ codes, indicating that further details are not specified in the code set. That is one reason why matching MMS codes to the clinical modifications leads to gaps where MMS does not have any codes for certain concepts. MMS does not have pre-coordinated codes that match many of the pre-coordinated concepts in the clinical modifications and would require post-coordinated code clusters in many cases to achieve a (nearly) complete match.

An important aspect of preparation will be training code users and physicians to access the concepts and codes necessary to carry out their work. That points to the need to educate clinicians and coders about how to produce code clusters that use MMS primary and secondary stem codes as well as extension codes. Although there are local users of SNOMED CT who might be facile with post-coordination logic and appreciate its advantages, by and large, moving the whole industry in this direction would be a huge undertaking. This and other learning curves can dampen productivity because new methods will require knowledge and experience, which must be gained even while conducting normal business (i.e., continuing to use the current coding system).

Are there compelling or commensurate benefits to justify ICD-11 MMS? There is some literature on features of ICD-11 that suggest additional capabilities such as details about patient safety

events. Such features along with post-coordination could offer new details and insights about clinical topics, but can clinicians and coders be motivated to learn and to use them faithfully and consistently without substantial new benefits to justify the effort? Some are pessimistic about that and point to subpar coding practices in many local environments and a lack of any compelling reason for wanting to improve coding practices.

As interesting and important as statistics on mortality and morbidity may be, producing more comprehensive or granular statistics is probably not a big motivator for stakeholders to invest capital and increase operating expenses. However, there could be other reasons or motivations to adopt ICD-11. The U.S. uses codes for many other purposes including communicating clinical descriptions of patients for care and referrals, as well as for billing, efficiency and quality performance evaluations, research, and technology assessments.

Many of those use cases often involve products and services that can directly affect private organizations' revenues and profit levels. As economics theory suggests, private organizations behave predictably as profit maximizers. Posturing for or against ICD-11 would likely be contingent on perceptions about how it would affect revenues, costs, and profit margins. This whole section makes the case that the effects of ICD-11 on those variables depend on which of the four options is selected and how that option is implemented.

An overriding consideration is what approach is optimal for society, including public health policy and the healthy functioning of markets. That points to the central question of the policy approach, code set, and rules that will be mandated under HIPAA and for submitting Medicare claims. What participants in the markets and profit-maximizers might not choose could nevertheless be worthwhile if such societal and systemic benefits could be realized.

An extremely important problem that has hobbled markets in healthcare and health insurance is asymmetric information, another concept from economics, that suggests transactions and market results can be harmed significantly when one party has bet er or more useful information than the other. This problem is more than theoretical: many of the reforms over the past decade and even quarter-century were premised on the ability of external parties to evaluate the performance of healthcare systems, organizations, and even individual clinicians regarding quality or cost outcomes.

Making valid inferences about performance, however, depends on the ability to establish valid expectations, whether longitudinal or cross-sectional. Well-known examples are case-mix and risk adjustments, which often rely on the one uniform and universal data source, namely claims data. There are large differences in the clinical and social information known by patients, clinicians, and payers. Much information residing in EHRs and clinical databases is trapped by lack of interoperability and the relatively scant documentation on claims submit ed "to get paid." The unfortunate result is that payers' statistical models for evaluating performance and making value-based payments must rely on a data source that many clinicians give lit le credence for such applications.

MMS omits from its code set many clinical concepts of less common, or perhaps specialty interest. There has been some mention of allowing coders to form code clusters that mix actual codes in MMS with non-semantic identifying alphanumeric strings at ached to clinical concepts in the Foundation. It does not seem likely that the mandated rules for ICD-11 in the U.S. would include such a work-around, meaning that uptake on that approach could be limited and idiosyncratic, and mainly for local purposes such as a clinical research study.

Another limitation in MMS is that while its ability to provide code clusters is useful, the code clusters are not regimented or formulated to optimize secondary data use cases. The same clinical information can be represented in a variety of ways based on discretionary choices made by the coder. These can include how the clusters are arranged and ordered. A practical implication is that while the common objective of reproducing ICD-10-CM codes in MMS can be realized, the reverse is not likely or reliable. In other words, matching ICD-11 MMS code clusters back to ICD-10-CM is a "many to one" task and would make difficult analysis of longitudinal data that combine time periods with ICD-10-CM and ICD-11 MSS data in seamless analytic files.

ICD-11 C-CLEAR. Optimistically, ICD-11 MMS could be a vehicle for improving clinical communication generally and reducing asymmetric information specifically. On the other hand, it does not appear fit or finished for user-friendly creation of code clusters that would be of robust benefit for secondary data use cases. This is where C-CLEAR could be a bet er option because its additional capabilities are intended specifically for such use cases.

C-CLEAR provides access and codes for all clinical concepts in the Foundation allowing clinicians and other coders to form code clusters comprehensively and without recourse to work-arounds. C-CLEAR can bring discipline and consistency to code clusters, allowing for a unique cluster that matches any given clinical concept such as an ICD-10-CM code. With that discipline, the unique code clusters, and the greater ability to match "one to one" in either direction, could facilitate more valid and robust analysis.

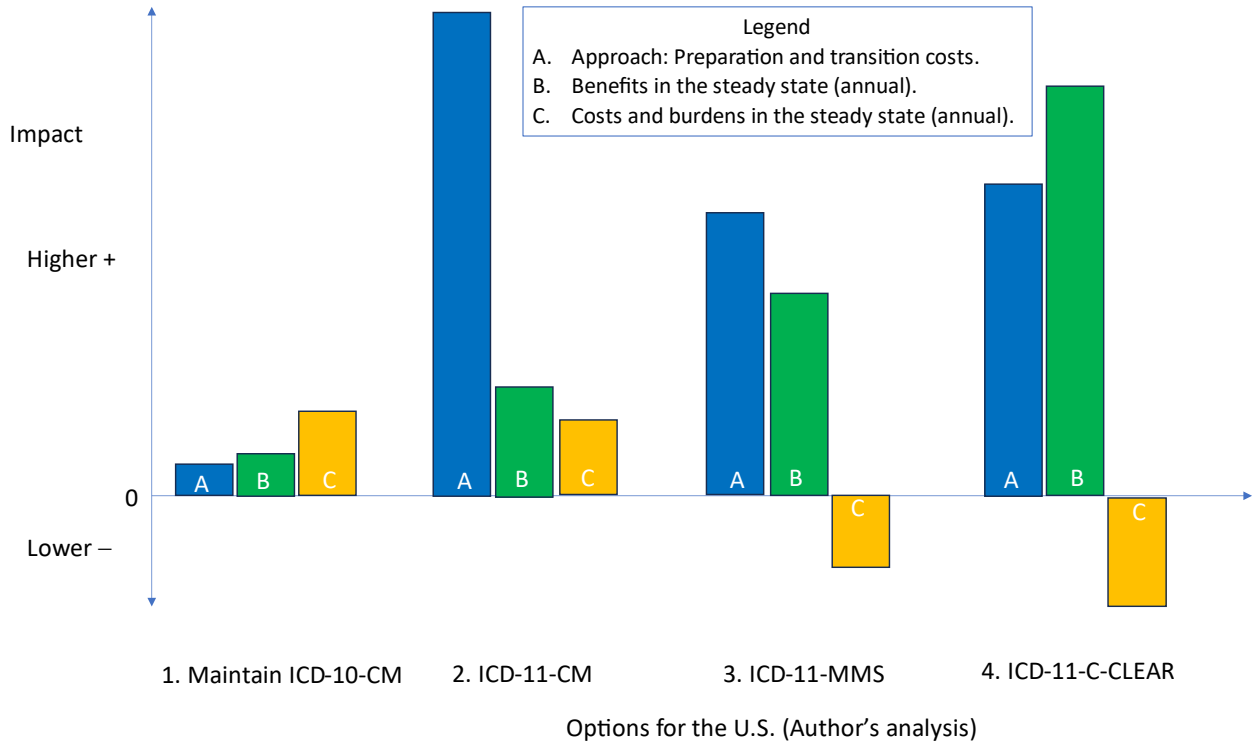
Many of the theoretical advantages of C-CLEAR, yet to be evaluated and confirmed, would depend on the mandatory rules for ICD-11 in the U.S. If pilot tests and expectations are favorable to C-CLEAR, the HIPAA and Medicare regulations could require submission and exchange of the reliable and clinically nuanced code clusters available from the C-CLEAR companion automated tools. With the uniform claim forms suitably updated to allow for such code clusters, the policy goals of interoperability could take a leap forward along with contingent use cases such as patient-centered price transparency tailored to clinical contexts, risk-adjusted value-based payments, context-sensitive digital quality measures, and an information infrastructure supporting clinical care and patient coordination.

The preparation costs for MMS and C-CLEAR should be rather similar with some of those costs used to test the two approaches before selecting the eventual policy option. Development of C-CLEAR might be a lit le higher because it involves more features and capabilities that require testing and support, and because so far it is not maintained or offered by WHO. In contrast, the

steady-state costs for C-CLEAR might be lowest among the policy options, including MMS, because the coding process can be almost entirely automated, with the outputs already in suitable form for claims, analysis, and other use cases. While the Foundation and MMS will be maintained by the WHO, C-CLEAR can piggyback off both for the adoption of new concepts and the assignment of new codes.

Notional net benefit-cost predictions for the four options, shown in Exhibit C, suggest that C-CLEAR could provide the greatest benefit, lowest annual cost, and highest net benefits. This is shown by the highest benefit impact (the green bars, B) along with the lowest annual costs (the gold bars, C). Any move to ICD-11 would involve higher preparation and transition costs than simply maintaining an ICD-10 coding system. An ICD-11 CM would involve the most intensive clinical input and the construction of a code set that departs the most from MMS.

Exhibit C: Notional Comparison of Policy Options based on Expected Benefit and Cost Impacts



The prior sections laid out a framework for the evaluation and selection of an approach to adopting ICD-11 in the U.S., or to continue with ICD-10-CM. The responses provided below are in light of that framework and its preliminary comments about the respective options.

1. Related to ICD–11 content and addressing U.S.-specific needs, which enhancements in classification content would be most useful?

The most salient and contentious U.S.-specific need is to replace the coding system in a way that improves the payment system. Among all the use cases and programs suggested to improve the healthcare system, affecting the payment system is perceived as "using real bullets." Stakeholders seeing gain opportunities will be eager to promote adoption of ICD-11, while those seeing or fearing threats to revenues and profits will urge great care and caution and resist adoption.

The overarching U.S.-specific policy question is whether the disruptions and advantages of moving to ICD-11 can lead to substantial favorable impacts on the unsustainability and relatively low-value of the U.S. healthcare system. This could include breakthroughs in data supporting clinical communication and care improvement, more valid performance measurement, and workable alternative payment models.

a. Coding to assess and address population health equity, social, behavioral, and community health

Any of the policy options in ICD-10-CM or ICD-11 could include new codes on these topics. The related question is whether a new coding system could be coupled with programmatic enhancements and requirements that lead to bet er coding conventions and the use of new codes. Here, ICD-10-CM would likely be a dead end, with an ICD-11-CM being a close second unless new conventions were introduced to code manifestations, acuity, severity, and other at ributes of clinical conditions. However, development of these new conventions would likely be prohibitively expensive.

b. Coding to measure health care quality and patient safety

See answer to 1.a. above. ICD-11 does provide clever enhancements to capabilities in coding patient safety events and medical errors. Its ability to greatly improve quality measurement likely depends on its ability to represent clinical nuance reliably in claims data.

c. Coding for rare diseases

These are least likely among the policy options to be accessible in MMS.

d. Content on other topics?

Framing the question to isolate coding for morbidity neglects some important context. First, the U.S. already is planning to implement ICD-11 MMS for mortality, which should give some credence and inertia for adopting MMS or C-CLEAR over the clinical modification options. Second, the ICD-11 Foundation includes domains other than ICD, specifically functional descriptors and healthcare interventions including pharmacotherapeutics. Used optimally, the implementation of ICD for morbidity (and mortality) should anticipate these other domains, which after all are integral to patient-centered healthcare. MMS may be limited to ICD but the logic and purpose of C-CLEAR extends to the whole patient (and population) with its emphasis on clinical care and the evolution of health status and response to healthcare interventions. Hence, adoption of ICD-11 can provide a range of topics that are interconnected and jointly related to patient and population health.

2. What is the potential to reduce burdens and improve quality/accuracy through the greater automation offered by the ICD–11 online classification systems?

It depends on how much of the work is automated and for what proportion of the total user community. Much of the advantage of post-coordination comes from the robustness and accessibility of extension codes, which are poorly organized in MMS. The burden is generally less when coding requirements are fairly simple and follow the combinations most easily implemented in MMS. That approach also could forgo many of the benefits of moving to ICD-11, by recreating a bare-bones patient record without the clinical nuance that is missing in clinical communications and data for programs intended to improve overall system performance.

a. How might automation reduce burdens of clinical documentation and coding for reimbursement, risk adjustment, clinical registry, and public health reporting?

The hope with ICD-11 is that integration with HIT and EHRs would allow software to input the data elements necessary to create patient summaries suitable for a given purpose. Realizing that benefit seems least likely with either an ICD-10-CM or ICD-11-CM approach to coding, which would reinforce traditional coding conventions. The WHO has provided MMS coding tools, and once again, C-CLEAR builds on those tools to automate the inputting of clinical data more completely into ICD-11 code clusters and outputting the results for review and submission. CMS will need to make sure that Medicare claim forms and quality measures are able to handle ICD-11 code clusters, or else there will be a block on useful information and substantial potential benefits of ICD-11 will be lost.

b. What might be the role of artificial intelligence for your organization?

Artificial intelligence, carefully implemented and with appropriate oversight and control, would likely be most useful in automating coding conventions and in providing self-correction to the

coding and translating processes involved in billing and data analytics. For example, recent studies have found that AI large language models can locate and retrieve data from EHRs and clinical text on the social determinants of health more reliably and cheaply than human reviewers.

c. What might be the role of standardized cross-maps to other coding systems?

A great potential of ICD-11 is to subsume legacy terminology and coding systems into an integrated suite consisting of compatible data structures and variable dictionaries. Organizations are maximizing profits under status quo circumstances, which heretofore have meant the existing data systems. Some legacy systems might have a continuing role for local environments but, by and large, the public interest would be bet er served by a comprehensive and integrated system. Standardized cross-maps will be a way to port the legacy data and systems into the new reality.

d. What other potential features could promote burden reduction?

Automated coding tools, likely built using artificial intelligence, could vastly reduce the burden of coding and data analytics. Searching for and confirming "just the right codes" has been an unfulfilled expectation under ICD-10-CM and would probably be worse under ICD-11 if coding continued to be a manual process. MMS goes a long way but produces idiosyncratic code clusters that would omit clinical concepts that are not included in the constrained taxonomy and would not have a consistent record format. Hence, MMS can reduce burden more on the input side but leave plenty of burden on code confirmation and secondary data applications. ICD-11 code clusters are "ugly" to the human eye but would be very suited to automated coding tools and analytics.

3. What standards, systems, workforce, and processes must change to accommodate ICD–11?

Generally speaking, all of them. That's bit ersweet because there will be headaches for everyone but an opportunity to make sweeping improvements to the basic data sets used by everyone for everything. It is an opportunity for constructive disruption, if done well.

a. How would your organization assess the cost and impact of these changes?

There should be a concerted research program to test the options in data laboratories. Participants should be commit ed to disseminating their findings in the form of implementation guides and empirical simulations of new data records. The enhanced data should evaluated for their utility in a number of common use cases such as clinical communication, risk adjustment in statistical models, and differences in performance evaluations (e.g., rank order of organizations) using the enhanced versus legacy data. Organizations should have access to periodic results to inform their own choices and likely consequences.

b. How might technical changes such as clustered (post-coordinated) coding be implemented in your environment?

Same as everywhere, using the automated coding tools that are companion to the ICD-11 linearization implemented through the regulatory process and made available in the public domain.

c. What other changes are related?

The 2004 report on transitioning from ICD-9 to ICD-10 included the following suggestion:

> "Give serious thought to having a major provider code diagnoses and procedures in both ICD-9-CM and ICD-10-CM/ICD-10-PCS to determine which codes are interpreted similarly. This process would help to develop a crosswalk between ICD-9-CM and ICD-10-CM/ICD-10-PCS in practice as well as in theory. It would also help analysts who work with time series interpret before-and-after changes in health statistics."

4. What are the most important considerations and requirements for a U.S. governing body for ICD–11?

In the WHO's implementation guide for ICD-11, it suggests that each country establish a National Centre of Excellence. The guide says,

> "A National Centre offers country level visibility and transparency of the process, and centralisation of efforts. Stakeholder engagement should be coordinated from this centre, to facilitate information-sharing about implementation, and its progress, with all involved parties and organisations."

Given the emerging consensus at the ICD–11 Expert Roundtable meeting on August 3, 2023 held by the NCVHS-Workgroup-on-Timely-and-Strategic-Action-to-Inform-ICD-11-Policy, the role of a National Centre might be fulfilled by a "public private partnership" under the auspices of a not-for-profit organization that could balance rather than undermine or overlook competing perspectives. The meeting discussed openly that the switch to ICD-11 will affect virtually every participant in the healthcare system, and many Federal agencies have roles to play, but no single agency or stakeholder group can garner the balance and trust across all functions and perspectives for a smooth transition. CDC and the National Center for Health Statistics track public health and other statistics, for example, while CMS is a payer and regulator of the healthcare and health insurance industries. Similarly, every type of stakeholder outside of government will inevitably face costs and uncertainties with the switch to ICD-11 and should have reasonable representation in reviewing and contributing to the final version and policies.

One approach for the Federal government to consider would be to replicate its own template that was seen a few years ago when the goal also seemed broad and disruptive. Legislation set

the goals and identified a lead agency, which in turn, put out an open RFP for an existing non-profit organization to work with the agency under a cooperative agreement over four years to usher in key aspects of the legislation. Specifically, the Cures Act authorized the Secretary, who selected the Office of the National Coordinator (ONC), which in turn awarded the winner, the Sequoia Project, with >$900k in the first of four years to be the "Recognized Coordinating Entity." The RCE was charged with drafting materials, convening stakeholders for feedback, establishing an implementation framework with milestones, and preparing for the steady state.

For ICD-11, the legislation would need to identify the importance of the goals, and then call upon DHHS to develop methods, rules, operational policies, and implementation milestones. Perhaps one type of deliverable would be a Report to Congress that lays out the goals and alternative approaches along with some pilot results to inform future decision-making. Once adequately informed, the Federal government can proceed with the requisite confidence and resources to make sure ICD-11 is the success it should be.

a. Developing and managing implementation plans and programs for ICD–11 in the U.S.

The U.S. might consider a voluntary phase for two years (e.g., 2026 and 2027) using an automatic coding tool that would permit input using either ICD-10-CM or the selected linearization (e.g., MMS or C-CLEAR), followed by a mandatory switch in 2028. Before entering the voluntary phase, the National Centre would need to work with the WHO to optimize ICD-11, e.g., enable robust changes to extension codes along with other changes to match all desirable ICD-10-CM concepts and to take full advantage of the benefits expected from ICD-11. The voluntary phase would facilitate early adoption, provide on-the-job training, refine and finalize the linearization and its automated coding tools, and allow developers time and specifications to convert their applications for their use cases.

b. Developing regulations or guidance for ICD–11 applicable to your organization.

The most crucial and pivotal milestone will be the HIPAA regulations mandating and enabling digital exchanges using full ICD-11 code clusters. Anything left to voluntary adoption will be and should be peripheral features that local environments might choose for their own purposes. We should avoid the mere appearance of progress toward the societal need for systemic improvements.

c. Ongoing management and maintenance of U.S. ICD–11 and its use.

The National Centre can recommend the roles that match each agency's mission. For example, CMS might continue to maintain ICD-10 Procedure Codes and help prepare and implement ICD-11 Procedure Codes sometime in the future. That changeover is not as vital and would be premature anyway given the nascent state of ICD-11 Procedure Codes. CMS might also consider how the International Classification of Health Interventions and its ICHI Coding Tools might be deployed in the public domain. Meanwhile, CDC should dovetail ICD-11 for morbidity along with

its existing mandate for mortality data and upgrade public health information systems to accommodate ICD-11 code clusters. AHRQ maintains tools such as crosswalks among coding and terminology systems as well as the Condition Categories and Patient Safety Indicators. FDA might upgrade market surveillance and Phase 4 trials to track utilization of various agents and interventions in light of much richer information about the clinical contexts in which they are used.

d. Other requirements not named above?

None

From: Lesley Delaney
To: NCVHS Mail (CDC)
Subject: Response from Carroll County Memorial Hospital regarding ICD-11 RFI
Date: Wednesday, October 25, 2023 7:18:31 PM
Attachments: image001.png
image002.png

Good evening,

In response to the email regarding ICD-11 updates, our biggest concern is certainly training. Because we have such a small staff the time and cost to train everyone would be significant. Our margins are small as is, so we don't have a lot of flexibility to hold charges from being coded while we train staff on new information. Our services have grown exponentially since ICD-10 began and that growth allowed our coders more time to learn as services expanded rather than the expectation of them learning everything at once. It often feels like more regulations are being placed on rural hospitals making it more and more challenging for them to get ahead and this will just be another item stacked against us.

Thanks,

CCMH
CARROLL COUNTY MEMORIAL HOSPITAL

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Cleveland Clinic

January 12, 2024

Re: National Committee on Vital and Health Statistics Request for Information Addressing the Potential Use of ICD-11 for Morbidity Coding in the U.S.

Submitted electronically via: NCVHSmail@cdc.gov

Cleveland Clinic is a not-for-profit, integrated healthcare system dedicated to patient-centered care, teaching, and research. With a footprint in Northeast Ohio, Florida, and Nevada, Cleveland Clinic Health System operates a main campus near downtown Cleveland, 22 hospitals, and 275 outpatient locations. Cleveland Clinic employs over 5,600 physicians and researchers and 19,000 nurses and advanced practice providers. Last year, our system cared for 3.4 million unique patients, including 12.8 million outpatient visits and 303,000 hospital admissions and observations.

Cleveland Clinic appreciates the opportunity to share our thoughts with the National Committee on Vital and Health Statistics (NCVHS) regarding the potential use of ICD-11 for morbidity coding in the United States.

Reducing burden and improving quality through automation in ICD-11 online classification systems

The true benefit of automation through the ICD-11 system is yet to be realized. Presently, many ICD-10 users in the U.S. utilize electronic billing and employ a tool to assist in code assignment, such as an encoder or an electronic codebook, so a searchable browser to find the correct code is not novel. The National Center for Health Statistics (NCHS) currently has an ICD-10-CM browser tool available at https://icd10cmtool.cdc.gov/.

Those who would benefit the most from the all-digital feature are countries that need to move from a paper-based system for national reporting to an electronic one.

Currently, artificial intelligence (AI) is utilized in medical coding in the form of Natural Language Processing (NLP) for computer-assisted coding applications and Machine Learning for code suggestions. With the increased granularity and complexity of the code sets, AI will require increased capabilities to accurately interpret intricate medical nuances, adapt to evolving coding standards, and effectively handle the growing volume of diverse healthcare data, ensuring precise and efficient coding processes.

Changes to accommodate ICD-11

Prior to ICD-10 implementation, the HIPAA electronic data standards required updating to Version 5010, which supported the use of the ICD-10 code set. A new electronic data standard that supports ICD-11 must be developed and tested before conversion.

Additionally, the following information technology (IT) systems will potentially need updating to accommodate changes in the electronic data standards and/or complex code structures:

- Electronic health records (EHR)
- Billing systems
- Reporting packages
- Decision-making and analytical systems
- Preference lists

The impact of adopting ICD-11 on claims processing is also a critical consideration. The current fields for diagnosis codes on the UB-04 claim form only allow up to eight characters, and the current fields for diagnosis codes on the CMS-1500 claim form only allow up to seven characters. Cluster coding in ICD-11 allows multiple codes to be combined to describe a diagnosis in detail and can be much longer than eight characters. Moreover, cluster coding uses non-alphanumeric characters – such as "&" or "/" – that have the potential to create syntax and/or script errors. This may create a challenge when submitting claims. Additionally, the UB-04 is currently limited to 26 diagnoses, and the CMS-1500 is limited to 12 diagnoses. We ponder how this will change with ICD-11. Thorough testing of claims processing systems should be conducted to prevent disruptions before fully adopting the ICD-11 system.

Systems converting to ICD-11 potentially face similar hurdles experienced during ICD-10 implementation. Challenges that must be addressed include:

- Productivity loss
- Changes in reimbursement
- Increased staffing need
- Dependency on contracted staff or outsourcing
- Provider burnout
- Claim-processing errors

With the increasing importance of value-based care, thorough analysis of the ICD-11 classification is needed prior to implementation to identify if the code set can appropriately identify the severity of illness, risk of mortality, and social determinants of health. Multiple factors contribute to the success of patient care, and it is essential that the collected data reflect when patients require greater complexity of care.

Considerations for a U.S. governing body

If ICD-11 is adopted, a detailed timeline is needed so that health care providers and organizations can accurately and thoughtfully prepare for the conversion. The World Health Organization's (WHO) ICD-11 rules for developing a national modification may inhibit or delay the U.S.'s current methods of coordination and maintenance of the classification system, since national modifications will need approval from the ICD-11 maintenance bodies:

> *"For developing a national modification of ICD-11 the following rules must be adhered to:*
>
> 1. *Ideally, modifications will be agreed by the ICD-11 maintenance bodies before they are implemented nationally.*

2. *Modifications should not impact on morbidity and mortality statistics, and should not conflict with the foundation.*
3. *Approval of all national modifications will be subject to consideration of whether suitable additional detail already exists in the foundation.*
4. *If a change is made to the international version of ICD-11 the respective national modification must incorporate the change as soon as possible."*[1]

The U.S. has historically adopted a clinically modified version of the ICD. Thorough research will be necessary to determine if there is an actual need to convert from ICD-10-CM to ICD-11. There are clinical modifications in the current ICD-10-CM that are not currently captured in ICD-11. We share the following examples:

- ICD-10-CM has a specific code for Danon disease, which is assigned to E74.05 Lysosome-associated membrane protein 2 (LAMP2) deficiency; however, Danon disease would be assigned to a non-specific code – 5C51.3 Glycogen storage disease – in ICD-11.
- For FY 2024, ICD-10-CM added a specific code to identify treatment resistant hypertension with I1A.0 Resistant hypertension. Currently, no code equivalent exists in ICD-11.

Earlier this year, WHO reported 64 member states are in various stages of ICD-11 implementation. We inquire whether any members that have fully adopted ICD-11 reported a true benefit in using the newest ICD system. It must also be stressed that the majority of countries use the ICD classification system solely for reporting morbidity and mortality, unlike the U.S., which uses it not only for morbidity and mortality, but also reimbursement, resource allocation, administration, safety and quality, and research.

Resources for implementing and managing ICD-11

ICD-10 implementation was federally mandated without any funding. A similar mandate for ICD-11 would cause much strain for hospitals and health systems that are already facing financial challenges as they rebound from the COVID-19 pandemic.

Training on any new or revised documentation requirements and coding nomenclature would need to be developed and provided for all who would be impacted by the change (including but not limited to physicians, nurses, allied health providers, coders, billers, clinical documentation integrity, etc.).

The Centers for Medicare & Medicaid Services (CMS) provided General Equivalence Mappings, or GEMs, from ICD-9 to ICD-10, and similar mapping would be needed from ICD-10 to ICD-11; however, it may create complexity due to the numerous amounts of one-to-many (ICD-10 to ICD-11) matches caused by the cluster coding and post-coordination in ICD-11.

Noncovered entities such as workers' compensation programs and disability insurance programs were not required to adopt ICD-10; consequently, healthcare providers were burdened with maintaining dual coding methods and dual processing systems to submit claims to covered entities using ICD-10

[1] World Health Organization, ICD-11 Reference Guide, Section 1.6.4 National Modifications for Morbidity Coding, https://icdcdn.who.int/icd11referenceguide/en/html/index.html#national-modifications-for-morbidity-coding.

and noncovered entities using ICD-9. The same issue will occur if noncovered entities are not required to adopt ICD-11 at the same time as covered entities.

Thank you for conducting a thoughtful process that allows us to provide input on such important issues and for your consideration of this information. Should you need any further information, please contact me at xxxx@ccf.org.

