



NCVHS

National Committee on Vital and Health Statistics

April 12, 2024

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Urgent Need for a Central Coordinating Entity for Planning and Adopting ICD-11 in the U.S.

Dear Mr. Secretary:

This letter conveys recommendations from the National Committee on Vital and Health Statistics (NCVHS) about actions urgently needed to allow the U.S. to partner with the World Health Organization (WHO) in the development of multinational agreements regarding the International Classification of Diseases, Version 11 (ICD-11), and to participate fully as decisions are being made that may affect U.S. interests and policy options.

NCVHS is your advisory body on health data, statistics, privacy, and national health information policy. One key role for NCVHS is to monitor the continued effectiveness of adopted health data standards pursuant to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This role includes making recommendations about regulatory adoption and implementation of ICD-11 in the United States. During the April meeting of the full Committee, members unanimously approved the following two recommendations:¹

- **Recommendation 1:**
HHS should immediately designate one office or agency to be responsible for overall coordination of ICD-11 morbidity coding in the U.S. This office or agency should further be charged with, and allocated sufficient resources for, federal government coordination of all ICD-11 morbidity coding research, funding, rulemaking, and resources relevant to adoption, implementation, and maintenance of ICD-11 as a U.S. regulatory code set.
- **Recommendation 2:**
While HHS is in the process of organizing a coordinating office or agency, the Department should appoint a federal representative to represent the U.S. to WHO for comprehensive coordination of morbidity coding.

¹ The agenda and a full recording and transcript of the NCVHS April 11-12, 2024, Full Committee meeting is available at <https://ncvhs.hhs.gov/meetings/full-committee-meeting-16/>

Rationale

ICD-11 became available for use globally on January 1, 2022, after its formal adoption by the WHO in 2019.² This revised classification system leverages new digital capabilities and creates the potential for a more expansive and detailed view of patient health. If the U.S. is to avoid the unnecessary costs and resource burdens that characterized its protracted process and delayed implementation of ICD-10, it needs to immediately identify leadership specific to all ICD-11 morbidity-related activities as noted in these two recommendations.

U.S. coding based on ICD-10 is out of date. U.S. regulatory transition to a modified version (ICD-10-CM³), managed by the National Center for Health Statistics (CDC/NCHS), became effective on October 1, 2015. This is still in use today, even though it is based on the 1993 publication of ICD-10. WHO retired ICD-10 following its final update in 2019.

Better coordination of U.S. participation in ICD-11 developments is needed. Multiple federal government employees and private sector experts represent the U.S. in multiple WHO ICD-11 reference groups and Collaborating Centers. At present, the wide-ranging activities of these talented experts is not coordinated or managed by a designated lead office or agency on behalf of the U.S.

U.S. representation in many such groups is appropriate because nationwide, our expected uses of ICD-11 vary widely. The breadth of current U.S. interests in ICD-11 includes, for example, mental and behavioral health coding alignment with the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5); current patient safety and clinical quality measurement methods; hospital accreditation criteria; risk adjustment precision; clinician and coder ease of use; alternative code set mapping including with the Systematized Nomenclature of Medicine Clinical Terms (SNOMED-CT); and other regulatory code sets, post-coordination⁴ taxonomy standards for interoperability, evaluation of semantic equivalence, technical implementation in electronic health records systems, and the financial impact of reimbursements based on ICD-11 vs ICD-10-CM. No single WHO Committee, and no individual U.S. representative, is responsible for all of these factors. Coordinated input among all U.S. participants following a unified federal agenda that supports ICD-11 adoption and implementation to meet U.S. needs as a regulatory code set, would mitigate or eliminate unnecessary conflicts, rework, false starts, costs, and burdens across the U.S. health care and public health sector.

A central point of coordination for all uses of ICD-11 morbidity coding, including the above issues, also would complement and enable coordination with the CDC/NCHS office responsible for ICD-11 mortality

² 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 compare and share data in a consistent and standard way—among hospitals, regions, and countries, and over periods of time. It facilitates the collection and storage of data for analysis and evidence-based decision-making by enabling systematic recording, reporting, analysis, interpretation, and comparison of mortality and morbidity data: <https://icd.who.int/en>

³ Centers for Disease Control and Prevention, National Center for Health Statistics (NCHS), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM): <https://www.cdc.gov/nchs/icd/icd-10-cm.htm>

⁴ Post-coordination is the process of linking or clustering multiple codes together to obtain new or more detailed meaning. Mabon K, Steinum O, Chute CG. Postcoordination of codes in ICD-11. BMC Med Inform Decis Mak. 2022 May 17;21(Suppl 6):379. doi: 10.1186/s12911-022-01876-9. PMID: 35581649; PMCID: PMC9112606.