Sincerely,

Nicholas Judd, MBA, RHIA
Interim Senior Director, Revenue Cycle Management – Health Information Management

Epic

Rebecca Hines, MHS
Executive Secretary, NCVHS
National Center for Health Statistics
Centers for Disease Control and Prevention
3311 Toledo Road, Hyattsville Maryland 20782

RE: Request for Information on ICD-11 (4150–05–P)

Dear Ms. Hines:

Thank you for the opportunity to provide input on the NCVHS's request for information regarding the transition to the use of ICD-11. Epic is a health IT developer based in Verona, Wisconsin that works with stakeholders across the health IT ecosystem to deliver efficient, high-quality care to patients. We have extensive experience supporting the use of ICD diagnosis codes in our software to improve clinical, revenue cycle, and healthcare coverage processes and to facilitate interoperability across healthcare organizations.

ICD-11 offers many welcome enhancements over ICD-10 that could enhance interoperability, increase automation, and reduce burden. However, it will be challenging for the industry to realize those benefits without a clear transition roadmap that takes lessons learned from the challenges with implementing ICD-10. Specifically, when defining a roadmap for ICD-11 adoption, NCVHS and its partners in government (including CMS) should consider:

- Development needs. Health IT developers will need to design, develop, and test changes to the software features used by providers, billing staff, and health plans to enable users to accurately adopt ICD-11 coding in their workflows. We typically recommend providing 18-24 months for the development of updated software capabilities and a further 12 months for users to install upgrades to their software systems and implement the revised toolsets. Before development can begin, standards development organizations like HL7 need to publish updated implementation guides for FHIR, CDA, and other standards that incorporate the use of ICD codes to ensure they can accommodate the revised codes.
- Training. New code systems often result in significant changes to workflows and analytic processes. Healthcare provider organizations, health plans, and others will need to train their clinicians and other staff on the differences between ICD-11 and other coding systems to ensure accurate usage and avoid disruption to downstream processes that accurate coding supports.
- Consistent implementation timelines across stakeholders. One of ICD's primary use cases is communication between disparate stakeholders. It will be important for health plans and providers to transition to ICD-11 at the same time so that information exchange between them is not disrupted and to avoid for the costly need to maintain the use of multiple coding systems.
- Support during transition windows. A comprehensive mapping between ICD-10 and ICD-11 is needed to ensure that stakeholders can continue to communicate with each other during the transition period.

Below, we offer feedback on specific questions from the RFI. We are happy to address any questions you might have on our response. Thank you for your consideration.

Sincerely,

David Hoyt

Epic

Epic

1. **Related to ICD–11 content and addressing U.S.-specific needs, which enhancements in classification content would be most useful?**

The ability to use post-coordination of stem codes to document relationships between conditions enables EHRs to display related conditions together or hierarchically. This enhances usability by more closely matching most clinicians' mental model for conditions.

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 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?**

The granularity and enhanced usability offered by ICD-11 offered by post-coordination could improve the precision and accuracy of mapping terminology when sharing data between organizations, EHRs, and other code-reliant systems. A common problem we've observed is that terminology used to describe a diagnosis is more detailed or robust than ICD-10-CM codes that are used. This can result in a loss of information when interoperating. Post-coordinating extension codes could help to prevent this issue and thus improve the accuracy of clinical data shared between systems. The nuance contained in the diagnosis terminology would be more likely to transmit accurately between organizations. Thus, the data available to treating clinicians would be more comprehensive and precise enabling better informed care. Additionally, improved accuracy could reduce administrative errors or burden when processing claims, improving patients' coverage experience.

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?**

Interoperability standards in use across the industry would potentially need revisions to accommodate ICD-11 codes—especially since some of them may not support the lengthy codes ICD-11 supports. HHS should work with ONC to identify commonly used interoperability standards and follow up with the relevant standards development organization. ONC's Interoperability Standards Advisory could provide a starting point for identifying potential standards that need to be updated.

Once revised implementation guides for standards are available, health IT developers can begin development to support ICD-11 across their tools. Transitioning coding systems is a substantial development project because coding systems are used across numerous clinical, operational, and billing processes. Developers will need at least 18-24 months to design, develop, and test such changes, and stakeholders using such tools will need a further twelve months to update their software, transition analytics or other processes that will be disrupted by the change in coding systems, and train their staff.

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 organization.**
    c. **Ongoing management and maintenance of U.S. ICD–11 and its use.**
    d. **Other requirements not named above?**

When determining implementation plans and guidance, it will be essential to provide a comprehensive mapping between ICD-10-CM and ICD-11's US linearization. One of the most significant burdens we observed for our customers during the ICD-9 to ICD-10 transition was mapping existing data from the previous code set to the new. Since ICD-10-CM is much larger than the standard international ICD-10 release, the mapping between ICD-10 and ICD-11 provided by the WHO is not sufficient. Such a mapping will be essential during the transition window to ensure that systems can still interoperate and that clinical, billing, and administrative processes are not disrupted if they upgrade to ICD-11 on different timelines.

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?**

Developing support for ICD-11 in Epic's software would require substantial effort. We will need 18-24 months from the availability of revised standards and a comprehensive mapping between ICD-10-CM and ICD-11 to work with our customers to design updated workflows as well as develop and test the corresponding software changes. Our customers will then need at least twelve months to deploy software updates and train their users on updated processes.

From: Fabyanic, Lori (Highmark Health)
To: NCVHS Mail (CDC)
Cc: Onuoha-Obilor, Stella (Highmark Health)
Subject: Response from Highmark Health regarding ICD-11 RFI
Date: Monday, January 8, 2024 4:51:29 PM
Attachments: image001.png
ICD-11 for Morbidity Coding_Questions and Comments.docx

Hello –

Please find attached response from Highmark Health regarding ICD-11 RFI.

Kindly,

Lori

Lori Fabyanic, RN, MSN, CPHQ, CMCN
Director Health Plan Quality, Clinical Outcomes & Guidelines
Clinical Quality, Highmark Health

Request for Information (RFI):
Federal Register: National Committee on Vital and Health Statistics

This Notice also serves as a Request for Information (RFI) addressing the potential use of ICD–11 for morbidity coding in the U.S. We welcome responses from industry stakeholders, interested individuals and organizations, or any members of the public. The following questions are a guide to information the Workgroup would find particularly helpful, though respondents are invited to comment on any aspect of ICD–11 that they wish.

Question	Comment
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	X
c. Coding for rare diseases	
d. Content on other topics?	
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 for your organization?	More defined computer assisted coding (CAC), Simple Visit Coding (SVC), Iodine, etc.
c. What might be the role of standardized cross-maps to other coding systems?	
d. What other potential features could promote burden reduction?	
3. What standards, systems, workforce, and processes must change to accommodate ICD–11?	If ICD-11 codes are to be leverage for morbidity coding, then ICD-11 codes have to be added to the HCCS (Health Care Code System).
a. How would your organization assess the cost and impact of these changes?	Decreased coding productivity, costs associated with updates to software programs
b. How might technical changes such as clustered (post-coordinated) coding be implemented in your environment?	The new clustered code structure has major ramifications. Data standards for electronic health record systems and databases will need to be modified to accommodate the longer character lengths necessary to store ICD-11 codes utilizing the “clustered” code structure.
c. What other changes are related?	
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 organization.	
c. Ongoing management and maintenance of U.S. ICD–11 and its use.	X
d. Other requirements not named above?	
5. What financial, educational, or human resources will be needed for:	*Note: Costs are unknown*
a. Implementing ICD–11 in your organization.	Updating our software to ICD-11, education/downtime
b. Managing and maintaining U.S. ICD–11 in your organization.	IT Support

c. Meeting the needs of smaller, less resourced, or less externally supported entities.	N/A – potential for outsourcing for educational needs
d. What other resources not listed here may be needed?	

General ICD-11 Comments:

ICD-11 has added a significant number of diagnoses, increasing from 14,000 to more than 55,000 unique codes. The addition recognizes conditions not included in ICD-10, so medical coders and billers can become more granular and accurate in their submissions.

The new ICD-11 contains 26 chapters, 5 more than ICD-10. New sections cover diseases of the blood or blood-forming organs, disorders of the immune system, sleep-wake disorders, conditions related to sexual health and traditional medicine.

Medical codes will have 4 characters before the decimal point, instead of 3 like in ICD-10 and may contain up to 3 characters after the decimal point. The second position is always a letter, and additional codes add specificity to the base code (e.g., associated conditions). ICD-11 codes also exclude the letters "O" and "I" to avoid confusion with the numbers "1" and "0".

HL7® International

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).

ICAHN
Illinois Critical Access Hospital Network

January 12, 2024

To the National Committee on Vital Health Statistics:

The Illinois Critical Access Hospital Network (ICAHN) manages the Small Hospital Improvement Program (SHIP) funding received for Illinois from the Health Resources and Services Administration's (HRSA) Federal Office of Rural Health Policy to fund small, rural, and critical access hospital investments in hardware, software, or training related to value-based purchasing. In the 2023 – 2028 funding cycle, activities for ICD-11 readiness are one of our funding priorities for all grant recipients. On behalf of our grantees, the Illinois/ICAHN SHIP program solicited feedback for the Request for Information on the potential use of ICD-11 morbidity coding in the United States. Thank you for this opportunity to provide input on behalf of our small, rural, and critical access hospitals. The responses we received are summarized below.

1. **Related to ICD–11 content and addressing U.S.-specific needs, which enhancements in classification content would be most useful?**

Coding to assess and address population health equity, social, behavioral, and community health	40.00%
Coding to measure health care quality and patient safety	50.00%
Coding for rare diseases	10.00%

2. **What is the potential to reduce burdens and improve quality/accuracy through the greater automation offered by the ICD–11 online classification systems and how might automation reduce burdens of clinical documentation and coding for reimbursement, risk adjustment, clinical registry, and public health reporting?**

HUGE benefit from a labor perspective
Increased automation could reduce errors and improve timeliness of documentation
Possibly help capture more of the Social and community needs.
Beneficial ,as finding experienced coders in a rural setting is getting more difficult; however, it will be critical that our EMR vendor can embed this in to their system in an efficient manner.
Accuracy, time saver and cost
Standardized questions for example SDOH that correlates with specific codes

3. **What might be the role of artificial intelligence for your organization?**

Interested in what it brings
Reduced errors and improved timeliness of documentation
Not sure
Currently most AI applications are cost prohibitive for a rural facility with a smaller EMR
Assigning diagnosis based on results
Standardized electronic health record for capturing certain codes such as SDOH

4. **What might be the role of standardized cross-maps to other coding systems?**

Extensive coding mapping and crosswalks between ICD-10 and ICD-11 will serve as a resource to support efficient adoption
More consistency across platforms
HCC maybe
This will be benficial at a higher administrative level but not at a front line coder level. Again it has to be available to us in an embedded and cost effective manner.
Sharing of data to ensure you a have a complete problem list
Unsure at this time

5. **What other potential features could promote burden reduction?** Most responded that they were unsure at this time.

Standardized procedures and policies with payers

6. **What standards, systems, workforce, and processes must change to accommodate ICD–11 and how would your organization assess the cost and impact of these changes?**

Cost would have to be budgeted for the year before implementation
Executive Review; Cost benefit Analysis
Cost passed on by EHR vendor and other coding vendors such as 3M. Cost to train coders.
Time, training, cost of training, implementation in systems
Will be determined by the technology cost vs the human capital cost.
EMR updates, review previous financial burden from ICD 9 to ICD 10 to estimate cost
UNSURE AT THIS TIME

7. **How might technical changes such as clustered (post-coordinated) coding be implemented in your environment?** Most respondents were unsure at this time.

At first look it appears to be a massive change and how will they be reported on a claim/sem,s difficult to data mine
Implemented into encoder and training

8. **What other changes are related?**

Updates to EHR software and coding vendors such as 3M
Ability for the EMR to absorb the new changes in an efficient manner.
Education

9. What are the most important considerations and requirements for a U.S. governing body for ICD–11?

Developing and managing implementation plans and programs for ICD-11 in the U.S.		30.00%
Developing regulations or guidance for ICD-11 applicable to your organization.		40.00%
Ongoing management and maintenance of U.S. ICD-11 and its use.		20.00%
Other requirements not named above?	Responses	10.00%

Comment: I think that implementation, training, and regulations/guidance are a given. I would like to see coordination among all major players on the absorption of ICD11 into technology and programs at a consistent pace - reimbursement/quality/P4P, etc.

10. **What financial, educational, or human resources will be needed for implementing ICD–11 in your organization.**

IT, HIM, Compliance, Patient Accounts
Expenses related to ICD-11 implementation must be included in the (MLR) calculation for plans
Education will be key
Training and financial support for the training
Educational, training for coders and physicians
Lots of education time to coders, staff and providers - while trying to keep up on current responsibilities.
Coding education, software updates and staff for provide services
Education of coders and providers and ancillary staff as it appears to be massive change, and changes in payment policies with payers

11. **What financial, educational, or human resources will be needed for managing and maintaining U.S. ICD–11 in your organization.**

IT, HIM, Compliance, Patient Accounts
Software support from EHR vendor
Systems monitoring.
Once it is rolled out then managing and maintaining is no different that what we do today with ICD10. There will be a few years of struggle as reports may contain 10 and 11 codes but we went through that before.
Normally this is done by the software vendor
Similar to current with ICD-10 after implementation

12. **What financial, educational, or human resources will be needed for meeting the needs of smaller, less resourced, or less externally supported entities?**

Training and financial support for the training
Community
We will find ourselves being teachers to smaller physician offices and other entities we work with on ICD11 because as a hospital entity, we are more aware and educated on coming changes than they are. This takes some toll on our resources. The more resources available online we can push them towards the better. They also don't all have updated I10 code books so to get them to understand the change to I11 and the need for new resources will be a challenge due to the cost of those paper resources.
Affordable education and assistance

13. **What other resources not listed here may be needed?** The majority of respondents were unsure at this time. Support for standards development organizations to work with industry stakeholders to create materials, crosswalks, and recommendations, including how to manage ICD-10 and 11 overlaps and how ICD-11 will incorporate into existing standards, such as FHIR documents. We note that implementation resources and needs will vary across entities.

Support for standards development organizations to work with industry stakeholders to create materials, crosswalks, and recommendations, including how to manage ICD-10 and 11 overlaps and how ICD-11 will incorporate into existing standards, such as FHIR documents. We note that implementation resources and needs will vary across entities.

Thank you for the opportunity for ICAHN to respond to the RFI regarding the transition to ICD-11 in the United States. We look forward to reviewing the summary of this second round of responses.

Sincerely,

Jackie King
HIM Consultant, Illinois Critical Access Hospital Network
1945 Van's Way
Princeton, IL 61356
www.icahn.org

From: Fillenwarth, Joyce
To: NCVHS Mail (CDC)
Subject: Response from IN State Office Rural Health Regarding ICD-11 RFI
Date: Monday, December 18, 2023 2:32:37 PM
Attachments: image002.png
image004.png
image006.png
image008.png
image010.png
RFI submitted dec 18 2023.xlsx

We had 8 hospitals respond. Note several follow-ups were conducted to obtain response.

Attached are the results.

Please note my email has changed to jfillenwarth@health.in.gov

Joyce Fillenwarth | ***State Office Rural Health Manager***
Division of Chronic Disease, Primary Care and Rural Health
office: 317-233-7734 • mobile: 317-450-9953 • fax: 317-233-7805
jfillenwarth@health.in.gov
health.in.gov

Hospital Identifier	Date	Related to ICD-11 content and addressing U.S.-specific needs, which enhancements in classification content would be most useful? (choice=Coding to assess and address population health equity, social, behavioral, and community health)	Related to ICD-11 content and addressing U.S.-specific needs, which enhancements in classification content would be most useful? (choice=Coding to measure health care quality and patient safety)	Related to ICD-11 content and addressing U.S.-specific needs, which enhancements in classification content would be most useful? (choice=Coding for rare diseases)	Related to ICD-11 content and addressing U.S.-specific needs, which enhancements in classification content would be most useful? (choice=Content on other topics?)	What is the potential to reduce burdens and improve quality/accuracy through the greater automation offered by the ICD-11 online classification systems?
Hospital 1	11/21/2023	Checked	Unchecked	Unchecked	Unchecked	Defining the ICD-11 online classification systems.
Hospital 2	11/21/2023	Checked	Checked	Checked	Unchecked	This allows the coder to process through questioning when assigning the correct codes.
Hospital 3	11/28/2023	Checked	Unchecked	Unchecked	Unchecked	there is no reduction in burden on the facility or the providers moving to ICD11
Hospital 4	12/5/2023	Checked	Unchecked	Unchecked	Unchecked	improve documentation and productivity
Hospital 5	12/8/2023	Unchecked	Checked	Unchecked	Unchecked	It sounds like there is an opportunity to get more specific codes through feedback.
Hospital 6	12/12/2023	Unchecked	Unchecked	Unchecked	Checked	
Hospital 7	12/15/2023	Unchecked	Unchecked	Unchecked	Checked	

Hospital Identifier	Date	How might automation reduce burdens of clinical documentation and coding for reimbursement, risk adjustment, clinical registry, and public health reporting?	What might be the role of artificial intelligence for your organization?	What might be the role of standardized cross-maps to other coding systems?	What other potential features could promote burden reduction?	What standards, systems, workforce, and processes must change to accommodate ICD-11?
Hospital 1	11/21/2023	The ability to submit data from the chart to public health reporting automatically instead of screenshots, copy/paste, etc.	Send triggers to healthcare professional to complete mandated reporting or investigate case.	No opinion	Care plan suggestions for nursing.	unknown within my systems.
Hospital 2	11/21/2023	Automation reduces the redundancy of documentation as well as requires certain fields to be completed to help increase the documentation required.	Not sure.	Cross-maps help in many areas in the hospital and clinics that assign codes.		Encoders, Billing systems, EMR to name a few.
Hospital 3	11/28/2023	there is no reduction in burden on the facility or the providers moving to ICD11	still looking into this to decrease physician burden and improve documentation	not sure what this question is asking	staying with ICD10	it will impact multiple departments, create physician burden, create coder burden, physcian practice burden, software development burden, decreased productivity and reduced AR.....
Hospital 4	12/5/2023	same	improved documentation and productivity as well as accuracy in reporting	?		
Hospital 5	12/8/2023	If it is good automation, it should save time.	None.	Not sure if it will apply.	Not sure until I see what ICD-11 looks like.	Our processes should be the same. We need to make sure forms and order entry screens are updated and that training for all is done.
Hospital 6	12/12/2023					None that I know of.
Hospital 7	12/15/2023		Do not think that will play much of a role.	Do not see it being something we use.		Do not anticipate big changes within our workforce/processes/systems.

Hospital Identifier	Date	How would your organization assess the cost and impact of these changes?	How might technical changes such as clustered (post-coordinated) coding be implemented in your environment?	What other changes are related?	What are the most important considerations and requirements for a U.S. governing body for ICD-11? (choice=Developing and managing implementation plans and programs for ICD-11 in the U.S.)	What are the most important considerations and requirements for a U.S. governing body for ICD-11? (choice=Developing regulations or guidance for ICD-11 applicable to your organization.)
Hospital 1	11/21/2023	ROI.	Unknown	Lack of awareness within the facility on potential impact to reimbursement.	Checked	Unchecked
Hospital 2	11/21/2023	We would need to speak with those vendors.	Not sure what this means.		Checked	Checked
Hospital 3	11/28/2023	coding training physician training prior approval training case management/UR training ITS resources EHR upgrades/costs Coding software costs Physician office coding changes Physician documentation education costs and many more items...	not sure what this question is asking	everything we do now regarding documentation and coding will change Do not see how ICD11 will improve outcomes and reduce provider burden, facility burden, payer burden, coder burden, etc.	Unchecked	Unchecked
Hospital 4	12/5/2023	evaluate training time and productivity			Checked	Checked
Hospital 5	12/8/2023	Loss of productivity due to training and getting used to the new codes will cost an estimate of 50% for several weeks and 30% for several more weeks, then 10% for another month or so.	Not sure what this means.	None that I can think of.	Unchecked	Checked
Hospital 6	12/12/2023				Checked	Unchecked
Hospital 7	12/15/2023				Unchecked	Unchecked

Hospital Identifier	Date	What are the most important considerations and requirements for a U.S. governing body for ICD-11? (choice=Ongoing management and maintenance of U.S. ICD-11 and its use.)	What are the most important considerations and requirements for a U.S. governing body for ICD-11? (choice=Other requirements not named above?)	What financial, educational, or human resources will be needed for implementing ICD-11 in your organization?	What financial, educational, or human resources will be needed for managing and maintaining U.S. ICD-11 in your organization?	What financial, educational, or human resources will be needed for meeting the needs of smaller, less resourced, or less externally supported entities?	What other resources not listed here may be needed?
Hospital 1	11/21/2023	Unchecked	Unchecked	Unknown within my system as coding is outsourced to corporate partners.	Unknown within my system as coding is outsourced to corporate partners.	Unknown within my system as coding is outsources to corporate partners.	Education to providers and nursing on how to document to explain SDOH.
Hospital 2	11/21/2023	Checked	Unchecked	This is why we are part of an ICD11 SHIP training program.	Same answer as previous question.	Same as above.	Not sure at this time.
Hospital 3	11/28/2023	Unchecked	Checked	It will be a huge financial burden on the facilities with IT resources, educational training and ongoing training resources both hospital based, and provider based, EHR changes and the costs associated with this modification	everything listed in the question	everything listed in the question especially the financial piece as most practices are not operating at significant profits.	unknown
Hospital 4	12/5/2023	Checked	Unchecked	additional staffing during training			
Hospital 5	12/8/2023	Checked	Unchecked	Will need the money and personnel to back-fill during training and during the productivity slow down the first several months. Will need educators.	Nothing more than we have now.	Not sure I understand this question.	None that I can think of.
Hospital 6	12/12/2023	Unchecked	Unchecked				
Hospital 7	12/15/2023	Checked	Unchecked				

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January 12, 2024

ICD-11 RFI Response

Dear National Committee on Vital and Health Statistics,

Thank you for the opportunity to provide information to address the Potential Use of ICD–11 for Morbidity Coding in the U.S. Based upon the questions outlined in the request for information, Intelligent Medical Objects (IMO) has the following comments and recommendations.

IMO recommends the Committee:

- Demonstrate the added value ICD-11 provides to healthcare, that is not already available via other terminologies or classifications, which justifies the cost of implementation.
- Provide full transparency of the underlying ICD-11 model for the U.S.
- Define the ICD-11 standard in relation to the code, post-coordination requirements, and transaction standards.
- Outline and fund research initiatives for ICD-11 through the lens of U.S. specific needs to determine potential enhancements.
- Provide guidance on clinical documentation as compared to the World Health Organization's (WHO) API code search look up since the U.S. is advanced in the use of terminologies in electronic records.
- Garner support for federal financial incentives to implement ICD-11.

Healthcare is currently operationalized through multiple terminologies and classifications serving different purposes. The Committee should demonstrate how implementing ICD-11 provides added value to healthcare, that is not already available via other terminologies or classifications. ICD-11 must fit into this landscape while demonstrating decreased burden to capture, use, and report the codes. IMO welcomes the opportunity to further participate in implementation planning and analysis.

Best regards,

June Bronnert, MHI, RHIA, CCS, CCS-P
Vice President Global Clinical Services

Theresa Rihanek, MHA, RHIA, CCS
Mapping Informaticist

1. Related to ICD-11 Content & 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?**

The topics identified in the sub-bullets are important to advancing healthcare outcomes which the industry is currently working to address with existing systems. In the United States, various code sets such as ICD-10-CM are being modified to capture social determinants of health (SDOH), while other terminologies are being created for genetics and rare diseases. Without further research, such as outlined in earlier Committee letters, it is difficult to objectively state which enhancements will be the most useful. We recommend the Committee outline and fund research initiatives for ICD-11 through the lens of U.S. specific needs to determine potential enhancements.

Regardless of U.S. specific content enhancements, the Committee must define a content governance process. The governance process must account for the areas for emerging diseases and population health factors while maintaining ICD-11's fundamental structure and principles.

Questions for the Committee to consider regarding governance are as follows:

- Will it be possible to change WHO-defined regulatory framework for adopting and revising ICD codes?
- How will the current U.S. bi-annual update process fit within ICD-11?
- How will code changes impact reimbursement and interoperability systems?
- Will it be easier to add extension codes without disrupting the reimbursement system?

In the U.S. the adoption of a new ICD-10-CM code can take years based upon the current process requirements and timeframes. Depending upon the governance of how content is added to ICD-11, we anticipate it will be easier to accommodate various types of factors, such as SDOH, genetic information, patient safety. We anticipate it being quicker and easier to assign and report on these conditions without the underlying complexity of implementing and maintaining a full pre-coordinated text description.

a. Coding to assess and address population health equity, social, behavioral, and community health?

Classifying conditions that impact health but are not a disease state present challenges as the industry is currently experiencing within our current coding systems. It will be important for ICD-11 to create a structure/schema to consistently incorporate evolving topics. For example, would it be necessary to create a separate linearization, chapter of stem codes, or type of extension code for SDOH?

ICD-11 currently includes etiology extension codes for "genetic" which describe hereditary or non-hereditary. However, these are very limited options in comparison to the granularity many ICD-10-CM proposals are requesting. In today's healthcare environment, genetic information is much more prevalent, advanced, and more easily obtained. As demonstrated in NCHS ICD-10 Coordination and Maintenance Committee proposals, there has been an increased demand from the public to create

codes to specifically incorporate genetic information which includes the specific gene. What path is the WHO providing to capture genetic information related to disease to maintain uniformity in capture

ng specific gene information? The Committee should explore the ability of ICD-11 to capture gene related information for various diseases. Would it be possible to create extension codes which identify the gene(s) involved for a specific disorder?

b. Coding to measure health care quality and patient safety?

The current ICD-11-MMS contains aspects of healthcare quality and patient safety that should be researched to determine which aspects of the current codes are applicable to U.S. reporting requirements. For example, present on admission (POA) extension codes are available within the classification system. The U.S. could leverage the codes and retire their current indicators. The POA rules would need to be updated to reflect this potential change.

The ability in ICD-11 to post-coordinate data will support a more complete data picture rather than the fragmented one that exists in the U.S. now as a list of individual codes. Currently in ICD-10-CM there is no mechanism to identify that a postoperative complication code is associated with the specific complication and external cause codes. The same is true for injury codes and external cause codes as well as for infections that do not have a fully post-coordinated code that require the infection type and causal organism to be separately coded.

Regarding quality and patent safety, ICD-11 provides a three-part model to capture harm, mode, and cause. This model allows for a comprehensive data picture as ICD-11's structure allows for relationships to be identified with clustering. The U.S. should evaluate how to leverage this structure within ICD-11 rather than creating a different system.

c. Coding for rare diseases?

ICD-11 is better structured to advance the care and treatment for patients with rare diseases. There appears to be greater opportunity to provide more granular codes for these diseases than the U.S. can currently provide within the ICD-10-CM structure. A strategy should be developed in collaboration with the WHO to capture rare disease in a systematic and structured way for consistency.

There is a unique opportunity to leverage aspects of ICD-11 by utilizing the unique resource identifiers (URIs) to obtain very granular information regarding a rare disease. This opportunity also presents a challenge. At this time, it is unclear how the connections between the foundation and a linearization URIs are to be maintained and shared externally when reporting ICD-11 codes. If rare diseases are uniquely identified at the foundation level but the MMS linearization identifier is less specific as the default is the 'other' ICD-11-MMS code, how will those identifiers be captured and stored for leverage across the ecosystem?

For example, Aicardi's syndrome is coded to LD20.Y, Other specified syndromes with central nervous system anomalies as a major feature, in MMS ICD-11. The diagnosis loses it granularity within the MMS linearization as it is classified into an "other" category and its associated MMS URI (http://id.who.int/icd/release/11/2023-01/mms/1800958996/other). However, if the Foundation URI is stored in association with this diagnosis, then the granularity of that diagnosis is maintained (http://id.who.int/icd/entity/2057245946). How should the U.S. incorporate Foundation and MMS URI's

as part of the system? There will be many interested stakeholders in the granularity of the Foundation URI information. The Committee should evaluate this structure prior to creation of content enhancements.

2. What is the potential to reduce burdens & improved 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 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?**

The current WHO tools still require an end-user to search, select and have knowledge of all the classification rules of ICD-11-MMS, such as post-coordination. Without further technological solutions, which may be publicly or privately developed, the burden remains on the end-user's knowledge. Forcing the user to search and post-coordinate only via a hosted-terminology server is overly proscriptive and likely to have multiple negative downstream impacts. If the expectation is the clinician will be the typical end-user, this places greater administrative burden on them. Providers will either spend more time attempting to capture clinical information or select a less specific term. Either action results in a trade-off between quality patient care or data.

a. How might automation reduce burdens of clinical documentation and coding for reimbursement, risk adjustment, clinical registry, and public health reporting?