statistical reporting, when appropriate.⁵

Urgency for immediate federal designation of a central coordinating authority is prompted by current and ongoing multinational efforts to develop ICD-11 morbidity coding agreements and derivative works, and by infrastructure planned or underway among other WHO member countries. Such agreements could have the effect of constraining the structure of ICD-11—and could materially disadvantage the U.S.— if an HHS morbidity coding lead is unable to exert its authority in these negotiations as soon as possible. A new office/agency designation is needed because, as cited above, none of the existing U.S. representatives have the necessary scope of work, expertise, authority to represent the variety of U.S. use case requirements, or funding authority necessary to coordinate the adoption, implementation, and maintenance of ICD-11 as a regulatory code set.

NCVHS Workgroup on Timely and Strategic Action to Inform ICD-11 Policy

In late 2022, NCVHS voted to establish a Workgroup on Timely and Strategic Action to Inform ICD-11 Policy, (“ICD-11 Workgroup”). The purpose of the ICD-11 Workgroup is to support development of recommendations that, if adopted, would put HHS in a position to lead the U.S. in preparing for ICD-11 policy and implementation.⁶ The standing up of the ICD-11 Workgroup came about primarily because the Committee was concerned by the lack of follow up on its recommendations to HHS in 2019, and again in 2021, identifying specific actions needed to ensure a cost-effective and timely transition to ICD-11 in the U.S.⁷

Since March 2023, the ICD-11 Workgroup has gathered information from a broad range of sources to develop advice and recommendations to HHS regarding adoption of ICD-11 as a HIPAA code set,⁸ issuing an initial report on its findings in December 2023.⁹

To inform development of our recommendations, NCVHS held an ICD-11 Expert Roundtable on August 3, 2023.¹⁰ The Committee also invited comments from experts in the healthcare industry through two

⁵ See CDC/NCHS, “NCHS Organization” (Jan. 1, 2024): <https://www.cdc.gov/nchs/about/organization.htm>.

⁶ Information about the charge and membership of the NCVHS Workgroup on Timely and Strategic Action to Inform ICD-11 Policy is available at: <https://ncvhs.hhs.gov/subcommittees-work-groups/icd-11-workgroup/>.

⁷ See Letter from William W. Stead, Chair, NCVHS, to Alex Azar II, Secretary of HHS: [“Preparing for Adoption of ICD-11 as a Mandated U.S. Health Data Standard” \(Nov. 25, 2019\) \(recommending the Secretary conduct research to evaluate the impact of different approaches to the transition and implementation of ICD-11 in the United States for mortality and morbidity classification; provide timely leadership on strategic outreach and communications to the U.S. healthcare industry about the transition to ICD-11; ensure appropriate federal priority, as needed, for the National Center for Health Statistics’ \(NCHS\) efforts to negotiate the ICD copyright issues to ensure that copyright will not be a barrier to U.S. adoption and use of ICD-11\);](#) Letter from Nick Coussoule, Chair, NCVHS, to Xavier Becerra, Secretary of HHS: [“Updated Recommendations for Immediate Action on ICD-11” \(Sept. 10, 2021\)\(reiterating the recommendations that HHS “conduct research to evaluate the impact of different approaches to the transition to and implementation of ICD-11” and “conduct outreach and communicate regularly to the U.S. healthcare industry about the ICD transition.”\)](#).

⁸ The Workgroup set out by conducting an environmental scan of ICD-11 research available in published literature and other sources, July 27, 2023: <https://ncvhs.hhs.gov/wp-content/uploads/2023/11/Presentation-NCVHS-ICD-11-Environmental-Scan.pdf>

⁹ See NCVHS, ICD-11 Workgroup, “Phase I Findings Report” (Dec 2023), available at: <https://ncvhs.hhs.gov/wp-content/uploads/2023/05/ICD-11-WG-Phase-I-Findings-Report.pdf>

¹⁰ The agenda, video recording and transcript of this meeting are available at: <https://ncvhs.hhs.gov/meetings/icd-11-workgroup-meeting/>

Requests for Information (RFI) in 2023 – one prior to the August Expert Roundtable Meeting¹¹ and one after.¹²

The Committee received overwhelming input from the healthcare industry indicating that designation of a lead office or agency is critically important as summarized here:

- **Theme from Submissions Sent in Response to the NCVHS October 2023 RFI:**¹³
It is critical that ICD-11 implementation involves a central coordination across all authoritative agencies and entities involved in health care and public health regulation to prevent significant disruption due to unintended misalignment of code sets or associated policies.
- **Themes from August 2023 ICD-11 Expert Roundtable Meeting:**¹⁴
HHS should centrally coordinate and ensure federal funding of an additional national ICD-11 research agenda that may involve multiple agencies and departments, to address unique U.S. needs for:
 - managing and integrating complex and fragmented health care delivery;
 - funding and reimbursement systems;
 - addressing social determinants of health (SDOH) and essential human needs, sexual and gender identity, language differences, and cultural diversity, and;
 - maintaining ICD-11 content including linearizations and optional extensions¹⁵ without a full clinical modification.