ICD-11 has incorporated many aspects of a reference terminology into its model. However, its primary use case is to function as a classification system and not a clinical documentation system. Current WHO tools still require an end-user search and selection as noted above. The Committee should not underestimate the challenge of post-coordination within clinical documentation workflows. From IMO's evaluation of ICD-11, post-coordinating common clinical concepts were difficult due to ICD-11's syntactical rules. The sheer number of post-coordination combinations and rules to apply an ICD-11 code is a greater burden.

As the U.S. is a member organization of WHO, the Committee should collaborate with them to provide access to the underlying ontology to leverage its power for automation. Obtaining licensure agreements with WHO to commercialize ICD-11 is difficult and not very transparent. Licensing ICD-11 is the first step towards advanced automation and potentially reducing burden by allowing other entities to engage in leveraging the full ontological model.

The current ICD-11 WHO coding system rules do not reflect any specific U.S. payment or reporting requirements. The Committee will need to address how systems are impacted by ICD-11, such as reimbursement, quality measure reporting, and interoperability requirements. It may further complicate reimbursement, as well as other tertiary uses of data depending upon the amount of post-coordination that is or is not required by third party payers.

b. What might be the role of artificial intelligence for your organization?

The role of artificial intelligence (AI) and ICD-11 will continue to evolve as the industry identifies and defines what AI is and where it fits within an organization. The ontology should be available to vendors and other interested parties so it can be leveraged with emerging technologies such as retrieval augmented generation (RAG) and natural language processing (NLP). Ensuring that data integrity is maintained between the source content, the foundational system and specialized knowledge representations such as ICD-11 should be a priority. ICD-11 will need to be part of the discussion to determine where the coding system aligns with an organization's data and AI strategy.

c. What might be the role of standardized cross-maps to other coding systems?

Without further defined ICD-11 U.S. based standards, it is difficult to fully address this question. Creating and using a cross-map will be challenging due to the foundational differences between ICD-10-CM, SNOMED CT, and ICD-11. The Committee must address the anticipated interplay between ICD-11 and SNOMED CT within the U.S. Each is a distinct model.

The role of standardized cross-maps to other code systems would be helpful for legacy projects that require data conversations for payer policy, research studies, and potentially clinical decision support systems based upon ICD-10-CM codes. It would be important for the creator of the cross-map to follow the International Organization for Standardization (ISO) mapping principles and highlight any loss of information between the two systems.

d. What other potential features could promote burden reduction?

The underlying value of ICD-11 is in the connections of the URIs to alleviate burden of downstream use cases, such as clinical registry, reimbursement, public health reporting, research, and other areas where case identification is critical. Burden reduction could occur if there are requirements to maintain, store and/or report the more specific disease captured in Foundation URI. This URI provides granular information that is not available within ICD today.

3. What standards, systems, workforce, and processes much 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?

Nationally, there are many standards, systems, including workforce and processes that must be evaluated to accommodate ICD-11. All these areas will impact the cost to implement. All lines of software code that are reliant upon the submission, reception or other interplay with an ICD-10-CM code will need to be evaluated to determine potential changes to capture the characters associated with an ICD-11 code as well as accommodate the URIs as required. This will impact a multitude of software applications, electronic health records, interoperability and payment policy, research programs, quality programs, and more.

Thoughtful analysis must occur throughout the data lifecycle, beginning with how it is currently captured and distributed. This includes current system designs such as existing screens/forms/value-sets. These data fields currently expect certain terminology, and this must persist when transitioning to ICD-11. Otherwise implementing ICD-11 will be inefficient and costly for all involved. Refactoring all those data input/documentation mechanisms to only address ICD-11 APIs is a major undertaking and unlikely to be acceptable without appropriate funding.

a. How would your organization assess the cost and impact of these changes?

While currently, the cost and impact to accommodate ICD-11 is an unknown, we anticipate the cost to be extremely high. The ability to assess cost and impact is dependent upon the U.S. defining many basic aspects of transitioning to ICD-11.

There are a host of questions that must be delineated as a standard in the U.S. before the cost question can be adequately approached:

- What is the full length of an ICD-11-MMS code?
    - Will there be a long and short form of an official code descriptor?
    - Is a 4-character stem code a complete code or will there be a definition to utilize the "unspecified" representation of the stem code?
- Is there a minimum and maximum length of a code?
    - Will there be a method to truncate a code for reporting an ICD-11 code if it is too long?
    - How many characters will be allowed?
- Once an established transaction standard identifies the number of characters required for reporting, how will organizations that wish to capture more information beyond what is required account for that in their systems?
- What are the requirements for post coordination?
    - Will there be minimum and maximum post coordination requirements?
    - Will the minimum post coordination requirement vary based upon care setting, inpatient versus outpatient clinic versus outpatient surgery, etc.?
    - Will there be a hierarchy of order to report extension codes in?
        - For example, a specific injury identifying type, site, laterality, open/closed, etc. can be post coordinated in ICD-11 extensively in addition to the external cause information. Will there be an expectation of sequencing order within the post coordinated ICD-11 code?
    - What is the 'official' code descriptor of a post coordinated code?
    - How will the message transactional standards change to account for post coordination?
- How many codes can be reported on a claim form?
- What requirements will be established for storing and submitting the Foundation URI and the MMS URI?
- Will the U.S. develop or require any additional linearization?

b. How might technical changes such as clustered (post-coordinated) coding be implemented in your environment?

A standard to determine what a complete code looks like needs to be established before technical impact can be identified. Please see the questions above.

Regardless of an ICD-11 standard, being able to deconstruct cluster codes will need to be part of the technical changes. Properly interpretating the components supports the idea of 'capture once, use many'. The components are available to leverage for other tertiary use cases, so end user is not required to re-capture the same data. The effort and cost to develop the technical support for clustered coding is significant.

c. What other changes are related?

NCVHS will need to evaluate current resources and staffing to accommodate ICD-11's structure and processes to provide the code set to all who utilize ICD-11. Other processes questions to address are as follows:

- What will be free to the public as taxpayers?
- What licensing will be required?
- What data structure will code information be available, such as PDF, XML, TXT or WHO's excel files?
- Do the code changes have to be published in the Federal Register such as with the Inpatient Prospective Payment System (IPPS)?
- If modification is made to extension codes only, will that also have to go through the rule making process?
- Currently ICD-10-CM is published on CDC/NCHS and CMS websites. Will the delivery format be similar?
- What is the anticipated update cycle for publication of changes and effective dates for the changes? Will the U.S. still follow April 1 and October 1 for ICD-10-CM code changes?
- How does this align with timing of various reimbursement related rule making processes?

ICD-11 will impact multiple regulatory agencies, at state and national level requiring evaluation of all current standards wherever ICD-10-CM is noted. Here are examples of other agencies and areas who will need to evaluate the impact of ICD-11 on the regulations and standards:

  - Office of the National Coordinator
    - United States Core Data for Interoperability (USCDI)
  - HL7 and the FHIR Accelerator Organizations
    - Gravity
    - CodeX
  - Quality measure organization-(AHRQ)
    - Quality measures, including electronic measures
    - Healthcare cost and utilization project (HUP)
  - Department of Health and Human Services
    - CMS
    - Office of the Assistant Secretary for Planning and Evaluation (ASPE)

- State Medicaid
- Workers Compensation
- Department of Veterans Affairs
- Department of Defense
- Bureau of Indian Affairs
- ANSI X12 Committee
- National Uniform Billing Committee (NUBC)
- National Association of Health Insurance Providers
- National Institute of Health
    - Value Sets Authority Center (VSAC)
    - National Library of Medicine (NLM)

Tracking the underlying URI for the Foundation and MMS linearization will be important as noted earlier. Changes within the underlying architecture to capture this additional metadata will need to be determined once fundamental standards are defined. Questions for the Committee to address are as follows:

- How will the URI information be submitted?
- How will more than one URI be captured in an efficient user experience?
- How will rare disease capture be different from ICD-10-CM when many conditions roll up to the MMS Linearization category for "other" if the Foundation URI is not submitted and retained?

Transaction standards (i.e., claim forms) will need to be updated to accommodate ICD-11 codes. This goes back to defining the standards regarding the system, such as what is a complete code. Another consideration is what new content is available within ICD-11 that is currently a separate system such as Present on Admission (POA). The POA reporting requirements for inpatient hospital claims could change to accommodate the extension codes available in ICD-11, therefore, eliminating the need to for separate fields on the claim for POA.

Each type of claim form and related rules need to be evaluated. Claims for professional services (837P) are limited to four diagnosis codes. This amount is very restrictive considering the expansion of ICD-11. Other claim forms such as 837D for dental services along with 837I for institutional claims need to be evaluated for number of codes and/or characters per code acceptable on the forms.

Assessment forms impacting reimbursement, such as Minimum Data Set (MDS) and Outcome and Assessment Information Set (OASIS) also need to be included in the evaluation of ICD-11 impact. The current forms have unique ICD-10-CM requirements to ensure proper reimbursement.

4. What are the most important considerations & 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 organization.
c. Ongoing management and maintenance of U.S. ICD–11 and its use.
d. Other requirements not named above?

a. Developing and managing implementation plans and programs for ICD–11 in the U.S.?

The development and management of implementation plans and programs for ICD-11 is a critical necessity. This step cannot be done without the development of regulations and guidance for ICD-11 at a national level to make plans against. There are many aspects of ICD-11 that will impact a significant number of applications for various actions. Please reference Section 3a.

The impact on healthcare information interoperability as specified by the United States Core Data for Interoperability (USCDI) could be substantial. Reporting requirements may change based upon the defined structure of ICD-11 in the U.S. There may be information that is no longer necessary to report. A comprehensive evaluation of all applications, policies, procedures and so forth that utilize an ICD-10-CM code should be evaluated for its necessity in a transition to ICD-11.

There needs to be an authoritative source for implementation and maintenance of ICD-11 within the U.S. Managing the implementation requires clear and objective milestones for each phase of implementation. An adoption timeline must be established, funded, and demonstrate the benefits of ICD-11 implementation.

***b. Developing regulations or guidance for ICD–11 applicable to your organization*.**

This is a critical first step before an implementation plan can be created. The regulations and guidance are applicable to anyone who uses ICD-11 data. Establishing these foundational items impacts every aspect of capturing and reporting ICD-11 codes. For example, it will be critical information for third party payers to develop their transition plans which includes converting ICD-10-CM based policies.

Identifying what must be considered in implementation or what will change will be based upon the established regulations and guidance. Please reference Section 3.A., where we identified questions, we felt are critical to answer before engaging on the development of comprehensive implementation plans. It will be difficult for organizations to estimate the burden of implementation without knowing this information.

c. Ongoing management and maintenance of U.S. ICD–11 and its use.

It is necessary for the U.S. to define what elements will be under the control and coordination of the NCHS for ICD-11 based upon the current ICD-10-CM/PCS Coordination and Maintenance process.

- This will need to be defined as current ICD-10-CM decisions do not require changes to the international edition of ICD-10.
- Current ICD-11 process allows for any registered user to submit a request which include new codes, revised codes, or changes to post-coordination. The current U.S. process requires public request proposals to go through the NCHS review and refinement prior to public committee meetings. Will this process for requests from the U.S. need to be coordinated rather than using the open forum available in ICD-11?
- How will post coordination options for various extension codes be managed and incorporated into the foundation ontology?
    - Example: MMS Linearization –Pain of right knee
        - Coding Tool with search for “pain knee” directs to ME82. Post coordination is available for identifying the specific joint. There is no post coordination option

incorporated to allow for laterality of the joint. If laterality is a desired extension, how will it be incorporated? How will a user know if an extension is inappropriate?

- How will users adapt to not having an index to assist in the assignment of codes?
    - How will that impact audits for inappropriate payment?
    - What is 'accurate' without indexing and rules/guidance?

The Committee should also define a maintenance process for public input into the underlying ontological structure. IMO envisions this process would function similarly to a U.S. defined maintenance process for other ICD-11 system changes.

d. Other requirements not named above?

As noted previously, this group will need to work with other healthcare industry standards, such as interoperability and data exchange. This group will also need to collaborate with WHO to ensure the U.S. adoption and maintenance of ICD-11 are coordinated and maintains alignment with international standards.

Each industry group will have their own unique requirements based upon their use case. For example, extensibility and the ability to support local codes in specific implementations is key to the flexibility of HL7 FHIR. Payment policies and reimbursement methods will be another key area to address. The public will want to understand the impact to their income streams to further assess burden and return on investment.

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?

All the elements listed below will need to be addressed to implement ICD-11. The challenge in estimating the necessary resources, requires the provision of the ICD-11 foundational standards, rules, and guidelines that the U.S. will adopt.

a. Implementing ICD–11 in your organization.

In addition to the availability of the ICD-11 foundational standards, rules, and guidelines in the U.S., outlining licensing agreements will be important to appropriately address organizational implementation. ICD-10-CM is licensed by a variety of different types of organizations, i.e., vendors. The U.S. will need to maintain parity for these organizations. For example:

- What type of licensure will be required across the healthcare?
- Will the licensing process be managed by NCVHS or WHO or both?

- What limitations are placed upon organizations from WHO's licensure requirements, i.e., adaptations of ICD-11 and the ability to map or crosswalk between ICD-11 and other terminologies?

***b. Managing and maintaining U.S. ICD–11 in your organization*.**

The delineation of the questions outlined in Question 3 are key to determining internal resource needs. While basic education can occur, a robust educational plan cannot be developed without knowing the U.S. requirements for ICD-11.

Once the ICD-11 standards are defined, managing ICD-11 within our organization will be greatly impacted by the update cycle. Will there be updates effective April 1 and October 1? Will there be minor updates (i.e., extension code changes only) outside of those dates? What is the impact to an ICD-11 linearization when the ICD-11 foundation changes? Information regarding the underlying ontology must be provided in a timely manner to adequately support the changes.

c. Meeting the needs of smaller, less resourced, or less externally supported entities.

Evaluating the economic impact of ICD-11 for smaller vendors, providers, and other less resourced organizations is critical. Small providers are at greater risk due to limited resources to sustain the financial burden of implementation, maintenance and/or the ability to comply with the requirements. If these providers are unable to continue to provide their services due to financial burdens created by ICD-11, will this widen existing gaps in healthcare services in less resourced socioeconomic environments?

d. What other resources not listed here may be needed?

For ICD-11 to be successful in the US, we believe that the case for the return on the investment must be significant to garner support from all providers, payers, and other impacted organizations to implement. The Committee should consider the following:

- How will ICD-11 improve upon what has been gained with ICD-10-CM since its implementation?
- How will ICD-11 address and avoid negative impacts of ICD-10-CM such as stringent reporting requirements (i.e., unspecified codes not allowed for reimbursement in some situations) from a provider perspective?
- What other ways could ICD-11 be used/captured outside of payment models?
- What challenges/burdens does the additional specificity of ICD-11create or alleviate for the industry?

Most likely, it will be necessary to incorporate sizeable federal financial incentives to assist in the implementation. The providers bear a significant cost not only from the incorporation of ICD-11 into their EHR and billing processes but in their revenue stream when dealing with changing payer polices in the wake of the new system (i.e. delays, denials, increased scrutiny). Small providers may not be able to sustain the financial burden.

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January 12, 2024

Sharon Arnold, Associate Deputy Assistant Secretary
Office of Science and Data Policy
Office of the Assistant Secretary for Planning and Evaluation.

Rebecca Hines, MHS
Executive Secretary
NCVHS, National Center for Health Statistics
Centers for Disease Control and Prevention
3311 Toledo Road
Hyattsville, Maryland 20782

Submitted electronically to: NCVHSmail@cdc.gov

RE: Response from Kaiser Permanente regarding the ICD-11 Request for Information (RFI)

Dear Associate Deputy Assistant Secretary Arnold and Ms. Hines:

Kaiser Permanente offers the following comments on the NCVHS RFI addressing the potential use of ICD-11 for morbidity coding in the U.S. Kaiser Permanente[1] is the largest private integrated health care delivery system in the United States, with more than 12.6 million members in eight states and the District of Columbia. Our mission is to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve.

In posing a series of questions, NCVHS intends to collect and consolidate responses from this second RFI with input from the initial RFI and the August 3, 2023 roundtable to help formulate an initial set of observations and policy perspectives, and a workplan for the upcoming year.

NCVHS Questions and Kaiser Permanente Responses

Question 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?*

[1] Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., one of the nation's largest not-for-profit health plans, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 40 hospitals and more than 600 other clinical facilities; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan and its health plan subsidiaries to meet the health needs of Kaiser Permanente's members.

Program Offices
One Kaiser Plaza
Oakland, CA 94612

Response:

Question 1a
The coding construct should adequately reflect the various types of health equity, social, behavioral, and community health needs via standardized, consistent, and meaningful ICD-11 coding for social determinants of health (SDOH). Ideally, a more systematic approach would yield specificity that aligns with adopted SDOH data standards (e.g., those of HL7's Gravity Project) with flexibility to adapt as the understanding of how these social and environmental factors impact the health care system evolves.

Question 1b
As in our recommendation for a above, coding should align with standards assessed by regulatory entities and authoritative sources (e.g., AHRQ, CDC, NCQA, TJC)

Question 1c
The ICD-11 Foundation significantly increases the number of potentially codable conditions (incorporating 5,500 rare diseases from Orphanet), and Foundation entities can be exposed for coding in any specific linearization.

Question 1d
Additional content in ICD-11 covers new disease categories and medical disciplines (e.g., sleep-wake disorders, sexual health, and traditional medicine). Certain chapters and disease areas, specifically mental, behavioral and neuro-developmental disorders, have undergone comprehensive review to align with the latest advances in medical knowledge.

For mental, behavioral, and neurodevelopmental health, DSM-5-TR and ICD-11 should be considered companion publications. DSM-5-TR contains the most up-to-date criteria for diagnosing mental disorders and extensive descriptive text, providing a common language for clinicians to communicate about their patients. DSM-5 comprehensively reorders and regroups diagnostic classes compared to DSM-IV.

While ICD-10 and ICD-10-CM align with DSM-IV, ICD-11 aligns with DSM-5, and this reflects different constructs. DSM-IV (and thus ICD-10) diagnostic groupings are based primarily on common presenting symptom, e.g., anxiety disorder. DSM-5 and ICD-11 diagnostic groupings are based as much as possible on common underlying etiological factors, e.g., "Obsessive-Compulsive and related disorders: presumed underlying common neurobiological factors, a diagnostic grouping based on etiologically associated stressful life circumstances." To reflect current clinical diagnostic criteria, is important for the U.S. to fully transition to ICD-11 as soon as possible to align ICD-based measures, payments, reporting, and research with the DSM-5. CMS and CDC-NCHS should work closely with the American Psychological Association to minimize the need for significant updates.[2]

[2] To clarify, ICD-10-Procedure Coding System (PCS), a procedure classification system designed by CMS for coding hospital-based procedures, is separate from ICD-10 and will not update with the transition to ICD-11. WHO did not develop ICD-10-PCS and does not maintain its vocabulary.

Additionally, SNOMED and ICD need to work closely together and become better integrated for content coordination. They should work together to align models more closely and reach an agreement to work together in a way that allows each organization to maintain their representations.

Question 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 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?*

Response:

Question 2a

Ambient listening technology with speech-to-text capabilities is implemented to automate documentation of clinical visits in many settings and can be reviewed as needed to ensure accuracy. Computer assisted coding has a longer track record and when fully automated it frequently requires under 3% human review. As a fully online classification, ICD-11 is well positioned to integrate with and take full advantage of these technologies which together will alleviate many of the provider burdens of clinical documentation and coding. In addition to its contribution to burden reduction, an important benefit of these automation tools is that they may prevent provider burnout.

ICD terms can be used to drive automation in order sets, patient alerts, care pathways, and other clinician operations. The ICD can trigger intervention in EHR systems that may encourage patients, nurses, and physicians to act. These and other process automation rules can be built on ICD, and most of them can be maintained at a local level.

Close collaboration with EHR developers and coding software vendors could help create processes that ensure coding automation can be accomplished with the new construct. One of the noted benefits of ICD-11 compared to ICD-10 is the ability to post-coordinate codes in ICD-11 automation. Clustering will likely be required to meet reimbursement and risk adjustment specificity reporting.

Question 2b

Artificial intelligence currently helps coders and providers accomplish accurate and complete coding and reporting. As the technology evolves, administrative burdens that come with documentation and coding for reimbursement, risk adjustment, clinical registry, public health reporting, care delivery, etc. will lessen.

Artificial intelligence or methodologies like Natural Language Processing may help in scanning through patient notes to identify situations where a standardized code may apply. This can help

maintain and optimize coding and documentation in in cases when a formal ICD-11 is not documented in a patient's chart.

Question 2c
Crosswalks or cross mapping between ICD-10 and ICD-11, and from ICD-11 to SNOMED, LOINC, are essential to ease the burden of transition, especially where translation is necessary. For instance, NCQA requires LOINC codes to receive credit for their SNS-E measure.

We have experienced the following issues mapping to SNOMED:

- HIE/diagnosis reconciliation for new members and members returning after receiving care outside the organization can be hampered by incomplete/shallow (or even incorrect) mapping by other terminology vendors. The process would be improved by having mapping done prior to release/use.
- SNOMED-CT hierarchies for some content areas are too flat, with one SNOMED-CT parent (proximal primitive parent) representing many diverse concepts in the same bucket. This can variously impact both patients and providers. We recommend SNOMED US and SNOMED International acknowledge and address these areas.
- Relatedly, EHR matching logic may not sufficiently differentiate clinical/pseudo-clinic concepts with same SNOMED-CT parent concept, so users need more and more-refined logic tools to accurately distinguish among them.

Crossmaps are essential to enable integration of healthcare information. SNOMED-CT, ICD, LOINC and RxNorm all must to work together in an integrated ecosystem for U.S. healthcare. Bilateral crosswalks will be very costly and difficult to maintain, needing a one-to-one manual curation, therefore rules-based crosswalk implementations are needed. A rules-based crosswalk implementation would solve issues like ICD having "Anemia for children under 6" which is different from SNOMED-CT. To integrate information in this example a FHIR observation could be used to find children under 6 having a hematocrit of "x" to then go to LOINC to provide the test name and SNOMED-CT for the sample and type. This also indicates future opportunities for using machine learning and Artificial Intelligence tools to integrate information from diverse sources.

Question 2d
The World Health Organization (WHO) already provides digital tools including a browser, a coding tool and a suite of APIs (application programming interfaces) to ease adoption. Also, U.S. regulatory adoption should recognize frequently used post-coordinated expressions as predefined standard terms to simplify and standardize implementation. Post-coordination provides an efficient way to add specificity to existing codes and avoids combinatorial explosion of precoordinated terms.

Question 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?*

Response:

Question 3a
Adopting a phased approach would allow organizations to gauge operational readiness for transitioning from ICD-10 to ICD-11. Our integrated model would require participation across hospital, health plan, and medical groups to assess the cost and impact of the change.

Question 3b
We would need to determine how to reconstruct our Convergent Medical Terminology for provider use and what tools, systems, and automation can be used by our coding staff.

Question 3c
We anticipate having to revise training, coding references, internal guidance memos, benefit adjudication protocols, advanced explanation of benefits, public health case reporting and syndromic surveillance, and numerous other reporting or data feeds to state, federal, or accrediting agencies that involve ICD-10 coding or codes.

Question 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 organization.*
c. *Ongoing management and maintenance of U.S. ICD-11 and its use.*
d. *Other requirements not named above?*

Response

Question 4a
We recommend providing ample time to prepare for transition and implementation (e.g., three years from the decision to adopt) and allowing dual-coded data sets to be used for a reasonable grace period after cutover (i.e., both ICD-10 and ICD-11).

Question 4b
We recommend establishing a committee to “code” real cases from across the U.S. to evaluate any issues with use of the new coding construct prior to developing guidance and/or regulations. Such cases should come from all the domains addressed in the questions and feedback provided for Question 1 of this RFI. Also, t the US governing body should align or partner s with CMS, NCQA, and HL7’s Gravity Project in considering how standard codes and requirements are made in this space. Doing so will also make it more likely that health systems will adopt these standards.

Question 4c

NCVHS should consider recommending more frequent updates to the code set to keep up with the evolving needs of the healthcare industry. The current ICD-10-CM maintenance process is slow and includes processing steps that slow it further. Quarterly updates may help expedite code maintenance and better align with ongoing changes to the ICD-11 Foundation. Additionally, the Coordination and Maintenance Committee may consider how to prioritize feedback from industry experts if the existing process continues.

Question 4d
International comparability of public health, population health, and health research data should be an important goal for ICD-11 adoption and implementation in the U.S. This objective may be enabled by basing U.S. classifications on a linearization of the ICD-11 Foundation with minimal extensions, and by avoiding a full clinical modification of ICD-11. This leads to a requirement for the U.S. coordinating body to effectively facilitate and coordinate U.S. content requirements with WHO-FIC authoritative coordination bodies.

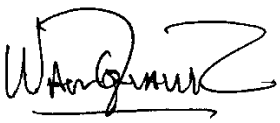
Question 5:

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?

Response:
The resources for a-c are significant and too numerous to list; examples would be as defined in these guides for ICD-10 implementation preparedness.[3]

Thank you for considering these comments. Please contact Megan Lane (megan.a.lane@kp.org) or Lori Potter (lori.potter@kp.org) if we may provide additional information or answer any questions.

Sincerely,



Walter Suarez, MD
Executive Director
Health IT Strategy & Policy

[3] ICD-10 Implementation Guide for Large Practices (cms.gov), *cms.gov/files/document/icd10payerhandbook0604131pdf*

From: Lori Groves
To: NCVHS Mail (CDC)
Subject: Response from Klickitat Valley Health regarding ICD–11 RFI
Date: Friday, December 8, 2023 4:17:13 PM
Attachments: image001.png

This may already be in the works (it's implied rather than stated in the information I've read).

I am hoping they will continue to add and expand codes that describe "social determinants of health". Most of the determinants that are available at this time are related to living conditions (e.g., homelessness) or codes that allow you to indicate that the patient's financial status impacted their healthcare (e.g., underdosing of prescribed medicines due to financial issues).

I think that social determinants like scarcity of specialty care, travel limitations and limits on public transportation, areas with aging populations, etc would be good additions. If you really want to know what the factors are that impact rural healthcare I think you need information about these social determinants.

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Lori Groves
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Goldendale, WA 98620

January 12, 2024

Rebecca Hines, MHS,
Executive Secretary, NCVHS
National Center for Health Statistics,
Centers for Disease Control and Prevention,
3311 Toledo Road
Hyattsville, MD 20782-2002

Submitted electronically to: NCVHSmail@cdc.gov

RE: Maryland Health Information Management Association Data Quality and Advocacy Committees on the ICD–11 RFI

Dear Ms. Hines and the National Committee on Vital and Health Statistics (NCVHS):

On behalf of the Maryland Health Information Management Association (MdHIMA), Data Quality and Advocacy Committees are submitting responses to the November 2023 RFI regarding adopting the International Classification of Disease (ICD-11) for the Department of Health and Human Services.

MdHIMA exists to serve its members, the healthcare industry, and the public by supporting activities and providing services that contribute to quality and efficiency within the healthcare system. MdHIMA is the Maryland component association of our national organization, the American Health Information Management Association (AHIMA).

MdHIMA in the past, was a leader in providing education to the healthcare industry during the transition from the ICD-9-CM to the current ICD-10-CM code system. The impact on the healthcare industry and MdHIMA members who hold positions throughout the healthcare ecosystem was significant. Our members look to MdHIMA and AHIMA to provide valuable insight to help inform us on the next transition to the ICD-11 system.

I appreciate your consideration of our responses to the RFI questions as the committee establishes an approach toward an implementation timeline for a successful transition to ICD-11.

Please do not hesitate to contact Brenda Watson at brendawatson@advantagovernementservices.com if you have questions for either committee or would like additional.

Sincerely,

Brenda Watson, MdHIMA Chairperson Data Quality and Advocacy Committees

RFI Questions and Responses

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?

-Does this question relate to chapter 21 of ICD-10 CM? If so, we agree and would like to see more codes related to the Z55-Z65 in I11.

b. Coding to measure health care quality and patient safety?

- yes, it is important to continue to be able to capture quality and safety metrics such as extension code for POA, other infection indicators (extensions cdiff, Cauti, Clabsi, and sepsis, to name a few), and how accidents or injuries happened these codes will represent causes and can be used to monitor and develop quality and safety programs.

- Will current coding clinics and official coding guidelines continue to be used to guide accidents and injuries coding that require reporting of the cause of the injury, which relates to patient safety and potential population health and health equity future policies?

-We agree that patient safety codes represent self or family non-compliance that caused the safety situation. For example, the family brought drugs into the hospital, the patient took drugs, and the patient overdosed, which is needed to fully capture the coding of situations. The healthcare industry can ultimately use these codes to monitor and develop future policies.

c. Coding for rare diseases?

- Yes, we would like to be able to capture rare diseases (similar to NEC); however, a condition could be rare in the US and not rare in another country. How will these situations be handled, and what guidance can be provided, especially if there is no clinical modification that would clearly remove the control of the code sets from the US and transfer the updates and control to an international level? According to the ICD-10 Coordination and Maintenance website, the committee is a Federal interdepartmental committee. Suggestions for modifications come from both the public and private sectors. Interested parties must submit proposals for modification before a scheduled meeting. Final decisions on code revisions are made through a clearance process within the Department of Health and Human Services. No final decisions are made at the meeting. Since the ICD codes are one of the foundational elements used in the US healthcare reimbursement system, consciously relinquishing updates to an international body seems to not be in the best interest of the healthcare industry.

Additional questions- What will the US process be for updating, adding, and revising ICD-11 codes? Will this process only be through the WHO process, or will the US have the ability to update similarly to the ICD-10 Coordination and Maintenance Meetings? These meetings give the healthcare industry a voice in requesting and changing the code set used for reimbursement, reporting, and other needs. The process is critical for the healthcare industry to have a stake in the code sets.

-Sequela conditions of these rare diseases need to be considered when codes are added or implemented.

d. Content on other topics?

- Our group was unclear on what this encompasses and how to respond to the question.

2. What is the potential to reduce burdens and improve quality/accuracy through the greater automation offered by the ICD–11 online classification systems?

-Health equity concerns surround access to the internet and technology if the classification system becomes fully an online classification system and all users can use the system. Analysis is needed to determine rural and inter-city health equity needs.

a. How might automation reduce the clinical documentation and coding burdens for reimbursement, risk adjustment, clinical registry, and public health reporting?

We still have to read and validate the AI that we currently have (speech recognition, CAC). We may have some data-mining automation in the future, but that will take time, and we still need that human element to validate and review. Variations in provider documentation styles will also limit automation ability. The committee believes there will be a need for human intervention and validation using automated tools. We also shared concerns about the workforce and how the current workforce would be upskilled to support the new technology that will be required while performing jobs.

b. What might be the role of artificial intelligence for your organization?

The committee still needs a human element to fine-tune AI resources. Variation will need to be incorporated into the AI platforms and further evaluation is needed. Specifically, AI infrastructure needs to be evaluated for rural hospitals, wifi access, and other technology for healthcare providers to see if AI can be supported in these smaller health systems.

c. What might be the role of standardized cross-maps to other coding systems?

- Similar to GEM during the transition to ICD-10, we will need a forward and backward crosswalk. Translate/standardize to SNOMED and other systems (DSM, LOINC, registries, etc.).

-Establish a partnership with key US industries that have coding encoders such as 3M, Optum, etc. if one doesn't already exist.

d. What other potential features could promote burden reduction?

- Gap analysis: what are current solutions capable of, and can current software platforms handle such an implementation? If not up to date, what is the timeframe to get to a baseline?

3. What standards, systems, workforce, and processes must change to accommodate ICD–11?

- HR burden (staffing analysis, current workforce will be ready to exit the workforce, and how do we recruit new talent?); is there any upskill we need to consider as we recruit new talent? We don't currently have the information about the code set to train adequately.

a. How would your organization assess the cost and impact of these changes?

- Gap analysis, risk assessment. We need to know if we will do a full clinical modification vs. a small subset that doesn't mirror the WHO.

b. How might technical changes such as clustered (post-coordinated) coding be implemented in your environment?

- Significant challenge in training to accommodate technical changes for how the ICD-11 codes are clustered. Gap analysis and risk assessments would be included to assess the training and development required. Need more analysis on how multiple stem codes and/or stem with extension codes will be accommodated in systems. In cases of multiple stem codes, how can we say that the additional stem code is modifying another stem code? (ex. An esophageal ulcer gets a stem code, and then a hemorrhage is another stem code – how do we say that the hemorrhage is from the esophageal ulcer based on those code assignments)?

c. What other changes are related?

- EHRs need to be updated, coding systems/encoders/computer-assisted coding, workflows are driven by diagnosis-specific codes, UB-04/payer software, and billing/reimbursement systems. Grouper updates (MS & APR-DRG, APC/APG, etc.)

4. What are the most important considerations and requirements for a U.S. governing body for ICD–11?

- Roadmap needs to be flexible to accommodate what is identified through gap and risk analyses. This will permit appropriate training and system updates for preparedness for implementation.

a. Developing and managing implementation plans and programs for ICD–11 in the U.S.

- Potential phased implementation to allow healthcare systems to follow along. Some have suggested a dual system but feel that would be challenging. Considering quality & safety reporting metrics – how would these be cross-walked and translated? Foundational changes will need to be made before organizations can adequately assess the training costs and needs for staffing.

b. Developing regulations or guidance for ICD–11 applicable to your organization.

- Details to support implementation cannot be defined until a decision on clinical modification, timeframe, and decisions about various resources are made. Foundational changes must be made before decisions can be made at the organization level.

-What resources or forums will be used to create and/or support/bridge existing Coding Guidelines that exist today (AHIMA, Centers for Medicare and Medicaid (CMS) in US)?

c. Ongoing management and maintenance of U.S. ICD–11 and its use.

- Coding Clinic advice/Coding Guidelines/CMS Local & National Coverage Determinations – How are these impacted? How will they be updated to reflect changes brought about by ICD-11?

d. Other requirements not named above?

- Losing the ability to update/modify/revise biannually if we relinquish to the WHO. Does not seem conducive to our payment models and U.S. system. Forward/backward crosswalk to ICD-10. Groupings to DRG (MS and APR). Quality Metrics such as PPCs (Potentially Preventable Conditions), Patient Safety Indicators (PSIs). Quality Reporting Agencies (AHRQ, LeapFrog, Vizient, US World News….) Period 0 data for quality and performance metrics (i.e., Vizient does this). Historical data within HIEs after ICD-11 implementation – what does that do for population health data, etc.? State-specific requirements – how will these be taken into consideration?

-Will there be a committee like the one that exists today (ICD-10 Maintenance and Coordination Committee in the US) that allows a forum for providers to speak and state

cases that would benefit the population at large to add, modify diagnoses and/or procedures and their codes?

5. What financial, educational, or human resources will be needed for:

a. Implementing ICD–11 in your organization.

- Will need ICD-11 trainers, will need programs similar to AHIMA's ICD-10 Trainer Programs); Productivity Study – assess HR needs (how much more or less productive this code set is).

-Training structure should be considered for the Medical Staff in the Medical Schools and professional CEUs for Attending physicians, PAs and NPs.

b. Managing and maintaining U.S. ICD–11 in your organization.

- Maintenance potentially less of a burden if done within a reasonable cadence (twice a year, similar to ICD-10, could be manageable)

c. Meeting the needs of smaller, less-resourced, or less externally supported entities.

- Low or no-cost education must be made available; exploration of cost-sharing for technology solutions—small hospitals banding together to partner with a vendor for a potentially better rate.

d. What other resources not listed here may be needed?

Will there need to be physician-based training? Yes, all facets of the healthcare ecosystem will need time to update systems and train on the new concepts.

Language different for ICD-11 vs what we are asking in ICD-10 vs. Is this more provider friendly?

CDI Training?

Staffing to train up – staffing for the learning curve immediately post implementation (Coding and CDI); Rev Cycle hit from loss of productivity and managing cash flow from extensive training.

Training resources will need to be significant and sustainable for the first year of implementation.

HR Concern – exodus from the industry

HR/Financial/Technology ? – continuing current advances in technology while implementing a new code set. Agreed upon realistic timeframes for Facilities, Providers, Payers, AMA, etc.

NCVHS ICD-11 RFI 2 Comment

This document is submitted by the Massachusetts Health Data Consortium (MHDC) and its Data Governance Collaborative (DGC) in response to the second NCVHS ICD-11 RFI posted in the Federal Register on October 16, 2023 and found here: https://www.federalregister.gov/documents/2023/10/16/2023-22753/national-committee-on-vital-and-health-statistics

About MHDC

Founded in 1978, MHDC, a not-for-profit corporation, convenes the Massachusetts's health information community in advancing multi-stakeholder health data collaborations. MHDC's members include payers, providers, industry associations, state and federal agencies, technology and services companies, and consumers. The Consortium is the oldest organization of its kind in the country.

MHDC provides a variety of services to its members including educational and networking opportunities, analytics services on both the administrative and clinical side (Spotlight), and data governance and standardization efforts for both clinical and administrative data (the Data Governance Collaborative/DGC and the New England Healthcare Exchange Network, respectively).

About DGC

The DGC is a collaboration between payer and provider organizations convened to discuss, design, and implement data sharing and interoperability among payers, providers, patients/members, and other interested parties who need health data. It is a one stop interoperability resource. The DGC primarily focuses on three areas:

1. Collaboration: Development of common understanding of and specifications for data standards, exchange mechanisms, and what it means to participate in the modern health IT ecosystem
2. Education: helping members understand their regulatory obligations, the data and exchange standards they're expected to use, and modern technology and related processes
3. Innovation: Identification and development of projects and services needed to make modern health data practices and exchange a reality

MHDC History with ICD-9 => ICD-10 Transition

This section describes the Massachusetts-wide ICD-10 testing project run by MHDC and discusses how we think our experiences can help prepare for and improve the process of moving the healthcare community to ICD-11.

About the Project

Starting in 2012 and running through the official industry adoption date for ICD-10, MHDC ran a Massachusetts-wide universal ICD-10 testing platform for payers and providers across the state. In addition to MHDC serving as the overall project manager, the project management team included the Massachusetts eHealth Collaborative (MAeHC) to assist with provider integrations and a national vendor to assist with payer integrations.

The project had three primary goals:

1. Making sure that small providers and payers had the same access to testing as their larger

counterparts

2. Making sure the end-to-end workflows work
3. Helping folks be ready to transition on time

Overall, the project was a great success and we met these goals. 92 organizations participated in the testing including nearly every payer in Massachusetts, nearly all hospitals in Massachusetts (including behavioral health institutions), and several large provider groups. While smaller providers were given equal access, few of them took advantage of it, often citing lack of resources as the reason they did not participate.

Scope of Project

Some of the key choices made around the scope of the project and use of ICD-10 codes included:

1. ICD-10 would be used for new coding only, no attempt to migrate ICD-9 codes would be made and thus no such migrations would be tested. This was primarily because of the difference in definitional granularity/specificity between the two code sets and the inability to determine a consistent, straightforward way to map many ICD-9 codes to a single, clearly equivalent ICD-10 code.
2. This project was for connectivity testing only. The expectation was that each organization would independently do whatever work they needed to do to support ICD-10 within their internal systems and to support sending or receiving codes in that format. Only once that work was completed would an organization be considered ready to start interacting within the community test platform.
3. The project focused solely on the claims cycle and clarified the administrative and financial role of ICD codes versus other code sets like SNOMED. In keeping with this, no attempt was made to look at conversions or mappings between ICD-10 and any of the clinical code sets commonly in use by providers.

Lesson Learned 1: Benefits of Joint Testing Extended Beyond Scope of Project

While the scope of the testing project was limited to the connectivity between trading partners, we found the benefits of joint testing extended well beyond that. In particular, the project provided a forum for airing out challenges organizations ran into within their black boxes, turning to the community to help them solve those problems, and learning how others dealt with the same or similar issues.

Lesson Learned 2: Testing for Revenue and Payment Integrity Not Feasible

The biggest ask/concern from participants early in the project was assessing the impact of switching to ICD-10 on their revenue (for providers) or on payment integrity (for payers). We determined that it was not feasible to try to address these concerns in any realistic way for several reasons:

- It was too difficult to create realistic test data for a wide variety of scenarios
- It was too difficult to fully replicate entire payer systems in the test environments, meaning some potential components of the revenue cycle were not applied
- It was too difficult and too time consuming to run every possible scenario across every possible pair of exchange partners

Lesson Learned 3: Focus on Codes Used Already Not the Full Scope

In general, familiar codes were given preference by providers and the smallest changes possible were usually implemented rather than trying to find some completely new solution even if it fit slightly better. Thus, only a subset of ICD-10 codes that most closely matched the ICD-9 codes already in place were used and tested.

In addition to reducing the work on both implementation and testing to a more manageable size, this also meant organizations focused on the most useful components of ICD-10 and did not have to worry about issues, incompatibilities, or how to map ICD-9 codes they were already using to more complex ICD-10 codes that might capture more information but required adjustments to existing workflows and provider practices.

Lesson Learned 4: In General, Providers Ready Before Payers

In general, the lift for moving from ICD-9 to ICD-10 was heavier for payers than providers and it took them longer to complete their internal work in preparation for connectivity testing. This caused some churn with providers who were ready and chomping at the bit to start testing before their partners were ready to make the necessary connections.

Lesson Learned 5: Everyone Needed to Be Ready to Test Before Anyone Could Finish Testing

The project involved individual testing pairs between each organization and all of its trading partners. This meant that no matter how fast a particular organization was ready to test, it could not complete its participation until the last of its trading partners was also ready.

This caused some resentment, but it also meant organizations had difficulty budgeting how long and how many ICD-10 resources they'd need because there was no clear, set timeframe and the readiness of various organizations was staggered. This was an issue for everyone, but was particularly difficult for providers waiting for payers as they tended to be ready sooner (as noted above).

Additional Concerns Raised by Participants

Some additional concerns that were raised by participants throughout the project include:

- Payers were particularly concerned about impacts on risk adjustment and population health programs
- There was quite a bit of discussion around the need for education around the alignment between ICD-10 and DSM; it will be important to address this for ICD-11
- The need for clinical documentation specialists quadrupled in provider organizations to allow for updating of codes and this really hurt smaller providers. These specialists were needed to bridge the gap between the technology and the clinical workflows to limit clinician disruptions/changes to the physician experience.
- People didn't know how to search for codes, were unsure about how to apply new codes, or needed to augment documentation with secondary codes that weren't needed before which all caused churn.

Overall Takeaways from the Project

The high level takeaways from the project include:

- It was successful. The entire community switched to the new codes on the required day.
- it was less disruptive than expected.
- Don't make it more complicated than you have to; it was better to focus on a minimal viable set of interoperability testing.
- Make sure the transactions work, that's the basis for everything else.
- Don't invest in revenue/payment integrity testing.

General Comments

This section includes general comments on ICD-11 or comments on items that cross multiple questions in the RFIs.

Timeframe for Comment and Flexibility of Responses

We wish to thank NCVHS for providing a longer comment period on this RFI compared to the first ICD-11 RFI. We also appreciate the opportunity to respond to the questions from the previous RFI we were unable to address last summer in addition to the questions in the new RFI.

Timing of ICD-11 Adoption

Participants in our Data Governance Collaborative strongly urge that any required US adoption of ICD-11 codes be carefully scheduled around other major regulatory requirements, particularly major interoperability rules from CMS and ONC or the upcoming changes to race and ethnicity data proposed by OMB. Each of these regulations comes with a significant lift and requires a major commitment of organizational resources to meet. It is extremely difficult to comply when multiple major updates or new functionality are required at the same time.

Code vs Segment vs Other Terminology

As ICD-11 has a compound code structure, it is important to be clear whether an entire composite code or a segment of the overall code is being referenced in any discussions, presentations, or written materials. In various presentations by NCVHS, NIH, and others, the term “code” has often used both for the entire composite value and for a single segment therein. We strongly recommend defining consistent usage expectations with different words representing the entire ICD-11 code vs a single segment/component of the overall composite value. We like “code” to represent the entire value and “segment” to represent a single component of the whole, but would welcome any consistently applied terminology that provided clarity between the two types of entities.

ICD-11 Structural Issues

We realize these are likely not under the control of NCVHS, HHS, or anyone likely to see this comment, but our Data Governance Collaborative was struck by several of the choices made in the design and creation of ICD-11 codes.

Two issues stood out as extremely problematic to us:

1. Supporting individual code segments of different lengths. We understand that ICD-11 is built on composite codes with multiple segments, but in addition to the variation in length caused by differences in the number of segments, we have discovered that the individual segments are not all the same length. This seems extremely problematic from a data storage and validation perspective.
2. Some of the descriptive language for codes may be identical in ICD-10 and ICD-11 but have different meaning and be incompatible. For example, a presentation we attended in December given by NIH under the auspices of WEDI gave an example of the ICD-10 code K56.41 Fecal impaction. The ICD-11 code with the same name is a child of constipation and requires that the patient be constipated to apply the code. Unfortunately, the ICD-10 code explicitly excludes constipation and cannot be applied to patients with constipation. Thus, while the codes have exactly the same name, they are incompatible; the ICD-10 code cannot be mapped to the ICD-11 code with the same name.

Response to Specific Questions – RFI #1

This section will list specific questions asked about ICD-11 in the first NCVHS ICD-11 RFI and our responses to them.

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?

Our Data Governance Collaborative discussion resulted in quite a few areas where we feel additional research or analysis would be helpful including:

- What are the most commonly used codes in ICD-10 and what do they look like in ICD-11?
- What codes are unlikely to be used much or at all?

- Of the ~10% of codes that NIH has identified as not being compatible between ICD-10 and ICD-11, how many are commonly used?
- What percentage of organizations instituted ICD-10 codes iteratively, starting with codes deemed equivalent to what they used in ICD-9 but expanding use over time to encompass additional or more specific codes? Is this likely to be similar for the move from ICD-10 to ICD-11?
- Was the adoption of ICD-10 codes more difficult for certain types of care, specialties, settings, environments, etc. and is this likely to be similar in the adoption of ICD-11?

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 the Diagnostic And Statistical Manual of Mental Disorders, Fifth Edition (DSM–5)?

We believe all of these areas are important. We are not familiar with what is and is not supportable via ICD-11 in the listed areas or similar types of health concerns. If supportable, some additional areas that are similar to some of those listed that might be important to capture include:

- Disability status
- Need for disability accommodations
- Diet and nutritional concerns
- Telehealth and remote monitoring information

6. The World Health Organization (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?

We believe the Office of the National Coordinator for Health IT (ONC), in coordination with other agencies within HHS as needed, is the right home for this oversight. Extensive feedback from industry and the public at large will also be essential, including public meetings and comment periods and explicit consultation and coordination with different types of providers, payers, vendors, and other relevant parties.

ONC is already responsible for other industry data standards such as USCDI and USCDI+. Further, there is already a process for collaborative standards definition with the USCDI+ framework. The existing ONDEC framework could be used to request updates for evaluation by ONC. If deemed appropriate, ONC could then submit these requests to WHO or their delegate for universal adoption.

A US linearization could be handled the same way, with annual or semi-annual updates released on a regular, predicable schedule using existing commenting and feedback processes.

ONC is also well positioned to ensure that new versions of the US linearization do not coincide with other major regulatory requirements such as deadlines for interoperability rules published by ONC or CMS.

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

It would be very nice to have a standard national mapping for ICD-10 to ICD-11. We understand that approximately 10% of ICD-10 codes cannot be directly mapped to ICD-11 so understanding which codes fall into this category and how to handle them in a standard way would also be extremely helpful.

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

In order to support FHIR and common FHIR use cases, it is absolutely essential to support mapping between ICD-11 and other code sets in a bi-directional, idempotent way if at all possible. The most useful mapping would definitely be between SNOMED and ICD-11, but mappings between ICD-11 and as many other code sets with compatible codes should be developed and made available for industry use.

Response to Specific Questions – RFI #2

This section will list specific questions asked about ICD-11 in the second NCVHS ICD-11 RFI and our responses to them.

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?

We believe that a, b, and c would all be extremely useful. We do not have a good enough sense of what is possible with ICD-11 to comment beyond that.

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 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?

It is unclear to us that there is a useful role for automation or AI related to the application of or upgrade to ICD-11. The quality of the underlying clinical documentation is extremely variable so using AI to analyze or process it is unlikely to be very successful.

However, as noted in comments above, it is important to provide useful, industry standard cross-maps between ICD-11 and other code systems, especially SNOMED.

We note that the application of ICD-11 codes and related processes are every bit as much human processes as tech processes. Education, workflow consistency and ease of use, training, and being aware of

organizational culture will likely yield more positive results in terms of burden reduction than trying to automate everything, at least initially.

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?

As noted in the previous comment, we believe that the human factor is a major component of this process. One of the key factors to be careful about here is the implementation timeframe. If the timeframe for implementation is too far out people will ignore it because it's not imminent, but at the same time it's clear it will take a long time to implement ICD-11. This will be a challenging area to get right, but it's important. People will never believe they have enough time whatever choices are made here, so we believe it's better to err on the side of a bit faster – but within the constraints of scheduling around other regulatory requirement deadlines. If needed, there's always an option to use an enforcement delay to extend the implementation period.

We also note that clinicians usually don't code using codes, they pick terminology. As long as the terminology doesn't change significantly then clinicians likely won't experience a huge change in workflows. Overall, it's unclear how many folks at a provider office or other care setting interact directly with the codes rather than the related terminology. Updating the internal dictionary/mapping between codes and terminology is likely the largest lift at provider organizations.

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 organization.

c. Ongoing management and maintenance of U.S. ICD–11 and its use.

d. Other requirements not named above?

We believe that everyone has a role to play in the adoption of ICD-11. As noted under the RFI #1 responses above, we believe ONC is the right organization to oversee ICD-11 in the US, but with coordination with CMS and other agencies within HHS as well as the industry and public at large. We were more focused on the definition and rules for maintenance and usage as well as related guidance in our thinking and did not consider all of the activities listed above (such as developing implementation plans which we see more as a local effort likely to be very different across different organizations) but some components of an overall program could be farmed out or sectioned off elsewhere with some oversight from ONC to maintain a single seat of authority if activities not in their direct wheelhouse are considered important.

Having a public-private partnership of some sort would be helpful, with some form of public meetings that go beyond invitation-only listening sessions seem warranted. It's also important to involve different types of organizations and interest areas (payers, providers, vendors, data experts, revenue vs clinical, etc.).

From: Melissa Tracy
To: NCVHS Mail (CDC)
Subject: Response from Mount Desert Island Hospital regarding ICD-11 RFI
Date: Tuesday, October 24, 2023 9:56:12 AM

Concerns for our small rural hospital are related to:

1. Rising costs of software updates.
2. Lack of staff to implement properly and efficiently.
3. lost revenue and productivity for education of staff related to ICD 11.
4. ICD 10 is sufficient to relay the diagnostics of our patient population.

Melissa J Tracy C.P.C. I Revenue Integrity coordinator/educator
MDI Hospital I 10 Wayman Lane Bar Harbor, ME 04609
207- 801-1279
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From: Stacey Neset
To: NCVHS Mail (CDC)
Subject: Response from Mountrail County Medical Center Regarding ICD-11 RFI
Date: Thursday, October 26, 2023 10:46:31 AM

I think ICD-11 has many benefits for statistical analysis and for enabling the United States to participate in international data sharing. If our information is in the same format as that of other countries, it would streamline the data sharing and analysis processes.

The issue with ICD-11 implementation in the United States, and specifically in rural health facilities, is the difficulty with the transition. I am employed by a small rural facility that includes a rural health clinic, critical access hospital, nursing home, basic care, and assisted living. I am one of 3 total medical records staff. Coding is just a small part of our responsibilities. We do not currently have the time or capability to learn a new coding system, as we are already understaffed. A major issue with updating the coding system includes software issues. In order to successfully use ICD-11, all of the software systems must be updated. Our department must have access to 7 different systems in order to get a claim out the door. It is 26 days after the 2023 updated ICD-10 codes and we still haven't been able to get all of our systems updated with the new codes, as this is a manual process. Additionally, learning a new coding platform would take many hours for all three of us and we don't have the time or funding to accomplish this.

Stacey Neset, RHIT
Mountrail County Medical Center
sneset@stanleyhealth.org
Ph: 701-628-8628
Fx: 701-628-3823

January 12, 2024

Centers for Disease Control and Prevention
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Submitted via email: NCVHSmail@cdc.gov

Re: Response from National Association of Chain Drug Stores Regarding ICD-11 RFI

To Whom It May Concern:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on NCVHS' Request for Information (RFI) for the anticipated ICD-11 implementation and timeline. As with the transition from ICD-9 to ICD-10, a transition to ICD-11 will require updates to technology standards and healthcare provider systems. For the pharmacy industry, this will require updates to standards developed by the National Council for Prescription Drug Programs (NCPDP). Although the full implications of such a transition would require a more in-depth review, we are confident that this transition will impact pharmacy providers to a more significant degree than past transitions.

Since the transition from ICD-9 to ICD-10 in 2015, we are seeing greater interoperability among pharmacies and other health care practitioners. As an example, and partially due to some state law requirements, prescribers are more commonly providing diagnosis codes with prescriptions. This is also helpful as pharmacies are providing far more clinical services, and the expansion of pharmacists' scope of practice continues apace. Local community pharmacies provide patients increased options for safe, affordable and convenient patient care. Especially over the last decade, community pharmacists have been granted expanded authority to provide clinical care services, which has enhanced access to basic healthcare services like testing, immunizations and other routine clinical care. The following charts outline some of the expanded clinical care services that pharmacists can now provide at local pharmacies:

Allowances to Test & Initiate Treatment for COVID, Flu, Strep and/or Other Conditions
18 States: Alaska, Arkansas, Colorado, Connecticut, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Kentucky, Michigan, Missouri, Montana, Nevada, New Mexico, Oregon, Virginia

Allowances to Prescribe or Furnish Specific Drug Therapies	
Naloxone	All 50 states + District of Columbia
Contraceptive drugs	25 States: Arizona, Arkansas, California, Colorado, District of Columbia, Delaware, Hawaii, Idaho, Illinois, Indiana, Maryland, Michigan, Minnesota, North Carolina, Nevada, New Hampshire, New

	Jersey, New Mexico, New York, Oregon, South Carolina, Utah, Vermont, Virginia, West Virginia
"Uncomplicated minor ailments"	7 States: Alaska, Delaware, Florida, Idaho, Kentucky, Montana, Washington
HIV PEP/PrEP	15 States: Arkansas, California, Colorado, Connecticut, Idaho, Illinois, Maine, Missouri, Nevada, New Mexico, New York, North Carolina, Oregon, Utah, Virginia
Tobacco cessation	20 States: Arkansas, Arizona, California, Colorado, Iowa, Idaho, Indiana, Kentucky, Maryland, Maine, Missouri, New Hampshire, New Mexico, North Carolina, North Dakota, Oregon, Utah, Vermont, Virginia, West Virginia
Other specified therapies	14 States: California, Colorado, Delaware, Idaho, Kentucky, Maryland, New Mexico, New York, North Carolina, Oregon, Utah, Vermont, Virginia, Wyoming

Moreover, in the aftermath of the COVID pandemic, pharmacies achieved unimaginable access for the nation to receive needed pandemic services. Consider that the nation's pharmacies administered more than 300 million COVID vaccines, more than 42 million tests, dispensed 8 million antiviral courses, and were the top provider of OTC COVID tests in a CMS' demonstration program. Using conservative estimates, pandemic interventions by pharmacists and pharmacy personnel averted >1 million deaths, >8 million hospitalizations, and $450 billion in healthcare costs.[1]

State Medicaid and commercial insurers are recognizing the expansion of pharmacists' scope, while at the federal level, there are ongoing efforts to secure payment for pharmacist care services under Medicare Part B. The chart below provides examples of where state Medicaid and commercial payers have recognized the expansion of pharmacists' scope of practice:

Examples of states with policies for coverage of certain pharmacist-provided clinical care services	
Medicaid coverage	18 States: California, Colorado, District of Columbia, Illinois, Indiana, Iowa, Maine, Maryland, Missouri, Montana, Nevada, New Hampshire, New Mexico, North Dakota, Ohio, South Carolina, Tennessee, Virginia
Commercial coverage	10 States: Kentucky, Maryland, New Mexico, Ohio, Oklahoma, Oregon, Texas, Virginia, Washington, West Virginia

As NCVHS reviews feedback received in response to this RFI, we ask NCVHS to recognize that a transition from ICD-10 to ICD-11 will have a much greater impact on pharmacies than the transition from ICD-9 to ICD-10 had. With this in mind, we urge NCVHS to consult with NCPDP, NACDS, and other pharmacy associations as NCVHS considers a transition to ICD-11. Moreover, we ask that NCVHS provide appropriate technical assistance and training to ensure that pharmacists, as well as all health care professionals, experience a smooth transition.

[1] https://www.japha.org/article/S1544-3191(22)00279-5/fulltext

Again, NACDS appreciates the opportunity to provide comments in response to the NCVHS RFI. For questions or further discussion, please contact NACDS' Sara Roszak, Senior Vice President, Health & Wellness Strategy & Policy at sroszak@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

# # #

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.