Additional Input Received in RFI Responses and from Subject Matter Experts:

- U.S. ICD-11 governance options should be evaluated for their potential to best manage and coordinate with the WHO Family of International Classifications Network (“WHO-FIC”) and oversee implementation, including linearizations, post-coordination, and optional extension content, for all use cases.

¹¹ See Federal Register Notice, June 13, 2023: <https://www.federalregister.gov/documents/2023/06/13/2023-12617/national-committee-on-vital-and-health-statistics-meeting-and-request-for-information>

¹² See Dept. of HHS, NCVHS, “Notice of meeting (virtual); notice of request for information (RFI)” 88 Fed. Reg. 71369 (Oct. 16, 2023): <https://www.federalregister.gov/documents/2023/10/16/2023-22753/national-committee-on-vital-and-health-statistics>

¹³ Responses to the October 2023 RFI received as of January 18, 2024, are posted at this link: <https://ncvhs.hhs.gov/wp-content/uploads/2024/01/NCVHS-ICD-11-RFI-Responses-final.pdf>

¹⁴ The ICD-11 Workgroup produced two summarizing documents after the August 3, 2023, Roundtable meetings. The first addresses continuity and sustainability issues. See ICD-11 Workgroup, “ICD-11 Expert Roundtable Meeting Summary of Expert Panel Discussions: Continuity & Sustainability Topic” (Aug. 3, 2023) available at: <https://ncvhs.hhs.gov/wp-content/uploads/2023/11/Presentation-ICD-11-Expert-Panels-Summary-of-Sustainability-Topic.pdf>; the second summarizes research needs. The second addresses research issues. See ICD-11 Expert Roundtable Meeting Summary of Expert Panel Discussions: Research Topic” (Aug. 3, 2023), available at: <https://ncvhs.hhs.gov/wp-content/uploads/2023/11/Presentation-ICD-11-Expert-Panels-Summary-of-Research-Topic.pdf>.

¹⁵ Linearizations are subsets of the full ICD-11 database created for specific purposes. Optional extensions can be codes needed in the U.S. but not used worldwide.

- Participants in the Roundtable made consistent statements about the needs for and critical role of centralized and coordinated governance, additional research, sustainable funding, and pilot testing.¹⁶
 - Views from invited experts varied on the question of what entity would be best suited to lead the U.S. efforts. Suggestions for a lead entity ranged from specific agencies (including NIH/NLM, CMS, CDC/NCHS, or ASPE), or a combination of federal agencies (including CMS, CDC, ONC, NIH, White House OSTP), to a new public-private partnership entity, or a medical specialty society.

Conclusion

The Committee finds that it is essential for the U.S. to take a proactive, coordinated approach to ICD-11 developments to support national healthcare and public health priorities, optimize benefits, reduce burdens, and minimize costs. Coordination is needed not only for development of the content and structure of the ICD-11 coding system itself, and its regulatory adoption under HIPAA, but also for policies affecting its many uses across the healthcare and public health sector including its licensing agreements, derivative works, mappings to other coding systems used in the U.S., systems infrastructure and software tools, database access, and associated publication rights.

NCVHS wishes to thank you for the opportunity to submit these recommendations and is available to answer questions and provide any additional information, consultation or guidance regarding next steps. We look forward to your timely decision.

Sincerely,

/s/

Jacki Monson, J.D., Chair
National Committee on Vital and Health Statistics

CC:

Tisamarie Sherry, ASPE
Stella Mandl, CMS
Michael Cimmino, CMS
Monica Bertagnolli, NIH
Susan Gregurick, NIH
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Micky Tripathi, ONC
Arati Prabhakar, OSTP

¹⁶ See NCVHS, Full Committee Meeting, presentation by Jamie Ferguson, Chair, ICD-11 Workgroup, “NCVHS Workgroup on Timely and Strategic Action to Inform ICD-11 Policy — Update (Apr. 11, 2024), available at: <https://ncvhs.hhs.gov/wp-content/uploads/2024/04/C-Presentation-NCVHS-FC-Day-1-ICD-11-Ferguson.pdf>