January 12, 2024

Centers for Disease Control and Prevention/
National Committee on Vital and Health Statistics (NCVHS)
3311 Toledo Road
Hyattsville, MC 20782-2002

Submitted electronically via email

Re: ICD-11 Request for Information (RFI)

To Whom It May Concern:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) Accredited Standards Developer (ASD) consisting of more than 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

NCPDP appreciates the opportunity to review and submit comments to NCVHS in response to its RFI regarding timely and strategic action to inform ICD-11 policy. NCPDP is invested in the successful adoption of ICD-11 given the coding system's pivotal role in pharmacy workflows, operations and interoperability. As such, we urge close collaboration with industry partners including NCPDP when strategizing the ICD-10 to ICD-11 transition and offer the following additional recommendations:

The full impact of transitioning from ICD-10 to ICD-11 remains under analysis, so the precise implications for stakeholders in the pharmacy industry cannot yet be quantified. However, unlike the last major code set update from ICD-9 to ICD-10, which had limited pharmacy ramifications, this migration will significantly impact both the medical and pharmacy settings. While the transition to ICD-10 required updates to NCPDP standards and all payer and provider systems, meaningful use of ICD-10 codes within NCPDP transactions did not occur until after the 2015 transition date. Meaningful use of ICD-10 codes includes, but is not limited to, the use of diagnosis codes within formulary designs that tailor coverage of drugs predicated on specific indications and the expansion of pharmacist scope of practice inclusive of professional treatment services. One of the major advantages of the NCPDP transactions that support the communication of this clinical detail is these transactions occur in real-time, at point of care. Additionally, efforts to increase interoperability across healthcare systems and standards have become critical to improve healthcare outcomes. To facilitate a smooth transition from ICD-10 to ICD-11 within real-time environments and across healthcare systems, a concerted effort across all stakeholders and cross-agency communication will be critical. Areas of consideration include, but are not limited to, timing, transition periods,

standardized code mapping, coverage of new codes, etc. to mitigate patient access to care and financial risks.

While providers and health plans will be at the forefront of adoption and deciding appropriate coding, the pharmacy industry and other stakeholders must be prepared for downstream impacts and ensure they can accept, coordinate and meet provider and health plan implementation timelines. To that effect, NCVHS should take into consideration appropriate training to ensure health care professionals, system developers and other stakeholders understand the ICD-11 coding.

Given the ICD-11 architecture is profoundly more granular than ICD-10, the transition from ICD-10 to ICD-11 would also require NCPDP to update our standards to support the changes in ICD-11. In some instances, the updates would be simply adding a code value to an existing data element, but there are larger considerations regarding the nature of the coding system and associated requirements that would require evaluation such as ensuring our standards and pharmacy industry systems all support an alphanumeric ICD-11 coding scheme and analyzing the impact of special characters used in ICD-11.

As NCVHS moves forward with collecting information and identifying gaps to help inform policy decisions around U.S. adoption and implementation of ICD-11 for morbidity, NCPDP requests NCVHS consider the impact this change would have on the pharmacy industry and provide support to ease the transition. Ongoing management and maintenance of ICD-11 will be an important consideration for proper industry usage. NCPDP thanks NCVHS for consideration of our comments as future ICD-11 policy is considered and looks forward to continuing to serve as a trusted resource.

For direct inquiries or questions related to this letter, please contact:

Margaret Weiker
Vice President, Standards Development
NCPDP
standards@ncpdp.org

Respectfully,

Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)

January 12, 2024

Sharon B. Arnold, PhD
Associate Deputy Assistant Secretary
ASPE, Science and Data Policy
Department of Health and Human Services
Science and Data Policy
Humphrey Building, Room 442E.2
200 Independence Avenue, S.W.
Washington, DC 20024

Federal Registrar, Volume 88, Number 198: Response from the National Organization for Rare Disorders Regarding ICD-11 Request for Information

Dear Dr. Arnold,

On behalf of the more than 30 million Americans living with a rare disease, the National Organization for Rare Disorders (NORD) thanks the National Committee on Vital and Health Statistics (NCVHS) for the issuing the Request for Information (RFI) regarding ICD-11 codes. Meaningful progress in research and care for our community depends on rigorous research, made possible by robust, granular and fit-for-purpose data. Timely and efficient implementation of ICD-11 codes will play a key role in unlocking the potential of real-world data (RWD) and real-world evidence (RWE) for rare diseases, many of which continue to be inadequately captured by current coding practice.

NORD is a unique federation of non-profits and health organizations dedicated to improving the health and well-being of people living with rare diseases by driving advances in care, research, and policy. NORD was founded 40 years ago, after the passage of the Orphan Drug Act (ODA), to formalize the coalition of patient advocacy groups that were instrumental in passing that landmark law. Since that time, NORD has been advancing rare disease research and funding to support the development of effective treatments and cures; raising awareness and addressing key knowledge gaps; and advocating for policies that support the availability of and access to safe and effective therapies.

For the rare disease community, more accurate representation of disease states through timely and efficient implementation of ICD-11 codes will be crucial. Appropriately specific ICD codes are pivotal in allowing researchers and physicians to track how many individuals are impacted by a specific disease, which is vital for rare diseases which often lack validated disease prevalence or incidence estimates; it also is also indispensable for gaining a better understanding of natural history and disease progression, including morbidity and mortality estimates, as well as

streamlining coverage and reimbursement issues.[1] Given that over 95% of the more than 7,000 known rare diseases do not have an FDA approved treatment, leveraging real-world evidence effectively, including through appropriate coding practices, is vitally important.[2,3] Appropriate implementation of the new ICD-11 codes is critical to unlocking its full potential, in particular for rare diseases, given the large number of diseases and pervasive issues with rare disease diagnostic, research, and care. NORD thanks the NCVHS for drafting this RFI, including its emphasis on leveraging the codes to help collect better data on historically underrepresented populations to ensure real-world evidence can be fully leveraged to bring more effective rare disease therapies to market.

NORD is pleased to offer the specific recommendations below for how to maximize the impact of this draft guidance, informed by our 40 years of experience working constructively with all key stakeholders to help bring new and better rare disease therapies to more patients more quickly.

Recommendation 1: Ensure the implementation of ICD-11 codes for rare diseases is timely, smooth, and allows for robust, high-fidelity datasets that are fit for purpose and can support meaningful improvements in rare disease research and care

To date, only 7% of rare diseases have disease-specific ICD-10 codes, and without disease-specific codes, physicians are often left to use codes that only describe (some of) the symptoms a person is experiencing,[4] making it difficult to identify rare disease patients for clinical trials and leverage RWD and RWE to ultimately improve patient care.[5] Implementation of ICD-11 will substantially increase the number of disease specific codes to 24% of all rare diseases. Importantly, another 71% of rare diseases will fall under broader, not disease-specific codes in ICD-11; although these diseases will experience remaining uncertainty in coding, it will represent a meaningful improvement over current coding available in ICD-10.[6]

Considering that more than 5,500 rare diseases will be represented at some level in ICD-11, a drastic increase from 500 through ICD-10, education and technical support around the new rare

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[1] Feinstein JA, Gill PJ, Anderson BR. Preparing for the International Classification of Diseases, 11th Revision (ICD-11) in the US Health Care System. JAMA Health Forum. 2023 Jul 7;4(7):e232253. doi: 10.1001/jamahealthforum.2023.2253. PMID: 37505488; PMCID: PMC10495107.

[2] Office of the Commissioner. (n.d.). *Rare diseases at FDA*. U.S. Food and Drug Administration. https://www.fda.gov/patients/rare-diseases-fda

[3] World Health Organization. (n.d.). *International Classification of Diseases (ICD)*. World Health Organization. https://www.who.int/standards/classifications/classification-of-diseases

[4] Luxner, L. (2019, February 5). *ICD-10 codes, "really important" to rare disease patients, soon up...* Pompe Disease News. https://pompediseasenews.com/news/icd-10-codes-really-important-to-rare-disease-patients-soon-up-for-fresh-consideration/

[5] June 2023 - World Health Organization. World Health Organization. (2023, June). https://cdn.who.int/media/docs/defaultsource/classification/icd/icd-10/icd-10-to-meddra-mapping-conventions.pdf?sfvrs

[6] A. Rath, personal communication, January 10, 2024

disease ICD-11 codes for providers, hospitals, and the broader healthcare ecosystem will be vital to success. This should include raising awareness about the new ICD codes that are available for rare diseases patients and about how their use will help better meet the needs of our community.[7] NORD's Rare Disease Center of Excellence (COE) Program, as well as organizations that represent the rare disease community, including NORD and its member organizations, can play a key role in these efforts.[8,9]

As a part of its mission, NORD's Rare Disease COE Program is committed to sharing knowledge and best practices to improve rare disease care and advance rare disease research, while solving the greatest medical challenges and unmet needs of the rare disease patient community. These centers are a unique network of 40 academic medical centers, children's hospitals, clinics, and institutions with the shared goal of advancing care and expanding access for rare disease patients. Through collaboration and knowledge sharing, the network aims to create a scalable model of treatment and research for all rare diseases that would otherwise be unattainable, providing a much-needed national infrastructure to help accelerate advancements in rare disease diagnosis, treatment, and research. Given NORD's Rare Disease COEs have extensive ties to the rare disease community and to providers, researchers, and other experts in the fields, and are tracking the implementation of ICD-11 closely, NORD would like to work together with the Centers for Disease Control and Prevention (CDC) and the key stakeholders to ensure appropriate coding is available to all medical entities and researchers to uplift rare disease research and bring more effective therapies to market.

Recommendation 2: Start engaging the rare disease community now as you look ahead to ICD-12 to further improve coding for rare diseases, and to address any challenges with the ICD-11 implementation that may need more fundamental corrections.

Critical stakeholders in the rare disease community, including NORD and its 330+ member organizations, and medical experts in the rare disease field can also play a key role in the planning for ICD-11. Recognizing the importance of accurate coding for the rare disease community, NORD has already committed to working with Orphanet, our Rare Disease COEs, and other patient organizations to help bridge existing gaps in rare disease coding, and to collect evidence to help prioritize which rare diseases would benefit most from disease-specific codes in future iterations. The experiences from the NORD's Rare Disease COE program to date clearly emphasize the importance of community ties and multi-sector partnerships to achieve these goals. NORD is looking forward to working with CDC, the Office of the National Coordinator, and other key stakeholders to further improve coding for rare disease patients as part of ICD-12.

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[7] The EveryLife Foundation. (n.d.). *ICD Code Roadmap Resource Guide*. https://everylifefoundation.org/wp-content/uploads/2021/06/ICD-Code-Roadmap-Guide-FINAL.pdf

[8] Feinstein JA, Gill PJ, Anderson BR. Preparing for the International Classification of Diseases, 11th Revision (ICD-11) in the US Health Care System. JAMA Health Forum. 2023 Jul 7;4(7):e232253. doi: 10.1001/jamahealthforum.2023.2253. PMID: 37505488; PMCID: PMC10495107.

[9] Bearryman, E. (2015, January). Does your rare disease have a code?. EURORDIS. https://www.eurordis.org/does-your-rare-disease-have-a-code/#:~:text=Nearly%20500%20rare%20diseases%20have,available%20in%20over%2050%20countries.

Without implementing ICD-11 codes for rare diseases, providers will only be able to report codes that describe (some of the key) symptoms but not the rare disease, thus making it impossible for researchers to access symptoms and manifestations under the specific diagnosis.[10] By only reporting symptoms of a disease without more specific ICD code, researchers have difficulty tracking health care quality and outcomes for rare disease patients, costs of certain rare diseases, as well as struggle to find patients to access clinical trials.[11]

Recommendation 3: Learn from past experiences including the implementation of ICD-9 and ICD-10 codes as well as experience with ICD-11 implementation internationally

To ensure the transition from ICD-10 to ICD-11 is timely, smooth and not unnecessarily burdensome for healthcare providers and the broader healthcare ecosystem, lessons learned from the ICD-9 to ICD-10 transition should be applied where possible. For example, in a study conducted on emergency departments in Illinois on the transition from ICD-9 to ICD-10, researchers found that 27% of a subset of ICD-9-CM codes billed to Medicaid were convoluted, while 8% of these codes were found to be incorrect.[12] Errors such as those observed during the ICD-9 to ICD-10 transitions can have significant impacts on the lives of rare disease patients, not only by creating negative clinical research implications, but also implications on the reimbursement and coverage of rare diseases, which have severe financial impacts on patients and families.

Similarly, experience with the implementation of Z-codes, which are designed to capture social determinants of health (SDOH) and can give vital insight into the social, environmental, and economic barriers patients experience, show the challenges associated with the implementation of novel codes, including the impact of limited incentives for use, and suggest the need for training physicians on the appropriate use of these codes.[13] The lack of incentives and coding for SDOH bares similarities with the lack of disease-specific coding rare disease patients, and provides useful lessons learned. Given the greater complexity of rare diseases, it is sensible to expect an even longer learning curve and larger disruptive impacts during the transition period, in particular for those providers that do not regularly care for rare disease patients.

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[10] Luxner, L. (2019, February 5). ICD-10 codes, "really important" to rare disease patients, soon up... Pompe Disease News. https://pompediseasenews.com/news/icd-10-codes-really-important-to-rare-disease-patients-soon-up-for-freshconsideration/#:~:text=%E2%80%9CFor%20one%2C%20it%20help

[11] The EveryLife Foundation. (n.d.). *ICD Code Roadmap Resource Guide*. https://everylifefoundation.org/wp-content/uploads/2021/06/ICD-Code-Roadmap-Guide-FINAL.pdf

[12] Krive J, Patel M, Gehm L, Mackey M, Kulstad E, Li JJ, Lussier YA, Boyd AD. The complexity and challenges of the International Classification of Diseases, Ninth Revision, Clinical Modification to International Classification of Diseases, 10th Revision, Clinical Modification transition in EDs. Am J Emerg Med. 2015 May;33(5):713-8. doi: 10.1016/j.ajem.2015.03.001. Epub 2015 Mar 7. PMID: 25863652; PMCID: PMC4430372.

[13] *Utilization of Z codes for Social Determinants of health among Medicare ...* Centers for Medicare and Medicaid Services: Office of Minority Health. (2021b, September). https://www.cms.gov/files/document/z-codes-data-highlight.pdf

To date, more than 60 countries have transitioned to using ICD-11 codes[14] and learnings from such international implementations can also be useful. For instance, a study from Canada on developing effective training materials for ICD-11 by measuring coder performance suggested the value of standardized training in this subject.[15] Effective training included a user guide, line codes, healthcare-related harms, as well as medical-surgical cases followed by a quiz for coders. This allowed researchers to see which areas needed more clarity and training, as well as create feedback on which codes are missing or need to be more thorough.[16] Since ICD-11 has major updates from ICD-10, proper guidance and training is needed to ensure all end-users of ICD-11 are engaged on how to use transition tools and other technologies associated with the update. The CDC should engage with users on how ICD-11 will impact their current systems and develop mechanisms for transition that meets the needs of the healthcare system.

Ensuring appropriate tracking and accountability, in particular for the implementation of rare disease codes, will be equally important to assess in near-real time how the transition from ICD-10 to ICD-11 is going, whether course-corrections will be needed, and to ensure appropriate data quality and fidelity during the transition. This will ensure that CDC vital statistics and surveillance systems will remain intact during the transition.

NORD again thanks NCVHS for the opportunity to provide comments on this important RFI, and we look forward to continuing the dialogue around ICD-11. For questions regarding NORD or the above comments, please contact Hayley Mason, Policy Analyst, at hmason@rarediseases.org

Hayley Mason, MPA
Policy Analyst
National Organization for Rare Disorders

[14] Feinstein JA, Gill PJ, Anderson BR. Preparing for the International Classification of Diseases, 11th Revision (ICD-11) in the US Health Care System. JAMA Health Forum. 2023 Jul 7;4(7):e232253. doi: 10.1001/jamahealthforum.2023.2253. PMID: 37505488; PMCID: PMC10495107.

[15] Eastwood CA, Southern DA, Doktorchik C, et al. Training and experience of coding with the World Health Organization's International Classification of Diseases, Eleventh Revision. *Health Information Management Journal*. 2023;52(2):92-100. doi:10.1177/18333583211038633

[16] Eastwood CA, Southern DA, Doktorchik C, et al. Training and experience of coding with the World Health Organization's International Classification of Diseases, Eleventh Revision. *Health Information Management Journal*. 2023;52(2):92-100. doi:10.1177/18333583211038633

From: Holly Bush
To: NCVHS Mail (CDC)
Subject: Response from Nevada Regional Medical Center regarding ICD-11 RFI
Date: Monday, October 23, 2023 12:05:16 PM
Attachments: image002.png

To Whom it May Concern,

Our answers are in green. Thanks!

. 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 it is hard to tell if this would be beneficial or not, if it will reduce the burden of chart abstraction for other unfunded mandates, then that is good
b. Coding to measure health care quality and patient safety If this will reduce the burden of chart abstraction for Value Based Purchasing it would be a good move
c. Coding for rare diseases Understand the need, really will not affect our small hospital
d. Content on other topics? If it would focus on reducing the burden of chart abstraction for VBP then great
2. What is the potential to reduce burdens and improve quality/accuracy through the greater automation offered by the ICD–11 online classification systems? The potential is great, it is important to ensure the systems are not clouded by competing agendas
a. How might automation reduce burdens of clinical documentation and coding for reimbursement, risk adjustment, clinical registry, and public health reporting? It could greatly reduce it, however the training for such a change is also a cost and if not beneficial in streamlining, then would be just another expense that is unjustified
b. What might be the role of artificial intelligence for your organization? It is very unclear if medicine would agree to or trust AI currently, it could be beneficial if evidence based studies with a large database prove safety and accuracy are present.
c. What might be the role of standardized cross-maps to other coding systems? Cannot see that would have much benefit for us, unless simply cross walking to ICD-10
d. What other potential features could promote burden reduction? Well the shift from chart abstraction to ICD11 would be good for the quality initiatives for data gathering, it would appear to shift detail into a physician or provider work flow, potentially slowing down the care of pts due to more burdensome documentation demands. More detail means more clicks for these professionals, who already are burdened with documentation that may or may not be about the care they have provided to a patients, and may be more about throughput and other CMS initiatives.
3. What standards, systems, workforce, and processes must change to accommodate ICD–11? I do not know enough about this initiative, however my concern is that professional workforce demands could go up, there will be delays in billing due to queries back to providers and there will need to be costly systems changes. This in the face of continued financial losses due to payer mix in our rural area and a change to an electronic health record that was much less costly and much less intuitive, much more clunky and much more challenging for us all.
a. How would your organization assess the cost and impact of these changes? We will need to look

at productivity standards and see how a new system will affect the workflows. This system is already very complicated and will require an extensive plan crossing several months to absorb into the system. We are already so lean, we will require extensive contracted support for training and implementation. We will need estimates of how this will affect productivity as well, when the system is analyzed by professional coding organizations.

b. How might technical changes such as clustered (post-coordinated) coding be implemented in your environment? That would require extensive re training and upgrading of systems, it is unclear if our current electronic health record could, in its current state even absorb the required functionality.

c. What other changes are related? How data is gathered, how documentation will occur, will we need to move toward more scribes (which we cannot find in a small town) or other ways to support our physicians and providers. Anything we need to do to support will cost dollars, is there an increase in reimbursement coming as well with this?

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 organization. This is another unfunded mandate, it will cost thousands of dollars to implement and enforce. It will take our providers away from patient care and into a classroom to again learn how to chart to satisfy payer sources.

c. Ongoing management and maintenance of U.S. ICD–11 and its use. Training costs will go up with cluster coding, both with coders and providers. Software systems will required updates, those costs will be absorbed by facilities.

d. Other requirements not named above? Software systems will required updates, those costs will be absorbed by facilities.

5. What financial, educational, or human resources will be needed for:

a. Implementing ICD–11 in your organization. As with ICD 10, we will required external trainers for coders and providers

b. Managing and maintaining U.S. ICD–11 in your organization. Ongoing training will increase

c. Meeting the needs of smaller, less resourced, or less externally supported entities. We are a sole community hospital that is financially stressed and at risk. We will need to spend thousands of dollars to implement and support ICD 11.

d. What other resources not listed here may be needed? Training for the clinical staff that quite often data gather to assist the provider with documentation.

Holly

NR
MC
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Cooperative Exchange
The National Clearinghouse Association

Jan 11, 2024

To: National Committee on Vital and Health Statistics

RE: Response from Cooperative Exchange Regarding ICD–11 RFI.

The Cooperative Exchange is pleased to provide some additional comments to NCVHS having already responded to the first RFI on ICD-11. While clearinghouses will not be selecting diagnoses codes for our customers, we will be accepting, validating/editing, and transmitting the ICD-11 codes when they are adopted for use in the US.

Our specific recommendations are:

1. There should be a recognized set of test data that all entities, both small and large, can access and use to test their systems. This could help start the testing process, save resources, and enable comparisons among entities.

2. Regarding a US governing body, that body should be tasked with developing a national schedule for implementation including the needs of vendors to develop software. Intermediate milestones should be included and monitored. Clearinghouses can assist in monitoring the readiness of their provider and health plan customers.

3. Matching providers and plans to establish testing is critical. Clearinghouses can assist in identifying entities ready to test with each other.

4. From our experience with ICD-10 implementations, end-to-end testing of the claims process is vital to ensure successful implementation. End-to-end testing should be a requirement and must be monitored nationally.

Sincerely,

Pam Grosze, Board Chair, The Cooperative Exchange,
Vice President, Product Manager Lead, PNC Healthcare

The Cooperative Exchange Background

The Cooperative Exchange is a nationally recognized association representing the healthcare clearinghouse industry in the United States. Our 23[1] clearinghouse member companies represent over 90% of the nation's clearinghouse organizations and process over 6 billion healthcare claims, reflecting over 2 trillion dollars in billed services annually. Our association members enable nationwide connectivity between over 1 million provider organizations, more than 7,000 payers, and 1,000 Health Information Technology (HIT) vendors. The Cooperative Exchange truly represents ***the U.S. healthcare electronic data interstate highway system*** enabling connectivity across all lines of healthcare eCommerce in the United States.

The Cooperative Exchange member clearinghouses support both administrative and clinical industry interoperability by:

- Managing tens of thousands of entities and connection points
- Exchanging complex administrative and clinical data content in a secure manner
- Supporting both real-time and batch transaction standards
- Enabling interoperability by normalizing disparate data to industry standards
- Delivering flexible solutions to accommodate varying levels of stakeholder readiness (low tech to high tech)
- Providing strong representation and participation across all national healthcare standard and advocacy organizations with many of our members holding leadership positions

Therefore, we strongly advocate for standardization and administrative simplification within the healthcare industry.

R1 RCM Inc.
433 W. Ascension Way, Suite 200
Murray, UT 84123

Date: January 12, 2024

Sharon Arnold
Associate Deputy Assistant Director
Office of Science and Data Policy
Office of the Assistant Secretary for Planning and Evaluation

Re: Response from R1 RCM Regarding ICD-11 Request for Information

Associate Deputy Assistant Director Arnold:

R1 RCM Inc. ("R1") is a leading provider of technology-driven revenue cycle management services for 93 of the top 100 health systems and more than 35,000 healthcare providers nationwide. Our organization supports the financial administration for more than 60 million patient encounters annually. Our enterprise solutions include scheduling, insurance verification, prior authorization, customer service, and patient financial counseling for some of the largest integrated health systems in the United States. At R1, we believe in making healthcare affordable, transparent, and accessible for patients. With innovative technology and automation solutions that simplify administrative tasks, we enable our customers to allocate more resources to patient care. Our interest in continuing to deliver this value to care providers is why we respectfully submit the below comments[1] in response to the National Committee of Vital Health Statistics' ("Committee") Request for Information Regarding ICD-11 (hereinafter "the RFI").[2]

I. Summary of R1's Comments

R1 is an industry expert in patient financial experience and delivers technology solutions to support patient-centered care. R1 is fully aligned with and supportive of federal policies designed to review the potential implementation of ICD-11 for morbidity coding in the U.S. To that end, our Comment identifies opportunities for the Committee to review its plans for implementation (based on developments within the healthcare industry) and identifies any possible shortcomings long before enacting ICD-11 nationwide.

Specifically, we are asking the Committee to continue reviewing industry trends for opportunities in both automation and artificial intelligence, particularly as they become more widely used tools by providers. We are also asking the Committee to contemplate resources, tools, and education for revenue cycle management ("RCM") teams to reduce the costs and impact associated with ICD-11 adoption. Finally, we urge the Committee to consider a transparent implementation timeline for ICD-11 adoption, including a grace period while systems complete the transition from ICD-10 to ICD-11.

II. While greater automation offered by ICD-11 online classification systems can significantly reduce administrative burdens on providers and improve coding accuracy and quality, the Committee must consider and review automation and artificial intelligence trends within the healthcare industry to fully capitalize on their potential to reduce those burdens.

[1] Our statements are on behalf of R1 only and, in turn, are not intended to reflect or otherwise represent the viewpoints or positions held by R1 customers.
[2] *National Committee on Vital and Health Statistics Notice of Meeting*, 88 FED. REG. 71369 (Oct. 16, 2023), https://www.govinfo.gov/content/pkg/FR-2023-10-16/pdf/2023-22753.pdf.

ICD-11 has significant potential to simplify clinical coding through the adoption of automation. Automation has become an essential tool for providers and entities like R1,[3] who use it in healthcare coding and documentation workflows to assist coders and billers to be as efficient and accurate as possible. The burdens that are reduced when automation is introduced to a mundane, repetitive task is highly impactful in several ways.

a. Automation as a coding tool significantly improves coding accuracy while eliminating deficiencies.

Automation improves the accuracy of coding by removing human intervention in simplistic coding tasks. Intelligent automation[4] can be used to both remove human errors that occur in medical coding and handle labor-intensive work on simple tasks.[5] These tools aren't used in place of coders, but as a tool to alleviate the coding workflow and allow coders to focus on highly complex coding issues.[6] Where inconsistencies in judgment can complicate efficiency and accuracy in coding, automation assists in resolving these ambiguities that are often left up to human discernment. By providing uniformity on various coding tasks, automation allows coders to operate to a higher standard.[7] To that end, ICD-11 currently offers a level of automation as the ICD-11 Coding Tool has been designed to facilitate auto-generation of codes from clinical documentation.[8] This auto-generation of codes will reduce human error, while making the coding process more efficient and easier for anyone to learn.[9]

Automation can also be useful for pinpointing deficiencies in documentation, such as analyzing and proofreading documentation for providers to ensure a complete and accurate patient record.[10] For example, electronic health records can be reviewed via automation to ensure that everything has been completed correctly. This would augment coding and billing workflows by identifying corrections that need to be made prior to claim submission, reducing the administrative burden for both providers and payers.[11]

R1 strongly supports the current level of automation within ICD-11 tools because they allow for certain coding workflow challenges to be alleviated. However, ICD-11, as it currently exists, has a limited automated functionality and could benefit from additional automation tools to promote and support existing automation trends.[12] This lack of advanced automation could reduce the impact ICD-11 adoption has on coding. **As such, we strongly urge the Committee to review enhanced automation tools and current trends within the healthcare coding industry that could be paired with ICD-11 adoption and incorporate them where appropriate into the ICD-11 tools.**

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[3] R1 RCM uses automation for assistance in ambiguities that are often only left up to human judgement. *See generally Intelligent automation that unlocks human potential,* R1 RCM (last accessed Dec. 18, 2023), https://www.r1rcm.com/automation.
[4] *Id.*
[5] *See* WHY AUTONOMOUS CODING IS HAVING A MOMENT IN HEALTHCARE, HEALTHCARE FINANCIAL MANAGEMENT ASSOCIATION (2023), https://www.hfma.org/technology/why-autonomous-coding-is-having-a-moment-in-healthcare/#:~:text=The%20promise%20of%20autonomous%20coding,into%20the%20role%20of%20auditor.
[6] *Id.*
[7] *Id.* Nearly 70% of polled providers identified increased coding accuracy as an expected outcome of adopting better coding automation.
[8] https://icd.who.int/en/docs/ICD-11%20Implementation%20or%20Transition%20Guide_v105.pdf at 14.
[9] *Id.*
[10] WHY AUTONOMOUS CODING IS HAVING A MOMENT IN HEALTHCARE, HEALTHCARE FINANCIAL MANAGEMENT ASSOCIATION (2023), https://www.hfma.org/technology/why-autonomous-coding-is-having-a-moment-in-healthcare/#:~:text=The%20promise%20of%20autonomous%20coding,into%20the%20role%20of%20auditor.
[11] *Id.*
[12] *See generally ICD-11,* World Health Org. (last accessed Dec. 18, 2023), https://icd.who.int/en. The ICD-11 Coding Tool that has been implemented is promising in reducing cost and increasing efficiency. The Coding Tool creates an alphabetical index and functions like a web-based search such that the user can locate a diagnostic statement as recorded without using a lead term and/or secondary term. *See* Webinar: Using the ICD-11 coding tool, CIHI, https://www.cihi.ca/en/webinar-using-the-icd11-codingtool#:~:text=It%20displays%20the%20hierarchy%20of,term%20and%2For%20secondar%20term. The Coding Tool is linked to the ICD-11 browser, allowing access to further details on a category or code in the classification within the Coding Tool. *Id.* This coding tool will be helpful for automation and influence billing because it will become more effective and easier to integrate into systems. *Id.* Creating new tools that involve automation for coding is going to be essential in the future to eliminate potential human errors that result in missing reimbursement opportunities, backlogs, and claim errors.

b. The Committee should continue to review how artificial intelligence will impact automation processes pertaining to ICD-11.[13]

R1 applauds the Committee's interest in understanding the potential of Artificial Intelligence ("AI") to optimize ICD-11's automation features. We anticipate there are several areas where artificial intelligence can play a critical role. One such area is clinical coding. An "expensive, time-consuming, and error prone" process, the accuracy of clinical coding could be greatly improved through the effective implementation of AI.[14] However, R1 encourages greater insight into what AI processes are best suited to be paired with ICD-11, as numerous studies have pointed to the different capabilities of machine learning and deep learning approaches.[15]

The Committee should also be aware of the downstream impact of medical record documentation on effective AI use. For example, a potential barrier to effective AI assisted coding is "note bloat," which can occur when information is copied and pasted into clinical notes in a way that makes notes repetitive and redundant; essentially confusing the algorithm that would be interpreting the notes.[16] Consequently, any capability of AI to assist not only with coding, but also with creating a more efficient clinical documentation process, would be worth evaluating and implementing.

Additionally, AI can help maximize diagnostic-related group ("DRG") validation by efficiently and effectively estimating DRGs at the time of admission.[17] This is due in large part to the extensive amount of data available in EHRs that allows algorithms to learn how to accurately predict DRGs from prior cases.[18] As a result, it is expected that the use of an automated DRG coding system would help improve hospital performance and more fairly allocate medical resources by allowing these groupings to be predicted at an early stage.[19]

Even outside of active processes, AI promises to be a gamechanger for passive trend identification. In addition to processing significant number of claims in a short period of time, AI can identify and notify stakeholders of coding and documentation shortfalls, as well as denial trends among payers.[20] This information could potentially allow providers to be more responsive to coding issues and allow errors to be identified, reconciled, and rectified significantly faster.[21] In an era where providers across the country are facing a shortage of coders who are able to perform these tasks, AI could help solve a workforce shortage and contribute to a timelier resolution of claims.[22]

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[13] For the purposes of this Comment, R1 is only reviewing how artificial intelligence impacts processes on the provider side. However, R1 is aware that payers have come under increasing scrutiny for their use of automation and artificial intelligence in reviewing claims. *See* Jakob Emerson, *UnitedHealth, Cigna face lawsuits over alleged automated claims denials*, BECKER'S HEALTHCARE (Nov. 27, 2023), https://www.beckerspayer.com/payer/home-page/unitedhealth-cigna-face-lawsuits-over-alleged-automated-claims-denials.html. The Committee should ensure that payer-related uses of automation and artificial intelligence are factored into any decisions related to these topics moving forward.

[14] Kauer, R., et al. *AI-Based ICD Coding and Classification Approaches Using Discharge Summaries: A Systematic Literature Review* (2022) https://www.sciencedirect.com/science/article/abs/pii/S0957417422020152; *see also* Teng, F., et al. *A Review on Deep Neural Networks for ICD Coding* (2023) (stating that it can take "an average of 34 minutes to assign codes" to a single patient and improving coding efficiency and accuracy in the US could save $25 billion per year) https://ieeexplore.ieee.org/document/9705116.

[15] Kauer, *supra*, at 9-11, 15 (pointing to several studies showing the use of machine learning to categorize clinical narratives while also addressing the growing belief that deep learning has the greatest potential to improve the accuracy of assigning clinical codes).

[16] Liu, J., et al. *"Note Bloat" Impacts Deep Learning-Based NLP Models for Clinical Prediction Tasks* (2022) (finding that the duplicative and redundant information that is copy and pasted into clinical notes has resulted in issues with the accuracy of artificial intelligence assisted coding) https://www.sciencedirect.com/science/article/pii/S1532046422001617?via%3Dihub.

[17] Islam, M., et al. *DeepDRG: Performance of Artificial Intelligence Model for Real-Time Prediction of Diagnosis-Related Groups* (2021) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8701302/pdf/healthcare-09-01632.pdf.

[18] *Id.* at 2, 11.

[19] *Id.* at 12; *see also* Liu J., et al. *Early Prediction of Diagnostic-Related Groups and Estimation of Hospital Costs by Processing Clinical Notes* (2021) https://www.nature.com/articles/s41746-021-00474-9.

[20] Jacqueline LaPointe, *Medical Coding is the Next Stop for Artificial Intelligence in Healthcare*, REVCYCLE INTELLIGENCE (Oct. 3, 2022), https://revcycleintelligence.com/features/medical-coding-is-the-next-stop-for-artificial-intelligence-in-healthcare.

[21] *Id.* Given that payers continue to deny claims at historically high rates, allowing providers additional flexibility to identify errors through the use of artificial intelligence could offset this trend. *See id.*

[22] *See* Jennifer Lubell, *Addressing another health care shortage: medical coders*, AM. MED. ASSOC. (Apr. 19, 2023), https://www.ama-assn.org/about/leadership/addressing-another-health-care-shortage-medical-coders. The AMA estimates that providers face an estimated 30% shortage in health care coders as of 2023.

While AI has the capability to revolutionize how medical coding is performed, it requires deeper consideration to properly maximize its potential. **Accordingly, R1 strongly encourages the Committee to consider AI-related opportunities as it pertains to ICD-11 adoption.**

III. While ICD-11 ushers in improvements for coding and billing, the Committee must consider the cost and impact of implementing these changes for RCM services and payers.

The Committee has acknowledged that ICD-11 is the global standard for health data, clinical documentation, providing a common language for uniformly recording encounters with patients.[23] The revision's key features are certainly an improvement from ICD-10, however, the Committee must consider that implementation may be challenging in the U.S.[24]

a. The Committee must recognize that organizations would incur high costs of human capital, technology upgrades, and training; allocating an appropriate timeline and resources for such implementations is crucial.

ICD-11 touts an easy implementation that would improve documentation of clinical details and lower long-term costs.[25] However, the materials do not discuss, let alone mention, the short-term costs. For any RCM organization, implementation will require various investments in human capital.

To properly educate applicable teams for ICD-11's implementation, various organizations and providers within the healthcare industry would need to employ additional workforce members and resources such as: (1) information technology resources to ensure all required and appropriate technology is securely in place; (2) coding staff already familiar with ICD-11 to serve as internal experts and to provide downstream education; (3) additional educational resources for expand the skills of current staff and to establish an education program for future hires; and (4) a consulting firm to manage and to coordinate a proper implementation plan. A firm would be necessary for rigorous monitoring and evaluation, as well as honest and transparent assessment of progress.[26]

For technological tools, R1's operations and coding teams would need to not only acquire certain upgrades but familiarize themselves with them through education and training. These tools can include but are not limited to: (1) coding abstracting systems; (2) billing/host systems; (3) electronic medical records; (4) any additional coding applications; (5) charge description master; (6) revenue integrity systems; (7) learning management systems; and (8) data analytics systems. The sheer number of current tools that would require thorough updates and determinations for continued usage, in addition to potential new tools, would contribute to high costs to ensure accuracy.

Applicable training would likely need to include areas such as physician services, clinical documentation improvement, coding, revenue integrity, coding quality reviewers, scheduling, and billing teams. For the initial trainings and additional opportunities going forward, materials would need to be created and established. R1 suggests the Committee consider a large-scale associate training and testing environment to assist with consistency and offsetting individual organization costs. The following teams or groups will likely be needed: task force for research and organizational navigation; compliance/regulatory; coding; product engineers and developers;

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[23] *Id.* at 71370.

[24] *See* Sean Barrett and Ronald Haduch, *The Case for Intelligent Automation in Revenue Cycle Management as Part of Your System-wide Technology Upgrade*, R1 RCM (last accessed Dec. 20, 2023), https://f.hubspotusercontent20.net/hubfs/4941928/R1-Case-for-IA-White-paper-Oct-14.pdf?__hstc=154389415.ef8772c2b3d95960c31725fb921fb546.1703096420012.1703096420012.1703096420012.1&__hssc=154389415.3.1703096420012&__hsfp=1654019965&hsCtaTracking=f9fb4bdd-3103-4dc7-b4a5-4ae2e02b3e89%7C9496856e-c4bb-4cb0-aa64-141c1553b17d. While healthcare organizations are motivated to upgrade their core technologies, these investments and their implementations can require multiple years to be implemented and subsequently improve operational efficiency.

[25] *ICD-11 Implementation or Transition Guide*, WORLD HEALTH ORG. (2019), https://icd.who.int/en/docs/ICD-11%20Implementation%20or%20Transition%20Guide_v105.pdf.

[26] Thomas R. Frieden, *Six Components Necessary for Effective Public Health Program Implementation*, 104 Am. J. Pub. Health 17 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3910052/.

analytics; customer facing support; accounts receivable and payer impact evaluations; and increased support for effective guidance.

To reiterate, it would be an immense achievement to welcome ICD-11's technological and scientific advancements in the U.S. healthcare industry. However, the Committee would be remiss to overlook the initial, steep costs of overhauling ICD-10. **R1 urges the Committee to acknowledge these costs when introducing a timeline for and allow organizations ample time to get resources in place to be successful with ICD-11 implementation.**

b. The Committee must assess the impact on expected payment methodology for providers, their RCM providers, payers, and most importantly, patients.

The actualization of ICD-11 will bring in changes that significantly influence billing at all stages in the revenue cycle.[27] While this can be a valuable upgrade, it also has the potential to disrupt an already heavily-delayed process.[28] The Committee is urged to consider the delays and denials that could result from poor payer readiness, and potentially consider an extended yet firm timeline for implementation.

Currently, healthcare facilities and providers face significant challenges related to widespread payer failures to timely and accurately adjudicate claims. Offenses such as unnecessary coding denials and payment delays are already common. These issues then trickle down to patients who are surprised or frustrated to learn about these denials and delays through mailed communications months, if not years, after they received the related items and services. R1 fears that such instances will only increase post-implementation and that they will become a subject of further payment contention for RCM organizations, payers, and patients. The Committee would be wise to evaluate payer behavior with practices specific to ICD-11 with guidance around its intended applicability, coverage, and payment structure linked to ICD-11 output. Again, we would like to emphasize that while we believe ICD-11's advances are an achievement, financial implications for providers and guidance for payers should be an equal focus to make implementation a collaborative achievement. **R1 suggests that the Committee consider a timeline that allows grace for all ICD-11 users as well as accountability through guidance; however, the timeline and standards should be clear and firm to all parties involved**.

IV. The Committee Should Evaluate Implementation Constraints and the Effects of Updated Code Lists on Existing Systems

Since ICD-11 became available for global adoption in 2022, R1 has appreciated the Committee's commitment to understanding the challenges facing its successful implementation in the U.S. In furthering that commitment, we recommend the continued pursuit of stakeholder feedback regarding the appropriate timeline for transitioning to ICD-11 and the production of a clear and consistent guidance on what that timeline will ultimately be. At R1, we support the estimated implementation timeline of at least four to five years for entities with a "highly sophisticated information system."[29] However, given that some systems are better positioned to transition than others,[30] a plan that clarifies whether all systems are required to have implemented ICD-11 by a certain date or whether implementation would be rolling based on user complexity is necessary.[31]

R1 also requests that information be provided on the use of grace periods during the beginning of ICD-11 implementation. During the transition to ICD-10, a one-year grace period was implemented to allow practitioners

[27] ICD-11 Fact Sheet, WORLD HEALTH ORG. (last accessed Nov. 16, 2023), https://icd.who.int/en/docs/icd11factsheet_en.pdf.
[28] Ctrs. for Medicare and Medicaid Servs., *Request for Information*, 88 FED. REG. 44281, 44282 (July 12, 2023).
[29] WHO, *ICD-11 Fact Sheet*, 3 (2022).
[30] *Id.*; *see* ICD-11 Implementation or Transition Guide, Geneva: WHO, 14 (2019) ("the transition to [ICD-11] for legacy countries will require a more tailored approach").
[31] We encourage working in concert with payers, health systems, independent clinicians, and revenue cycle management companies to ensure all implications are examined prior to finalizing an appropriate implementation timeline.

under Medicare Fee-for-Service Part B to gain experience with ICD-10 coding sets.[32] We ask for clarification on whether similar grace periods will be implemented and their scope. Once the grace period is over, we also encourage the provision of information surrounding denials that will organizations to identify trends and where their processes may be falling short.

Additionally, we request more information on ICD-11's impact and effect on current DRG groupings and whether there would be changes in payment methodology. In particular, replicating the effort made during ICD-10 PCS implementation to provide information regarding conversion activities and its incorporation into the DRG system is encouraged during the transition to ICD-11.[33]

Moreover, while ICD-11 presents an opportunity to grow and build on the previous iteration, it is also an opportunity to create a long-term, sustainable design that can be built upon when developments inevitably arise, rather than being discarded. To ensure such longevity, intentionally building ICD-11 to be compatible with updates and adaptable to new technology is imperative. As a result, we urge the Committee to consider how ICD-11 can accommodate and integrate future updates, technologies, and processes.

In short, for a transition to ICD-11 to be both seamless and successful, the Committee must provide more clarification and transparency into any adoption timeline, along with its impact on current billing practices during a transition away from ICD-10. We understand that this information may not currently be available as the Committee continues to review the regulatory landscape and determine the best path forward. **However, as this information becomes available, we strongly urge the Committee to provide updates and a regulatory roadmap to providers and payers so stakeholders may begin making the proper preparations.**

V. Conclusion

We appreciate the Committee's consideration of our Comment to this RFI and look forward to working with the Committee in reaching its policy goals. Should the Committee have any questions about this Comment, please feel free to contact us by email at RegulatoryCompliance@R1RCM.com.

Sincerely,

Scott Remmich, MHA, MBA, CHC, CHPC, CPC
Vice President
Regulatory Affairs & Regulatory Compliance
R1 RCM, Inc.

Connor McLarren

Connor McLarren, JD
Manager

[32] CMS, *Clarifying Questions and Answers Related to the July 6, 2015, CMS/AMA Joint Announcement and Guidance Regarding ICD-10 Flexibilities* (2016).
[33] NCVHS, *Letter to the Sec'y – ICD-10 Recommendations- Attachment I* (2003); *see also* Feinstein, James et al. *Preparing for the ICD-11 in the US Healthcare System* (2023) (suggesting that publicly available tools such as crosswalk mapping files, translation software, and dual-coded datasets are needed).

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Submitted on behalf of
SNOMED International by Dr. James Case

January 12, 2024

11 January 2024

Department of Health and Human Services
Centers for Disease Control and Prevention
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

Submitted electronically to NCVHSmail@cdc.gov

RE: Request for Information on the "NCVHS ICD-11 Workgroup on Timely and Strategic Action to Inform ICD-11 Policy Phase I Findings Report"

SNOMED International acknowledges and applauds the effort of the National Committee on Vital and Health Statistics (NCVHS) Workgroup on Timely and Strategic Action to Inform ICD-11 Policy on this report and thank the entire NCVHS for continued support in health data morbidity and mortality reporting for the U.S. We appreciate the opportunity to provide comments on the "NCVHS ICD-11 Workgroup on Timely and Strategic Action to Inform ICD-11 Policy Phase I Findings Report"[1]. It is recommended that the NCVHS thoroughly evaluate the use of existing U.S. standards for morbidity reporting that have been widely adopted within U.S. healthcare systems, such as SNOMED CT, LOINC, and RxNorm, as this will continue to drive current and on-going implementation of these standards for clinical care, support improved data analytics, and avoid costly and time-consuming transition to a new terminology.

EXECUTIVE SUMMARY

The challenges for the United States to transition from the existing ICD-10-CM to ICD-11 for morbidity reporting have been well documented in the Phase 1 findings report published by the NCVHS. While the restructuring of ICD-11 is purported to reduce or eliminate the need for an ICD-11 clinical modification, primarily through the use of post-coordination, it does not address the potential need for U.S. specific extensions to ICD-11 nor eliminate the need for a wholesale replacement of the existing ICD-10-CM classification with an entirely new terminology standard.

SNOMED CT has a wide adoption within the United States for clinical recording, is mandated for use in the recording of problem lists, and is a recommended standard in both the Interoperability

[1] https://ncvhs.hhs.gov/wp-content/uploads/2023/05/ICD-11-WG-Phase-I-Findings-Report.pdf

Standards Advisory (ISA) and the U.S. Core Data for Interoperability (USCDI). As a clinical terminology it provides a comprehensive representation of morbidities and interventions routinely used in health care. It is proposed that NCVHS consider the adoption of SNOMED CT for morbidity reporting, rather than adopt a wholly new standard with its concomitant costs and implementation challenges. For mortality reporting, as required by the World Health organization, logical maps to ICD-11 MMS are being developed that would enable the automated conversion of SNOMED CT concepts to the appropriate ICD-11 classification term. This is similar to the current approach within the U.S. for mortality reporting using ICD-10.

About SNOMED CT

SNOMED International[2] is a not-for-profit organization that owns and maintains SNOMED CT, the world's most comprehensive clinical terminology. We play an essential role in improving the health of humankind, by determining standards for a codified language that represents groups of clinical terms. This enables healthcare information to be exchanged globally for the benefit of patients and other stakeholders. We are committed to the rigorous evolution of our products and services, to support the growing needs of our Members and deliver continuous innovation for the global healthcare community.

About SNOMED International and U.S. National Release Center

SNOMED International is Member-based with country representatives driving initiatives and priorities for the organization. The General Assembly is the highest level of authority of the organization and ensures that the purpose, objectives and principles of the Association are pursued and that the interests of the organization are safeguarded. The General Assembly makes binding decisions regarding all matters, inducing the organization's budget and strategy, subject to and in accordance with the provisions of the Articles of Association. In addition to the General Assembly, the organization is guided by the Member Forum, which acts as an advisory body and helps to optimize collaboration and coordination among Member countries. The U.S. is represented by the U.S. National Library of Medicine (NLM) at both the General Assembly and Member Forum and they provide information and guidance to SNOMED International on behalf of U.S. initiatives[3].

The United States also benefits from work at the NLM where they produce the U.S. Edition of SNOMED CT[4]. This terminology standard is based on the International Edition of SNOMED CT but has additional content that is required and needed by users within the U.S. This ability to include content specific for U.S. needs is critical as it allows for content to be added and

[2] https://www.snomed.org/
[3] https://www.snomed.org/member/united-states
[4] https://www.nlm.nih.gov/healthit/snomedct/index.html

modified quickly for U.S. users by the NLM. Because the use of SNOMED CT in health data systems across the U.S. is vast, it is beneficial to have the U.S. Edition of SNOMED CT. The following are examples of SNOMED CT use within and across federal and health data systems.

Considerations Related to SNOMED CT adoption and implementation in the U.S.

SNOMED CT adoption as a HIPAA code set

SNOMED CT is one of a suite of designated standards for use in U.S. Federal Government systems for the electronic exchange of clinical health information and is also a required standard in interoperability specifications of the U.S. Healthcare Information Technology Standards Panel and has also been adopted for use by the U.S. Federal Government, through the Consolidated Health Informatics (CHI) Initiative, for several clinical domains.

SNOMED CT adoption and implementation outside of HIPAA

The Office of the National Coordinator for Health Information Technology (ONC) and federal partners encourage, and in some instances require, stakeholders to implement and use standards and specifications identified within the Interoperability Standards Advisory (ISA). SNOMED CT has been listed as a standard with high adoption levels across many of the categories listed in ISA, and in some cases, as a federally required standard (see Representing Patient Family Health History[5] as an example).

Since its initial inclusions within Stage 2 Meaningful Use for documenting problem lists, requirements for use of SNOMED CT in U.S. health data has greatly increased. The U.S. Core Data for Interoperability (USCDI) establishes a standardized set of data classes and component data elements and expands on data required to be supported by certified EHRs. The USCDI incorporates health data standards such as SNOMED CT which is recommended for use in 17 data elements within 8 data classes and required in 3 data elements in the current 4th version of USCDI[6].

Beyond ONC, SNOMED CT is recommended and/or required for use by other HHS Agencies. Since May 2018, the FDA requires SNOMED CT for coding study data indications of the Investigational New Drug (IND) application, New Drug Application (NDA), Biologics License Applications (BLA), and Abbreviated New Drug Application (ANDA), which are FDA Forms 356h

[5] https://www.healthit.gov/isa/representing-patient-family-health-history
[6] https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#uscdi-v4

and 1571[7]. Additionally the FDA mandate for Structured Product Labeling requires SNOMED CT to represent Medical Condition in order to facilitate informed decision-making and to support long-term patient care. By identifying intended uses or indications for new drugs, and for representing medical conditions with the SNOMED CT standard terminology, this allows for the FDA to gather metrics to better inform review activities for applications with similar indications. The inclusion of SNOMED CT on these forms help the FDA to identify gaps for future drug development and can help to inform policy development. And with the use of SNOMED CT, this facilitates the ability for FDA data to link with other SNOMED CT coded data, such as from EHRs.

Also within the U.S. Federal government, the Veterans Affairs (VA) utilizes SNOMED CT within their electronic health care data. They maintain their own VA Extension of SNOMED CT which is based on the US Edition of SNOMED CT[8]. This allows for content (such as the VA-sponsored wound care project, focused on the capture of veteran assessment and treatment of wounds, to be encoded with SNOMED CT) to be easily captured and shared not just across VA hospitals in the U.S. but with anyone using SNOMED CT[9].

Another HHS agency, the Centers for Medicare and Medicaid Services (CMS), also depends on SNOMED CT and other standards as promoted by ONC such as LOINC, Consolidated Clinical Document Architecture (CCDA) and Fast Healthcare Interoperability Resources (FHIR)[10]. Specifically, SNOMED CT is used for the data capture and computing of CMS electronic Clinical Quality Measures (eCQMs) which are used to measure and report that a health care system is delivering effective, safe, efficient, patient-centered care in a timely manner as required by CMS. Use of SNOMED CT for these measures ensures that the health data can be recorded and the eCQM can be calculated quickly and utilize the standardized protocols for efficient reporting.

Vaccine certifications

Internationally, the European Commission developed the Digital COVID Certificate (EUDCC)[11] and the WHO created the Digital Documentation of COVID-19 Certificate (DDCC - and later DDCC:TR)[12]. In both of these initiatives, users requested the EU and WHO to include SNOMED

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[7] https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/updates-forms-356h-1571-commercial-vs-research-systematized-nomenclature-medicine-clinical-terms

[8] https://www.oit.va.gov/Services/TRM/StandardPage.aspx?tid=9527

[9] https://www.va.gov/vdl/documents/Clinical/Patient_Care_Encounter_(PCE)/pxum.pdf

[10] https://mmshub.cms.gov/sites/default/files/eCQM-Specifications-Testing-Standards-Tools-Community.pdf

[11] https://commission.europa.eu/strategy-and-policy/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en

[12] https://iris.who.int/handle/10665/352585

CT directly within the vaccine certificates or to include mappings to SNOMED CT. Because use of SNOMED CT was already implemented at the hospital sites, inclusion of SNOMED CT on certificates would facilitate cross-border vaccine data interoperability. Within the U.S., SNOMED International has worked with HL7 International, MITRE, and a number of other organizations to ensure that any clinical content needed for capture and exchange of data needed for the pandemic and beyond are included and available in SNOMED CT terminology[13]. By ensuring that SNOMED CT was included in these U.S. and global efforts, assists in the common goals of avoiding duplication of effort and facilitating interoperability.

International Patient Summary

SNOMED International also participates as part of a group of standards development organizations, including HL7 International, Integrating the Healthcare Enterprise (IHE), CEN (the European Committee for Standardization) and ISO, that are part of the Joint Initiative Council for Global Health Informatics Standardization, which first published the Patient Summary Standard Set, a minimal and non-exhaustive set of basic clinical data of a patient, specialty-agnostic, condition-independent, but readily usable by all clinicians for the unscheduled (cross-border) patient care[14]. These organizations, driven by global organizations such as the G7, G20 and the Global Digital Health Partnership (GDHP), work together to ensure a coordinated approach to maintaining and updating the International Patient Summary (IPS) to support its global implementation. The U.S. ONC, who are past chairs of the GDHP, actively promote the adoption and implementation of the IPS. SNOMED CT is the clinical terminology used within IPS artifacts and SNOMED International continues to support Member countries, such as the U.S., who are promoting IPS adoption.

Analytics & Research

SNOMED CT encoded data can be used for data analytics which may be used to describe, predict or improve clinical and business performance, and to recommend action or guide decision making. SNOMED's Expression Constraint Language (ECL) provides a robust mechanism to select and aggregate subsets of SNOMED CT concepts, allowing much greater focus and specificity when selecting concepts for analysis[15]. Use of SNOMED CT encoded health data are already providing value to U.S. researchers, decision makers, and health care. Within the United States, the All of Us Research Data has been a game changer for real data that can be utilized for research purposes. Much of the data captured within the All of Us Research Data is encoded in SNOMED CT[16]. This important data set has facilitated new

[13] https://vci.org/
[14] https://international-patient-summary.net/
[15] https://confluence.ihtsdotools.org/display/DOCECL/Expression+Constraint+Language+-+Specification+and+Guide
[16] https://www.researchallofus.org/faq/what-is-snomed/

knowledge such as factors that are able to be used to identify patients with hypertension[17], links between air quality and cancer risks[18] and more[19].

Overall, there have been and will continue to be high levels of adoption and implementation of SNOMED CT across Federal Agencies. Use of SNOMED CT and other federally recognized and funded standards helps to ensure to end users that the roadmap and goals of the government are towards health data interoperability.

Integration with other standards for interoperability

SNOMED International works with 25+ international collaboration partners to enhance SNOMED CT's global terminology and to facilitate interoperability. The quality, quantity and focus of existing and new collaborations, alliances and partnerships SNOMED International maintains and establishes reflect the organization’s ongoing commitment to harmonize healthcare terminology across multiple domains. The following are a sampling of some of the collaborations SNOMED International has to facilitate interoperability initiatives for Member countries such as the United States.

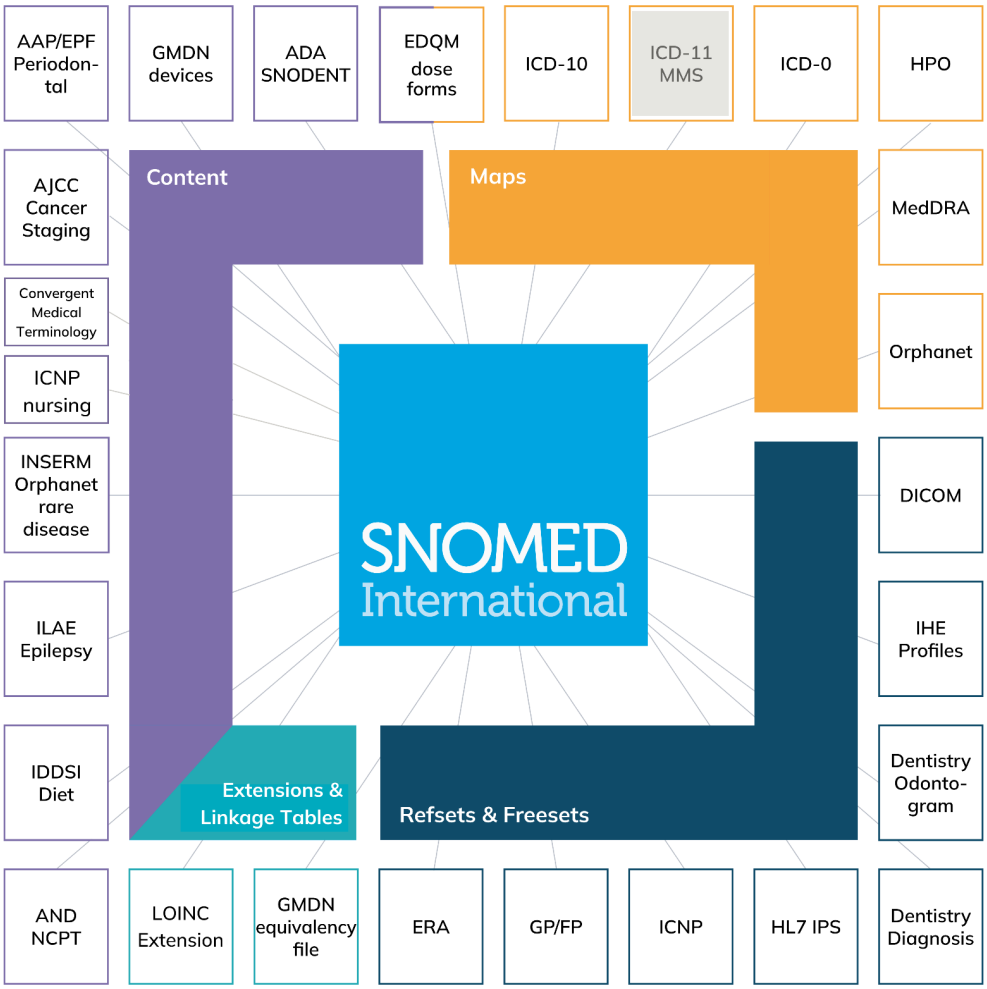
[17] https://pubmed.ncbi.nlm.nih.gov/34158555/
[18] https://pubmed.ncbi.nlm.nih.gov/38145439/
[19] https://allofus.nih.gov/protecting-data-and-privacy/research-projects-all-us-data

Submitted on behalf of
SNOMED International by Dr. James Case

January 12, 2024

SNOMED International Delivering SNOMED CT

Content partners and collaborations



LEGEND: In progress

Last updated: January 2024

HL7 International and FHIR

SNOMED International and HL7 International have a long history of collaboration. Current focus of the agreement is aimed at improving interoperability and working to ensure use of FHIR and SNOMED CT standards are implementable by users. This is especially important for countries such as the U.S. where FHIR exchange standards and SNOMED CT for clinical content are encouraged and in some cases, required, for health data. The collaborative SNOMED on FHIR has developed an implementation guide to facilitate the use of SNOMED CT in FHIR profiles[20]. This collaboration is especially beneficial as this will help implementers meet clinical and U.S. regulatory requirements.

Regenstrief Institute and LOINC

SNOMED International has also had a long history of collaboration with the Regenstrief Institute, owners of Logical Observation Identifiers Names and Codes (LOINC). The current agreement allows for the two organizations to work together to create an extension of SNOMED CT for the LOINC terminology and release a draft preview of the LOINC Ontology[21]. The ontology currently comprises 23,840 LOINC terms modeled as SNOMED CT observables built on a framework for naming and classifying the key attributes of clinical observations, providing consistent semantics for observations exchanged between systems for many uses. Completing this work will allow implementers to take a unified approach to implementing both standards, giving them a choice of which codes to use for ease of implementation.

This work is especially important for the United States as both SNOMED CT and LOINC are required for use. In the past, linkage and ability to exchange data between laboratory and clinical systems have been difficult to achieve; however, with harmonization and alignment between the two standards, U.S. data systems will be able to do this going forward. Furthermore, by working collaboratively, this will reduce duplication of effort in content areas where there is overlap, thus helping to reduce costs.

American Dental Association and SNODENT

SNODENT is the clinical terminology, produced by the American Dental Association, that enables the capture, aggregation and analysis of oral health data. Current Dental Terminology (CDT) codes are also produced by the American Dental Association and are used for consistency and specificity in reporting dental treatments. Both systems are recognized by the American National Standards Institute (ANSI) as an ADA/ANSI standard. Specifically, SNODENT has been harmonized with SNOMED CT, which provides rich detailed dental

[20] https://build.fhir.org/ig/IHTSDO/snomed-ig/
[21] https://loincsnomed.org/

content, used extensively by dentists and oral health facilities across the United States. This alignment also facilitates billing within the United States, reducing burden for the care professional. Additionally, via this partnership, there are many U.S. based dental professionals involved with the SNOMED International clinical reference group, ensuring that the needs of U.S. dental professionals are included in SNOMED CT for electronic dental record systems.

The American College of Surgeons and AJCC

The American College of Surgeons (ACS) and SNOMED International entered into a licensing agreement to include agreed-upon American Joint Committee on Cancer (AJCC) tumor staging values in SNOMED CT. The focus of the agreement enables SNOMED International to include updated AJCC staging concepts critical to understanding cancer and treating patients while eliminating outdated AJCC content no longer relevant to clinical care within SNOMED CT. This is especially important for the U.S. as they are key components of both cancer synoptic reports and communication to cancer registries.

The Academy of Nutrition and Dietetics and NCPT

A U.S.-based initiative for the inclusion of The Academy of Nutrition and Dietetics code system known as the Academy's Nutrition Care Process Terminology (NCPT) was promoted to SNOMED International to provide valuable nutrition and dietetics content more globally. This collaboration enables high-quality nutrition care content that includes nutrition assessment, diagnosis, intervention and monitoring and evaluation content. This content helps to support U.S. initiatives around social determinants of health, primarily in areas of malnutrition and food insecurity.

INSERM and Orphanet

SNOMED International works with INSERM, the French Institut national de la santé et de la recherche médicale, to include rare disease content in the SNOMED CT International Release and to provide a map to Orphanet. In 2023, the map, which is quality-assured by INSERM, included 7,025 terms. This alignment ensures that rare diseases can be captured in electronic health care systems and helps to facilitate the movement of rare disease information from the EHR to research and other uses of Orphanet data in a consistent and standardized way.

SNOMED CT alignment and mappings with WHO-FIC

The World Health Organization (WHO) and SNOMED International share and serve a common set of users. SNOMED International collaborates with the WHO to support the implementation efforts of those users globally.The two organizations have worked together to achieve this goal since 2010, primarily by creating maps between SNOMED CT and the WHO (ICD) versions 10

and 11. ICD 10 (10th Revision) is designed to promote international comparability in the collection, processing, classification and presentation of mortality statistics; ICD-11 (11th revision) allows the systematic recording, analysis, interpretation and comparison of mortality and morbidity data collected in different countries or regions and at different times and ensures semantic interoperability and reusability of recorded data for different use cases beyond mere health statistics, including decision support, resource allocation, reimbursement, guidelines and more.

SNOMED International creates and makes SNOMED CT mappings to ICD versions available to Members. A SNOMED CT to ICD-9 map was previously developed to support reporting of ICD-9 statistics. Now that most of the world has moved to ICD-10, SNOMED International developed and maintains a SNOMED CT to ICD-10 maps to assist Members who need to report mortality statistics. Within the U.S., the NLM produced a U.S. Edition of SNOMED CT to ICD-9-CM map and currently maintains a map to ICD-10-CM. These maps have been extensively used to assist U.S. hospitals and health care practitioners as health data are recorded with SNOMED CT and able to automatedly report statistics and billing of the ICD-10-CM (and ICD-10) codes.

Currently SNOMED International is testing and developing a prototype map, utilizing automated mapping technology, to create a SNOMED CT to ICD-11-MMS map. The purpose of this map is to help Members, such as the United States, who have a requirement as a WHO member nation to report mortality statistics. This is especially useful as healthcare data within the U.S. are encoded in SNOMED CT and other standards aligned with SNOMED CT. This map facilitates the ability for reporting without duplication of effort in trying to record and store data already encoded with SNOMED CT in other terminology standards such as ICD-11.

ICD-11 and SNOMED CT Comparison

Characteristic	ICD-11	SNOMED CT
Digital representation of health terms and classes, and polyhierarchical relationships between terms and classes, in an underlying semantic network	Polyhierarchy only available in the foundation. Digital availability only via an API. MMS - mutually exclusive hierarchy with residual classes. Digital availability via an API.	Formal digital distribution (RF2) files that include the terminology polyhierarchy and defining relationships. Also available through a FHIR API.
Designed to be continuously updated, potentially reducing	Updates are made in the foundation, which must then	Updates made directly in the terminology and released

the need for major upgrades in the future	be reflected in the linearizations, which are planned to be released annually	monthly (International) or biannually (U.S. edition)
Code structure allows flexible clustering of stem codes and extensions (post-coordination)	Rudimentary post-coordination syntax without explicit semantics.	Well-defined concept model that supports extensive post-coordination as part of the architecture of the terminology, driven through a machine-readable model to ensure the validity of post-coordinated expressions
Purpose-specific classification hierarchies may be derived computationally	Requires creation by the WHO as the inner workings of the foundation are not publically available.	As a clinical terminology, statistical classifications are not part of the terminology. Morbidity recording may be assigned using the core terminology. Domain specific sub-ontologies can be extracted.
Includes online tools and services designed to ease translation/mapping between ICD- 10 and 11 and to work with other terminologies	Mapping and translation tools are available from the WHO	SNOMED mapping and translation tools are open source and available
Includes digital tools and services to support implementation	Yes	Yes, all tools available under open source licenses
Content	Approx. 85,000 concepts in the foundation; 17,000 in the MMS	Approximately 365,000 concepts
Content request platform	Yes	Yes, both globally and specifically for the US

The use of ICD-11 for morbidity reporting in the U.S. will require the creation of a U.S.-specific linearization from the foundation to meet the clinical needs of U.S. healthcare. It is unclear whether the foundation contains the required stem codes necessary to meet the U.S. needs.

SNOMED CT, as a comprehensive clinical terminology, provides considerably more content than the ICD-11 foundation and is extensible to meet the needs of the U.S. through the U.S. national release center, which maintains the U.S. Edition to SNOMED CT.

SNOMED CT and artificial intelligence

As healthcare systems start to adopt solutions that use artificial intelligence (AI) technologies, it is important to note that SNOMED CT offers several vital advantages specifically beneficial for AI in healthcare.

Its rich semantic model allows for precise representation of healthcare data, enhancing machine understanding and interpretation of healthcare data. SNOMED CT's support for extensions enables AI systems to adapt to locally specific healthcare terms and conditions, allowing for the creation of personalized AI models. Its focus on interoperability allows machine learning models to train on diverse data sources, enhancing their predictive accuracy and generalizability.

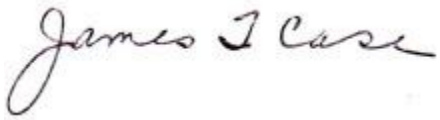
The proven use and presence of SNOMED CT in healthcare data enhances the efficiency and effectiveness of AI applications in healthcare significantly.

Conclusion

With wide adoption, strong governance, and processes to support rapid evolution, SNOMED CT provides a compelling argument for adoption by the U.S. government as a morbidity reporting terminology. The well-defined management processes as well as the ontological commitment of SNOMED CT demonstrates its stability, expressiveness, and longevity compared to other terminology standards. The digital architecture of SNOMED CT makes it straightforward to implement in healthcare systems due to its structured release format as well as its implementation in FHIR terminology services. The integration with other standards, both global and U.S. required, facilitates SNOMED CT as a terminology hub for health data interoperability.

As SNOMED CT is already adopted (and required in some cases) and implemented in health data systems across the U.S., the use of SNOMED CT for morbidity reporting in the U.S. would eliminate much of the cost and time-consuming implementation of a wholly new terminology such as ICD-11, which lacks the robust digital architecture and ontological framework of SNOMED CT. Furthermore, with SNOMED CT to ICD-11 mappings, reporting requirements for mortality would be implementable and not cause a huge setback for regulators, vendors, implementers, and health care providers with the introduction of a new terminology for morbidity. We urge consideration of SNOMED CT as an alternative morbidity reporting terminology for the U.S. healthcare system.

Sincerely,



Dr. James T. Case
SNOMED International Chief Terminologist

From: Gursky, Micah J
To: NCVHS Mail (CDC)
Cc: Fetzer, Lannette
Subject: Response from St. Luke"s Miners Hospital Rural Health Clinics (Pennsylvania) regarding ICD–11 RFI.
Date: Tuesday, November 21, 2023 3:56:31 PM

There are a lot of informative data on ICD-11 and the capabilities to take on numerous other applications along with the platforms. The coding department is currently in the transition to take on ICD-11 with the new 3M 360 encoder which incorporates the Professional and the facility coders on one platform and all data stored in the cloud. The 3M software has the capability of dual coding which we will be starting in 2024 or 2025 depending on the current waves as we process transitioning of the professional coders.
The dual coding will start with out patient cases first until the coders and trained and moved to more complex specialties.

3M and St. Luke's IT department has been collaborating on the coding platform. The coding department has been electronic (paperless) for a decade with very few paper documents mostly from outside providers.

Micah Gursky
Rural Health Clinic Administrator
St. Luke's Miners Hospital
360 W Ruddle St
Coaldale PA 18218

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Office of the Secretary
PO Box 47890
Olympia, WA 98504-7890

January 12th, 2024
Department of Health and Human Services
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

Re: Request for Information addressing the potential use of ICD–11 for morbidity coding in the U.S.

The Washington State Department of Health (DOH) offers the following comments in response to the questions posed in the Request for Information from the Department of Health and Human Services, National Committee on Vital and Health Statistics (NCVHS) Workgroup to Inform International Classification of Diseases (ICD) 11 Policy, published October 16, 2023 (88 FR 71369). As a public health agency, DOH operationalizes the ICD at the state level for recording, reporting, and monitoring diseases to support our national vital statistics system.

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

The codes to assess social determinants of health (QD71: Problems associated with housing or QD60: Problems associated with inadequate drinking water) address the need of diagnosis codes for social factors determining health of a person. The codes that have been defined may fulfill most of the stratification needs, but the social factors may need to be updated after pilot implementation if there are gaps in the assessment of social factors affecting health.

b. Coding to measure health care quality and patient safety

The safety of medical devices and environmental factors have been covered well. Aspects related to health care quality could be more specific and well differentiated.

c. Coding for rare diseases

Rare disease and new disease codes are well covered.

d. Content on other topics

Some diseases that were categorized by the body location have been re-categorized to different groups by etiopathology. This may or may not be significant depending upon the context. For example, some re-

categorization would matter more in terms of statistical calculations whereas some others may matter more in terms of reimbursement (although not directly in scope for National Vital Statistics System).

2. What is the potential to reduce burdens and improve quality/accuracy through the greater automation offered by the ICD–11 online classification systems?

Assuming that cause of death coding would still be done at Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS), the algorithm could be automated to increase accuracy and timeliness.

a. How might automation reduce burdens of clinical documentation and coding for reimbursement, risk adjustment, clinical registry, and public health reporting?

If a tool was available that was able to code death certificates in a timely manner, it would be helpful for monitoring trends near real-time without relying on laborious text mining or NCHS. The tool would be beneficial if the processing speed is faster than the existing Application Programming Interface (API), similar to the tool developed by the World Health Organization (WHO). If, however, this is tool that will mirror WHO's API for coding single records with ICD10s, the value is limited as it is time consuming to code even a few hundred records.

b. What might be the role of artificial intelligence for your organization?

Currently, master person indexing and linkage work is being done at DOH.

c. What might be the role of standardized cross-maps to other coding systems?

Cross-maps to ICD-9 and SNOMED CT would be useful and very helpful for some workflows at the agency. They will mostly be used in the estimation of morbidity and syndromic surveillance reports and perform comparative analysis against definitive diagnosis coded in ICD 11.

d. What other potential features could promote burden reduction?

If the computability of ICD-11 system makes it easier to implement on a terminology service, this would help in the automation and burden reduction processes.

3. What standards, systems, workforce, and processes must change to accommodate ICD–11?

DOH would have to update all the flags, code, and standards used for monitoring everything from drug overdoses to influenza reporting to match the new codes. Based on the current processes, text mining and use of 'regex' is the preferred method to assign codes. This might be more complicated with the new code format. As an alternative, standing up a terminology service and mapping text to terminology would be a simpler approach.

a. How would your organization assess the cost and impact of these changes?

Increase of FTE's dedicated to handling coding issue from ICD-11 evolve over time. There are also the requirements of DOH vendors to consider. Vendors will likely require a contract for maintenance and transition of systems within our database to adapt to ICD-11.

4. What are the most important considerations and requirements for a U.S. governing body for ICD–11?

For implementation of ICD-11 at DOH, guidance on the recommended modalities, methods, and architecture would be helpful.

c. Ongoing management and maintenance of U.S. ICD–11 and its use.

On-going maintenance, quality assurance and system management will be required so the plan needs to be in place beforehand.

5. What financial, educational, or human resources will be needed for:

a. Implementing ICD–11 in your organization.

Technical documentation and resources for database updates, system implementations and terminology services set up will be part of the implementation plan.

b. Managing and maintaining U.S. ICD–11 in your organization.

On-going maintenance, quality assurance and system management will be required so the plan needs to be in place beforehand.

c. Meeting the needs of smaller, less resourced, or less externally supported entities.

Education and support systems will be needed for the smaller entities to ensure mortality reporting is set up correctly.

Thank you for the opportunity to provide comments on the proposed rules.

Bryant Thomas Karras M.D.
Chief Medical Informatics Officer
Office of Innovation and Technology

Cc: Les Becker, Deputy Secretary for Innovation

Department of Health and Human Services
National Committee on Vital and Health Statistics
Centers for Disease Control
Request for Information (RFI) – ICD 11

To: NCVHSmail@cdc.gov

Subject: Response from Wipro Limited regarding ICD-11 RFI

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?

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 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?

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? All areas of the current system that use ICD-10 today will need to be analyzed. Will assess cost by the number of modules that are impacted.

b. How might technical changes such as clustered (post-coordinated) coding be implemented in your environment? It will require us to go through the normal system analysis process to determine the full impact. Increases the complexity of the validity editing and business processing of the diagnosis codes.

c. What other changes are related? Claims processing, business rules, vendor interfaces, adhoc data warehouse, etc. Whole new version of X12 270/271, 278, and 837 which have not been put out for public comment at this time.

d. TMSIS (TMSIS, Claims processing, business rules, vendor interfaces, adhoc data warehouse, etc.)

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 organization.

c. Ongoing management and maintenance of U.S. ICD–11 and its use.

d. Other requirements not named above?

5. What financial, educational, or human resources will be needed for:

a. Implementing ICD–11 in your organization. Number of resources will be determined once the impact is analyzed. We will need business analysts, testers, developers, project management, trainers, and customer input.

b. Managing and maintaining U.S. ICD–11 in your organization. May require additional full-time staff after implementation.

c. Meeting the needs of smaller, less resourced, or less externally supported entities.

d. What other resources not listed here may be needed? Not known at this time.

Jacki Monson, JD
Chair
National Committee on Vital and Health Statistics
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

January 12, 2024

Via: NCVHSmail@cdc.gov

Re: Request for Information (RFI) addressing the potential use of ICD–11 for morbidity coding in the U.S.

Dear Ms. Monson:

WEDI is pleased to submit the following letter in response to the Request for Information (RFI) from the National Committee on Vital and Health Statistics (NCVHS) entitled "*Request for Information (RFI) addressing the potential use of ICD–11 for morbidity coding in the U.S*." published in the October 16, 2023 edition of the *Federal Register*.

WEDI, formed in 1991, is the leading authority on the use of health information technology (IT) to improve health care information exchange to enhance the quality of care, improve efficiency, and reduce costs of our nation's health care system. WEDI's membership includes a broad coalition of organizations, including hospitals, providers, health payers, vendors, government agencies, consumers, not-for-profit organizations, and standards development organizations. WEDI was designated in the 1996 Health Insurance Portability and Accountability Act (HIPAA) legislation as an advisor to the U.S. Department of Health and Human Services (HHS).

Should implementation be mandated, the International Classification of Diseases, Eleventh Revision (ICD-11), as we have experienced with adoption of previous code sets, will present unique challenges for the health care industry. ICD-11 does present new opportunities to unify world diagnosis reporting and increase coding automation, leading potentially to improved public health reporting and decreased administrative burden associated with medical coding. At the same time, this new code set will impact billing processes, clinical documentation, quality reporting and other administrative transactions. The challenge remains weighing potential longer-term benefits against the up-front implementation costs and impact on productivity.

Lessons learned from the protracted implementation of ICD-10 Clinical Modification (CM) must be applied as failure to apply these experiences will impact the ability of the industry to realize a smooth transition to ICD-11, should it be mandated. Most importantly, government and industry stakeholders must come together to identify problems, reach solutions and work collaboratively toward a successful implementation.

WEDI Member Input

To address the June 2023 NCVHS RFI, WEDI leveraged our Member Position Advisory (MPA) process.[1] Our MPA process engaged the WEDI membership through a survey asking RFI questions specific to implementation issues and feedback from WEDI workgroups. On December 1, 2023, WEDI held an educational event entitled *The Future of Coding: Understanding the Potential Benefits and Implementation Challenges of ICD-11*. This event featured some of the leading national experts on ICD-11 and offered the opportunity for the WEDI community to submit questions and offer perspectives on a potential transition to this new code set. WEDI member input from these events as well as workgroup and leadership discussions were incorporated into this document.

RFI Questions

NCVHS Question

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?

WEDI Response

We recognize that avoiding a full clinical modification in the U.S. could save costs, shorten preparation time, and align with other terminologies. However, when addressing the issue of whether the U.S. requires a proprietary clinical modification of ICD-11, it is essential to determine if the ICD-11 code set, as it is currently designed, contains the specificity necessary to meet the needs of the industry and achieve the priorities set by the government. These requirements include the ability to address population health equity and identify social, behavioral, and community health needs and measure quality.

Community health and social determinants of health data

Health systems and health plans seek to address the societal factors that influence health, including the social needs of patients, social determinants of health in their communities and the systemic causes that lead to health inequities. These societal factors include access to food and transportation, housing security, education, violence,

[1] Access the WEDI response to the June 30, 2023 NCVHS Request for Information addressing the potential use of ICD–11 for morbidity coding in the U.S here.

social support, health behaviors and employment status. This data on the social needs of their patient population is currently captured using the ICD-10-CM "Z codes," which identify nonmedical factors that may influence a patient's health status. These concepts will need to be accommodated should the nation move to ICD-11.

Currently, ICD-10-CM codes come in nine broad categories of Social Determinants of Health (SDOH) data known to affect patients' health outcomes. Categories include issues related to housing and economic circumstances, or education and literacy. There are SDOH screening tools providers can use to identify these issues, and conversations between the provider and patient and patient self-reported information can also be sources of SDOH data. Z codes include: (i) Z55 – Problems related to education and literacy; (ii) Z56 – Problems related to employment and unemployment; (iii) Z57 – Occupational exposure to risk factors; (iv) Z58 – Problems related to physical environment; (v) Z59 – Problems related to housing and economic circumstances; (vi) Z60 – Problems related to social environment; (vii) Z62 – Problems related to upbringing; (viii) Z63 – Other problems related to primary support group, including family circumstances; (ix) Z64 – Problems related to certain psychosocial circumstances; and (x) Z65 – Problems related to other psychosocial circumstances.

In recent years, health care has been transformed by efforts to prioritize value-based care. One objective of this effort has been to recognize health risks before they can become health problems. By proactively mitigating those risks, patients have better health outcomes, and their treatment costs are significantly less. The challenge has been to better predict the future, essentially identifying potential health challenges in at-risk populations prior to any symptoms presenting. SDOH data, combined with predictive analytics, can effectively identify individuals considered at risk allowing proactive measures taken to improve future health outcomes.

SDOH data also can help identify hospitalized patients who have a high likelihood of readmission driven by negative outcomes after release. For example, a patient who lives alone and has no relatives nearby to help, may be more likely to relapse after an illness. Patients who do not have their own transportation are less likely to go to follow-up appointments, which can negatively impact their outcome. With knowledge of these types of patient challenges and more, health care entities can take action to mitigate risk such as recommending care interventions. Further, SDOH Z codes today represent information rather than a diagnosis and may be assigned based on medical documentation by clinicians involved in the patient's care, even if they are not the patient's medical provider. For example, coders currently use documentation from social workers, community health workers, case managers, or nurses if their information is included in the official medical record.

Should ICD-11 be mandated, ICD-11 based SDOH codes must be able to: (i) Improve quality, care coordination, and experience of care; (ii) Identify individuals' social risk factors and unmet needs; (iii) Inform health care and services, follow-up, and discharge planning; (iv) Trigger referrals to social services that meet individuals' needs; (v) Track referrals between providers and social service organizations; (vi) Be shared with social service organizations, providers, health plans, and consumer/patient advisory boards to identify unmet needs; and (vii) Be used to identify opportunities for advancing health

equity.

Overall, we strongly urge that research be conducted to determine if ICD-11 has the ability, absent a clinical modification, to continue permitting health care stakeholders to capture, collect, and utilize SDOH data at the same level or better than in today's environment. Comprehensive studies under to be undertaken to ensure that coding specificity in this area would not be lost in a transition to ICD-11.

Measuring Quality

The transition to ICD-11 would pose two major challenges for existing quality measure using diagnosis codes: (i) the effort required to translate the diagnosis codes used within the measure; and (ii) the assessment of the scientific acceptability of the measure after translation. As we experienced with ICD-10-CM, use of a General Equivalence Mappings (GEMs) tool alone is not likely to result in a comprehensive and accurate translation of the diagnosis codes between the two ICD systems. As an example, just half of the ICD-9-CM diagnosis codes matched directly (1:1) to ICD-10-CM diagnosis codes; 5% of these matches were exact, while the other 45% were only "approximate" matches, which do not provide the scientific acceptability expected in quality measurement.[2]

The only certain option to ensure the comparability of the ICD-10-CM diagnosis codes to the ICD-11 diagnosis codes generated by any translation tool is to conduct a time-consuming manual review of each code, which is consistent with National Quality Forum's (NQF) best practice approach. For example, the National Committee for Quality Assurance (NCQA), a leading national developer of quality measures, implemented a process for translating their measures from ICD-9-CM to ICD-10-CM. The process included GEMs, web searches for additional codes, expert panel review, and a public comment period. However, the financial and time-dependent resources to implement this best practice approach are currently lacking in most public, private or academic systems to accurately update all existing quality measures.[3]

Major stakeholders in quality measurement, including NQF, the Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention, health plans, medical specialty societies, and others will need to collaboratively to identify a path forward. Without a standard mechanism for translating diagnosis codes and reassessing the scientific acceptability of quality measures using ICD-11, the quality agenda in the US could be significantly compromised.

NCVHS Question

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

[2] Jones, L and Nachimson, S. Use Caution When Entering the Crosswalk: A Warning About Relying on GEMs as Your ICD -10 Solution, 2014, ICDLogic. Accessed Jan. 2, 2024.

[3] National Committee for Quality Assurance. How ICD-10 Codes Affect HEDIS: What You Need To Know. Nov. 1, 2015. Accessed Jan. 2, 2024.

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 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?

WEDI Response

The World Health Organization (WHO) contends that ICD–11 is a vast improvement on previous revisions. It reflects critical advances in science and medicine, aligning classification with the latest knowledge of disease treatment and prevention. There is more meaningful clinical content than ICD–10. A significant feature of ICD–11 is the improved ease and accuracy of coding requiring less user training than ever before, together with the availability of online and offline functioning. ICD–11 is digital health ready, for use in multiple IT environments, with a new application program interface (API). It is presented together with a suite of web services including multilingual support and in-built user guidance. A proposal platform allows all interested parties to suggest changes or additions to ICD–11 and to view and discuss transparently. The ICD–11 translation tool ensures internationally consistent translations and the addition of locally used terms.[4]

New core chapters include 'Diseases of the immune system', 'Sleep-wake disorders', and 'Conditions related to sexual health'. New supplementary chapters and sections permit the assessment of functioning, and the optional recording of traditional medicine diagnoses. All concepts for recording and reporting in primary care are included. Overall coding improvements in ICD–11 allow more precise and more detailed data recording and collection.

Additionally, newly available clinical precision is possible. Examples include:

- Codes for antimicrobial resistance, in line with GLASS1
- Codes for full documentation of patient safety, in line with the WHO patient safety framework
- Necessary detail for cancer registration is fully embedded in ICD–11
- Specific coding for clinical stages of HIV
- More clinically relevant coding for complications of diabetes.
- Codes for common skin cancers basalioma, and melanoma subtypes. Classification of heart valve diseases and pulmonary hypertension, now matching current diagnostic and treatment capacity.
- Coding for traffic accidents and causes of injuries is now consistent with current international practice for data documentation and analysis.
- The creation of extension codes allows flexible addition of detail relevant for clinical documentation, and device or substance safety.
- Extension codes provide for the recording of medicaments with WHO INN2 and WHO Medical Device nomenclature, as well as documenting the severity of conditions, anatomy or histopathology.[5]

[4] World Health Organization ICD-11 Fact Sheet. Accessed Dec. 27, 2023.
[5] *Ibid*

The American Academy of Professional Coders (AAPC) contends that because many countries use ICD modifications, such as the U.S. clinical modification, ICD-10-CM, these modifications are inconsistent, limit international data comparability, development of guidelines, and linkage to knowledge bases. This results in a lack of uniformity in translated terms. There is a clear need for an internationally standardized system that accurately reflects contemporary medical practice and generates the best and most useful data possible. Standardization is the key that unlocks global health data analysis.[6]

ICD-11 Improved Structure and Digital Focus

As the WHO outlines, the ICD-11 classification system underwent a 10-year major redesign. It is now structured as a database that can include more than a dozen dimensions, with changes ranging from making it more IT-friendly and better able to support data collection on morbidity, to lowering cost. It will also have a new name: ICD-11 for Mortality and Morbidity Statistics (ICD-11-MMS). To bring ICD into the 21st century, updates include a completely digital design; easy integration with electronic health applications and information systems; improved ability to address multiple topics, such as capturing quality and safety healthcare data; and a more user-friendly format. ICD-11's structure is defined in linearization's that incorporate properties and attributes with a focus on mortality, morbidity, the degree of primary care, research, and public health.[7]

According to the AAPC, these advancements have made ICD-11 more comprehensive than its predecessors. It can link with other ICD classifications, such as the International Classification of Functioning, Disability, and Health (ICF); the International Classification of Primary Care (ICPC); and the SNOMED CT and Orphanet terminology systems. In addition to being able to produce digital documentation on a granular level, ICD-11, for the first time, "will enable dual coding of traditional medicine diagnoses alongside mainstream medicine and now also permits the generation of a functioning score based on the WHO Disability Assessment Schedule (WHODAS)," as stated in the WHO Implementation Guide.[8]

ICD-11 Post-Coordination

The ICD-11 coding structure is different than that in ICD-10 and has a more simplified structure. ICD-11 also introduces two features, extensions and clustering, enabling two kinds of post-coordination (linking multiple codes to describe a concept) and the addition of specific detail to coded entities. An ICD-11 extension is a non-diagnosis code that adds flexibility to the classification. Extensions cannot be used alone, but rather are intended to be added to a stem code, replacing ICD-10 adjunct codes. Extension codes are appended to describe laterality, acuity, severity, and other dimensions of injury and external causes. Cluster coding is combining two or more ICD-11 codes to describe a documented clinical concept.

This approach is how ICD-11 explicitly marks codes that are post-coordinated to describe one condition. When a diagnostic statement is broken down into its component parts for simplicity, there needs to be a way to link them in the coded record; clustering is the feature that enables linking. It creates the ability to link core diagnostic concepts (meaning

[6] American Academy of Professional Coders. What is ICD-11. Accessed Dec. 27, 2023.
[7] World Health Organization ICD-11 Fact Sheet. Accessed Dec. 27, 2023.
[8] American Academy of Professional Coders. What is ICD-11. Accessed Dec. 27, 2023.

stem code concepts), when desired, and/or add clinical concepts captured in extension codes to primary stem code concepts. Cluster coding refers to a convention where a "with" operator, either a forward slash (/) or ampersand (&), is used to link ICD-11 codes together to create a diagnostic "sentence."

ICD-11 has been built in such a way that updating will be easier than it has been for past versions, potentially eliminating the need for ICD-12. Moreover, its developers suggest that there will be no need for national modifications of ICD-11 due to its flexibility and capability to produce digital documentation on a granular level.[9]

Advantages of ICD-11

According to one of the leading professional coding associations, the coding system is more contemporary and more easily integrated with electronic health records than past versions. ICD-11 will be completely electronic with a goal of user-friendliness, offering resources such as the online Coding Tool, Implementation or Transition Guide, Reference Guide, and Browser, all available on WHO's ICD-11 page.[10]

Digital capabilities-ICD-11's digital format enables it to be continuously updated, improves coordination with other classifications and terminologies, provides flexibility to reduce the need for clinical modifications, and improves the comparability of translations. ICD-11 is designed to be computable and is expected to facilitate greater auto-generation of codes from clinical documentation.

Improvements

There are 28 chapters in ICD-11, compared to 22 in ICD-10. Additions include chapters for immune system diseases, sleep-wake disorders, traditional medicine, developmental anomalies, sexual health, and functioning assessment, as well as a better representation of cancers, devices, medications, substances, severity, and causes of injuries. Each category features four characters rather than three, and there are two levels of subcategories. The range of potential codes is 1A00.00 to ZZ9Z.ZZ.

ICD-11 also includes an updated structure and content better reflecting current scientific knowledge. It also incorporates a reformulated chapter structure and indexing system requiring relocation of some existing codes. Besides diseases, ICD-11 includes external causes, disorders, signs and symptoms, anatomy, histopathology, and more.

In addition, ICD-11 allows for multiple applications to meet health system priorities. Examples include mortality, morbidity, primary care reporting, clinical recording, research, patient safety, antimicrobial resistance, epidemiology, population health, health system performance, resource allocation, and reimbursement.

ICD-11 could also enable improved coding quality more straightforward coding application. Simple coding can be done as well as coding of complex clinical detail. The introduction of extensions and clustering allows for the addition of specific detail to coded entities. The new coding structure allows for greater flexibility of application than in

[9] World Health Organization ICD-11 Fact Sheet. Accessed Dec. 27, 2023.
[10] American Academy of Professional Coders. What is ICD-11. Accessed Dec. 27, 2023.

previous versions; health conditions can be described to any level of detail by combining codes.[11]

In an article published in the Journal of the American Medical Association (JAMA) Network Open entitled "*Preparing for the International Classification of Diseases, 11th Revision (ICD-11) in the US Health Care System,"* Doctors Feinstein, Gill, and Anderson outline what they see as the benefits of the ICD-11 system. Foremost, the authors argue that the U.S. and other nations developing proprietary clinical modifications to ICD-10 lead to inconsistent worldwide implementation. As a consequence, the WHO redesigned the revised ICD-11 code set as a "more comprehensive, fully digital system that, theoretically, could be used off-the-shelf without the need for additional modifications and that would be continually updated and harmonized with other medical information terminologies."[12]

The authors also note that ICD-11: (i) includes many specific diagnoses that were left out of ICD-10, facilitating more precise and detailed data collection. New classes of codes, including Diseases of the Immune System and more than 5500 rare diseases are now represented in ICD-11; (ii) introduces a clustered code structure that includes a stem code joined to optional post-coordination codes. Multiple post-coordination codes can be combined to convey various clinical details (i.e., laterality and severity). This makes the system flexible and clinically useful without the need for local customizations that are time-consuming, costly, and interfere with international comparisons; and (iii) given its semantic linkage to the *Systemized Nomenclature of Medicine Clinical Terms* (*SNOMED-CT*, the international standard for the exchange of electronic clinical health information), *ICD-11* has the potential to support automated or artificial-intelligence–assisted coding.[13]

Artificial intelligence and ICD-11

Health care organizations in the US already manage 70,000+ codes in ICD-10-CM. With ICD-11 and its extension codes, that number is expected to increase. Artificial intelligence (AI) may off a solution, with AI-aided computer-based medical coding systems better identifying errors, enhancing patient care, and optimizing revenue cycle operations. AI-aided coding software could:

- Identify inconsistent code usage within a provider or health plan organization.
- Recognize coding errors.
- Identify the need for the deployment of a rare or unique code.
- Prompt a recommended code based on the services performed.
- Develop actionable data on code usage, patient activity, and medical services performed.

[11] *Ibid*

[12] Feinstein, J. Gill, P. and Anderson, B. *Preparing for the International Classification of Diseases, 11th Revision (ICD-11) in the US Health Care System*, JAMA Network Open, July 28, 2023. Accessed Dec. 23, 2023.

[13] *Ibid*

- Track codes within a patient's history-avoiding manual code entry with every visit.[14]

There is the potential that AI-based coding assistance software could perform a similar function to what medical coding specialists perform today.

NCVHS Question

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?

WEDI Response

We believe ICD-11 will impact many standards, systems, workforce, and processes aspects of for health care entities, including:

- *Staff education and training*
  Health care provider organizations will need to train not only the revenue cycle staff, but most, if not all, of the clinical staff as well. It will be critical for clinicians to understand the new coding structure and changes to documentation requirements. In addition, adding to the complexity of the process, the clinician may need to know health plan payment policy at the time the patient is being seen in order to accurately document the encounter and assign the correct ICD-11 code.

- *Business-process analysis*
  Providers and health plans will need to perform an analysis of current plan contracts, coverage determinations and documentation requirements.

- *IT system changes*
  Practice management system and electronic health record () software will need to be upgraded or replaced. In many organizations, these modifications will not be covered under the maintenance contract with the vendor. In addition, significant software upgrades often require hardware upgrades as well. Faster computer and increased storage space will add additional cost for practices moving to ICD-11.

- *Documentation costs*
  Clinicians are expected to see an increase in the time required to document the patient encounter, thus potentially increasing the time spent per patient. The ICD-10 implementation experience suggests that there could be a decrease in clinician productivity during implementation of a new version of the code set.

- *Value-based care programs*
  Providers and health plans that participate in value-based care programs and the vendors that support them will need to modify any of the programs that leverage

[14] HMI Corporation. Medical Coding with Artificial Intelligence: The New Frontier of Medical Coding. Jan. 27, 2021. Accessed Dec. 26, 2023.

diagnosis codes in the reporting requirements and risk adjustment processes.

- *Quality/performance measurement*
  As with the change to ICD-10, all quality and performance measures will need to be updated to accommodate and use ICD-11 diagnosis codes. The denominator of the measure, e.g., the patient population included in the measure, is determined by the diagnosis code.

- *Research*
  Medical research uses ICD codes for many purposes. By grouping patients according to their diagnoses, researchers use ICD codes to study patterns of disease, patterns of care, and outcomes of disease. Diagnosis codes are also used in clinical trials to recruit and track subjects. Organizational monitoring and performance. Medical coding is crucial as it helps summarize and analyze specific data sets. It helps provide control and consistency in clinical trials using clinical data management systems.

Assessing cost and impact

Organizations assessing the cost and impact of the transition from ICD-10-CM to ICD-11 may look at the following factors:

- Cost of retraining existing code users. Code users including coding specialists, coding supervisors and managers, and coding directors would need specific training tailored to their roles. Any clinical and administrative staff that use diagnostic data and would also need to learn ICD-11 coding. These training and retraining costs will need to be factored in.

- System changes. All IT and revenue cycle systems that interact with diagnostic codes will need to be updated. Data collection and analytic systems in particular are expected to be complex and expensive to update. Licensing fees and implementation costs (e.g. purchasing new vendor tools and software) must also be included.

- Productivity loss. Sufficient time will be needed to integrate and maintain the new ICD-11 system (e.g. fixing broken code pathways). A “break-in” period of perhaps 6 months to 2 years will be necessary before high-quality data is produced from ICD-11. Adoption of any new revenue cycle or EHR system will likely cause backlog of charts to code for providers and their staff.

- Cash flow disruption. Organizations that rely on diagnostic codes for billing may experience cash flow disruption following the transition to a new code set. As with the case with ICD-10-CM, many providers secured lines of credit and deferred large capital expenses to decrease the possibility that a disruption in the claims processing system would result in cash flow disruption.

ICD-11 Clustered coding

Clustered (post-coordinated) coding could be implemented in a value-based care (VBC) environment. Risk adjustment is an important component of VBC. As a way to calculate what to pay a health provider based on a patient's health, their likely use of health care services and the costs of those services, risk adjustment scoring relies on accurate coding. The transition from fee-for-service to a VBC delivery model is not only changing how patients are cared for but also how providers and health plans are measured and compensated for performance. With an ever-growing number of patients covered under VBC programs, it is crucial for health care organizations to ensure accurate risk adjustment workflow so that they can position themselves for financial success in risk-sharing arrangements.

Risk-based payment models in health care refer to the practice of accounting for the differences in the underlying risk (i.e., expected costs) of patient populations. It would be unfair to compare the costs incurred by a healthy member to those of a sick member without proper adjustment based on the member's existing health status. However, risk adjustment is not just a payment model mechanism. Successful capture of risk, Hierarchical Condition Categories (HCC) codes, enables obtaining a complete and accurate picture of a patients' acuity, which is critical to ensuring proper reimbursements, while effectively and appropriately managing the costs of high-risk patients.

However, ensuring accurate risk adjustment is not an easy task. Some of the key hurdles providers and health plans cite are the lack of access to accurate and comprehensive administrative and claims data, and the required risk adjustment workflow to effectively manage HCC code documentation and risk adjustment factor score derivation.

As we have referenced, one of the improvements of ICD-11 in comparison to ICD-10 is the ability to post-coordinate codes in ICD-11. Post-coordination facilitates users linking core diagnostic concepts (i.e., stem code concepts), and add additional detail captured in extension codes to stem code concepts. The linked codes are referred to as a cluster and a cluster must always begin with a stem code. Post-coordination also can allow for the capture and reporting of more precise description of the clinical diagnosis, a key element in VBC arrangements.

Post-coordination requires consideration of the two code types in ICD-11: stem code and extension code. Stem codes are found in the tabular list of ICD-11 and can be used alone. 'Section X Extension Codes' is the one section in ICD-11 in which the basis of post-coordination was envisaged since extension codes cannot be used alone. The extension codes are a special type of code that can be used to provide additional detail to a linked stem code. Extension codes provide information such as severity scale value; temporality; etiology; topology scale value; anatomy and topography; histopathology; dimensions of injury; dimensions of external causes; consciousness; substances; diagnosis code descriptors; capacity or context; and health devices, equipment and supplies.[15]

[15] Mabon, K. Steinum, O. and Chute, C. *Postcoordination of Codes in ICD-11*. BMC Medical Informatics and Decision Making. May 17, 2022. Accessed Dec. 31, 2023.

For certain clinical diagnostic statements, the ICD-10 encourages the use of multiple codes for reporting. With ICD-11 this instruction has been expanded and systematized through post-coordination and it offers a way to report clinical diagnoses at a detailed level for both main condition and all other conditions. The post-coordination tool embedded within the online ICD-11 browser and the online ICD-11 Coding Tool offers an easy way for the user to utilize post-coordination when coding in a VBC environment, another potential benefit of ICD-11.[16]

NCVHS Question

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 organization. c. Ongoing management and maintenance of U.S. ICD–11 and its use. d. Other requirements not named above?

WEDI Response

The governing body for ICD-11 will play a critical role in the implementation of the code set and its ongoing maintenance. We agree with the listing of roles for this governing body: (i) Developing and managing implementation plans and programs for ICD–11 in the U.S.; (ii) Developing regulations or guidance for ICD–11; and (iii) Ongoing management and maintenance of U.S. ICD–11 and its use. We also believe that this governing body should have additional responsibilities. These include:

- Serving as a convenor/coordinator/repository for all public sector ICD-11 research and education.
- Coordinating government cross-agency operational implementation of ICD-11.
- Coordinating government cross-agency industry assistance efforts (i.e., CMS, Health Resources and Services Administration, the Office of the National Coordinator for Health Information Technology, the Veterans Administration).
- Coordinating development and dissemination of a public-private sector developed GEMs tool.
- Serving as a convenor/coordinator/repository for public sector-developed ICD-11 research and education.
- Working with private sector organizations like WEDI to develop and disseminate a standardized set of survey questions. This will ensure consistency in the ongoing effort to measure industry implementation readiness.

NCVHS Question

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?

[16] *Ibid*

WEDI Response

WEDI members have indicated that the following will be critical resources their organizations will need to efficiently and effectively implement ICD-11:

- Education. Comprehensive and ongoing education on ICD-11 and the differences between ICD-10 and ICD-11.

- Mappings. Development of a crosswalk or GEMs between ICD-10 and ICD-11.

- Recommended industry implementation milestones. In order for organizations to effectively meet both internal and external goals, it will be helpful for the industry to collectively develop milestones to guide implementation efforts.

- Readiness website. Website(s) that list those vendors, clearinghouses and health plans that are ready to test.

- Industry issue portal. Industry portal to submit ICD-11 related issues and questions that will be addressed by subject matter experts.

- Multistakeholder forum. A collaborative forum to learn from early adopters and share implementation challenges and success stories.

- Government guidance. Rapid and helpful guidance from the federal government on emerging implementation issues.

- Workforce planning and training. Depending on the size of the organization and the role it plays in health care, workforce planning and training will be critical to the entity's successful implementation of ICD-11. Organizations need not only to prepare their workforce for an ICD-11 compliance date, but also may need to take additional actions to continue using ICD-10 codes as a valid code set for an extended period of time. This impacts applications, business processes and workforce training and availability of professional coders.

- Software updates. ICD-11 will represent a significant impact to IT applications and business processes. All software utilizing diagnostic codes must be updated and tested, with staff trained to use the new systems.

- External testing. The availability of testing and validation tools will be critical. As it is expected that ICD-11 testing will not be a required action for covered entities, WEDI recommends the government support testing to the greatest extent possible and urge organizations to make testing an integral component of implementing the new code set.

Identifying potential areas of concern in advance of the cutover, such as a need for new system use instructions, allows vendors and their customers to review and correct processes and documentation to minimize possible impact on production workflow or revenue following implementation.

Meeting the needs of smaller organizations

While ICD-11 is expected to present a significant challenge for health care stakeholders, smaller, less resourced organizations will face unique hardships in meeting this coding mandate. The implementation of ICD-11 will impact billing processes, clinical documentation, quality reporting and other administrative transactions. As well, these smaller organizations will need to modify workflow processes and undertake extensive staff training. Smaller organizations will need assistance that could include:

- Development of free educational resources and guidance materials.
- Development of and dissemination of a GEMs tool.
- Transparency of Medicare and Medicaid ICD-11 readiness and the deployment of easy-to-use testing platforms.
- Work closely with professional associations to ensure consistent messaging occurs and development of an informational feedback loop on ICD-11 takes place.
- Target an audience that includes smaller traditional and non-traditional providers and other stakeholders that will be impacted by ICD-11.

Recommendations

Should HHS move forward with requiring adoption of ICD-11, WEDI reiterates and emphasizes that the following steps be taken to minimize claims payment disruption and facilitate a smoother transition to ICD-11:

- Name an ICD-11 ombudsman and establish a dedicated HHS webpage. When appropriate, HHS should name an ombudsman to oversee and coordinate government policy and action and serve as a liaison to the private sector. In addition, HHS should establish a dedicated section of its website to post rules, guidance, frequently asked questions, and government and private sector resources.

- Complete a comprehensive cost-benefit analysis. HHS should complete and make public a comprehensive cost-benefit analysis to determine the impact the changes to ICD-11 will have on each health care industry sector. This analysis should include consultations with appropriate provider and payer organizations and HHS advisory groups. This cost-benefit analysis should identify each entity affected by the change to ICD-11 and the degree to which they would be affected. The analysis should, at a minimum:

    - Identify costs associated with the transition, including, but not limited to, information and revenue cycle system changes, rate negotiation, recalculation of reimbursement methodologies, training, and changes to forms;

    - Consider the timing of transition, including the impact of timing options on costs and benefits, potential return on investment, and interaction with other major health information investment tasks, including participation in other

CMS health IT and quality initiatives; and

- Identify immediate and future costs and benefits on health care organizations of ICD-11 based data for, but not limited to, patient safety, outcomes analysis, reimbursement, disease management, utilization review, and other health statistics.

- Analyze the administrative and financial impact of and coordinate with overlapping health IT mandates. Existing and anticipated federal health IT mandates on physicians, such as the prior authorization rule, attachments mandates, No Surprises Act requirements, and interoperability mandates, must be evaluated in the context of the burden and cost of ICD-11.

- Recognize the importance of establishing an appropriate implementation glidepath. We note that in an ICD-11 Fact Sheet, the WHO discusses that the time and amount of effort necessary for the implementation of ICD-11 largely will depend on two factors: whether a previous version has been in use and the level of penetration of ICD use in the national information infrastructure. [17]

  The Fact Sheet states: "As an estimate, a Member State newly introducing ICD-11 in a simple information system may need 1-2 years. Member States with a highly sophisticated information system where earlier versions of ICD are already in use calculate 4-5 years' time necessary for the implementation of a new version of ICD." We would assert the U.S. would fall into the category of a nation requiring 4-5 years.

- Review and apply lessons learned from previous HIPAA implementations. The industry has implemented several provisions mandated under HIPAA. The three administrative simplification mandates most comparable to ICD-11 are: the industry adoption of the 4010 and 5010 versions of the electronic transaction standards and, of course, the transition to ICD-10. Adoption of these mandates were protracted and costly—with implementation taking more time than expected and with no financial assistance from the federal government.

- Pilot test ICD-11. HHS should conduct comprehensive pilots of ICD-11 and analyze the results before national implementation. These pilots should include a wide range of health care organizations. We encourage CMS to identify WEDI to perform functions before, during and after the pilot. These functions would include identification and coordination of pilot participants, liaising with CMS during the pilot, and working with the agency to compile pilot results and disseminate them to the industry.

  The pilot should also be completed in a production environment to better replicate the transactions being used in the industry. Finally, to expedite the piloting process, we recommend that CMS provide funding for all pilot participants.

[17] World Health Organization ICD-11 Fact Sheet. Accessed Dec. 27, 2023.

- Monitor industry readiness levels. The NCVHS should reprise its role regarding the implementation of previous HIPAA regulations and closely monitor industry readiness levels throughout the ICD-11 implementation process. As the conversion will be extremely complex, the NCVHS is well-positioned to hold public hearings and develop important recommendations to the Secretary regarding the readiness level of various sectors of the industry and suggest steps to assist implementation.

- Establish clear milestones. Without milestones it will be difficult to measure progress. The milestones must be clearly defined regarding what constitutes meeting each milestone. Leveraging checklists may be useful in this regard. Metrics must be established in order to track industry advancement, especially in the areas of vendor readiness and clearinghouse and health plan testing. WEDI stands ready to work with HHS in identifying key milestones and tracking industry readiness.

- Communicate Medicare and Medicaid readiness. There is a need for improved transparency and readiness communication from government health plans. In particular, we encourage Medicare and Medicaid to publicly disclose all ICD-11 related readiness levels and expected testing timeframes. Sharing of new edits or revised medical policies due to ICD-11 would assist trading partners better understand what may or may not be changing and will assist them in determining where to place emphasis during testing.

- Understand the critical role played by revenue cycle and EHR vendors. A clear lesson learned from implementation of the 4010 and 5010 transactions and ICD-10 was that providers and others rely heavily on revenue cycle and EHR vendors to meet compliance deadlines. The protracted nature of the implementation of these HIPAA provisions was caused, in part, by the failure to develop and install software to customers in a timely manner. Vendors, as non-covered entities, are not required by law to upgrade their software to implement ICD-11 codes. We strongly encourage HHS to aggressively educate and monitor this sector of the industry.

- Develop software certification. For the transition to ICD-11 to occur, provider trading partners must be ready to accept ICD-11 codes. We recommend that ONC incorporate a requirement to support ICD-11 codes into its EHR Certification Program. While this will not affect every EHR being used by providers, it will impact a significant percentage of vendors.

  Certification of these products would greatly assist physician practices in identifying the software necessary to comply with federal mandates and in taking advantage of the numerous administrative simplification initiatives. Certification can also drive implementation by standardizing software requirements and leveraging market forces to ensure practices can meet federal requirements. The government could partner with one or more existing certification entities (Authorized Testing and Certification Bodies) currently participating in the EHR Incentive Program for this purpose.

- Conduct industry outreach. ICD-11 is such a complex and invasive change to health care that it will require considerable educational and technical assistance. Sufficient education will be critical to ensure minimal implementation delays and cash-flow disruption. In particular, smaller providers and health plans may require technical assistance in making the transition to ICD-11.

  Non-covered entities (not mandated to implement ICD-11) should also be targeted for outreach. These would include certain software vendors, public health and research entities, all key stakeholders in the healthcare ecosystem. We recommend that HHS begin provider and vendor roundtable conference calls as soon as possible after publication of the final rule and continue them on a bimonthly or quarterly basis until at least six months after the compliance date.

  HHS should also develop and publicize educational resources or other tools and work with WEDI and other national, regional, and local organizations to reach a broader audience. Industry associations should review their literature and terminology to assure consistent messaging exists to the extent possible. Communications should include success stories to illustrate that ICD-11 compliance can be done and how it can be accomplished. Messaging can also illustrate the positive aspects of ICD-11, including benefits to be realized by providers.

- Collaborate with state workers' compensation plans. There is concern that non-covered entities such as workers' compensation plans will not be required to adopt ICD-11 through federal law. While some states may voluntarily adopt or be required through state law to adopt ICD-11, those that do not will necessitate dual workflows and an increased administrative burden for providers. We recommend that HHS work with the appropriate state authorities and encourage the adoption of ICD-11 by workers' compensation and other property and casualty carriers that utilize diagnosis and procedure codes.

Conclusion

WEDI applauds the efforts of the NCVHS to continue soliciting industry opinions on the potential impact the potential adoption of the ICD-11 code set will have on the health care industry. WEDI shares the Committee's commitment to improving data exchange efficiency within health care and reducing administrative burden for all stakeholders.

The implementation of any new coding system in the US will be extremely challenging. The move to ICD-11 will require that more than 70,000 current ICD-10-CM codes be mapped to their corresponding new ICD-11 codes. This transition would also impact every ICD-dependent process, including the redesigning of all billing systems and quality reporting metrics. It will be necessary to upgrade the software, statistical programs, and data processing methods that use ICD codes.

Further, the new clustered code structure has important implications. The higher character lengths required to store ICD-11 codes using the clustered code format will

require changes to data standards for EHR systems and databases. Whether healthcare systems and doctors properly utilize clustered codes will depend on contextual reporting requirements, appropriate education, and the information technology and workforce required to deploy ICD-11, even with the right technology.

The WEDI community has discussed the potential benefits and challenges of transitioning to ICD-11. They have highlighted the possibility of integrating medical and technological advancements, enhancing standardization, and streamlining processes through automation. Potential advantages of the new system also include its flexibility and expandability, and how it could revolutionize the way information is captured.

The community has also discussed the challenges and strategies related to the implementation of a new system. They highlighted the importance of early engagement with stakeholders, particularly providers, and emphasized the need to work closely with vendors. They also note the need for early engagement of all stakeholders, effective communication, and close coordination between the public and private sector. Also discussed were the difficulties of coordinating with other regulatory timelines and initiatives-acknowledging the many regulatory burdens placed on stakeholders and the need to consider how to create an environment where they all can succeed.

WEDI also emphasizes the importance of mapping, early training, and addressing the documentation nuances. While there is a significant potential for ultimately reducing expenses and upscaling the workforce through automation, WEDI continues to be concerned that the health care system's current disparities could be further exacerbated by differences in implementation tactics amongst institutions, which could lead to varied data quality and impact income.

As the collective voice of the health care industry on health IT issues, we are pleased to continue our important partnership with the NCVHS as it continues its research and deliberations on ICD-11. Please reach out to WEDI President and CEO Charles Stellar at cstellar@wedi.com with any questions.

Sincerely,

/s/

Ed Hafner

Chair, WEDI

cc: WEDI Board of Directors

ICD-11 RFI Comments from X12

X12 appreciates the opportunity to provide input to NCVHS on the ICD-11 transition. Our comments are based on our role as a consensus-based standards organization and our experience during the transition from ICD-9 to ICD-10.

X12's answers to the specific questions in the RFI follow. If you have any questions or I can provide additional information, please let me know.

3. **What standards, systems, workforce, and processes must change to accommodate ICD–11?**
   The administrative standards mandated under the HIPAA regulations would need to be updated to accommodate the ICD-11 code set and its changes from ICD-10-CM in the United States. X12 understands the clustering and post-coordination requirements, and will update our standards to accommodate those.

   X12 will also need to know how industry participants (providers, health plans) will be changing their business processes to interpret these codes and combinations so that the transaction standards can support them. For example, hospitals may need to designate a primary diagnosis and secondary diagnoses. The combined codes may need to be broken down to accommodate that need. X12 will finalize the standards when the business needs are documented.

   a. **How would your organization assess the cost and impact of these changes?**
      X12 members assess their costs and impacts individually. The cost of updating the standards is built into X12's maintenance processes.

   b. **How might technical changes such as clustered (post-coordinated) coding be implemented in your environment?**
      X12 will finalize the standards when the business needs are documented.

   c. **What other changes are related?**
      Implementors will need to revise their policies and systems to reflect the updates. Regulatory updates supporting the use of ICD-11 will need to be promulgated.

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.**
      The US governing body should a set a firm schedule based on industry needs

   b. **Developing regulations or guidance for ICD–11 applicable to your organization.**
      The US governing body should define detailed regulation and guidance as soon as possible so that the standards can be updated to reflect the new requirements.

   c. **Ongoing management and maintenance of ICD-11 and its use.**
      The US governing body should define detailed management and maintenance revisions to the U.S. ICD-11 codes as soon as possible.

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