NCVHS Workgroup on

Timely and Strategic Action to Inform ICD-11 Policy

Submissions in Response to the RFI

(Received as of July 27, 2023)

	Organization	Signatory
1	3M Science	Michelle Badore Global Clinical & Nosology Content Manager Eric DeWitt, RFP Manager
2	American Clinical Laboratory Association • Request for additional time to submit • RFI Response	Adam Borden Senior Vice President, Policy & Strategy Joan Kegerize, JD, MS, CPC, CPMA Vice President, Reimbursement and Scientific Affairs
3	America's Health Insurance Plans (AHIP)	Danielle A. Lloyd Senior Vice President, Private Market Innovations & Quality Initiatives
4	American Medical Association (AMA)	James L. Madara, MD CEO, Executive Vice President
5	American Osteopathic Association (AOA)	Ernest R. Gelb, DO, FACOFP President, AOA Kathleen Creason Interim CEO, AOA
6	Brandeis University	Christopher P. Tompkins, Ph.D. Associate Research Professor
7	Coding Intel	Betsy Nicoletti, MS, CPC
8	Cooperative Exchange	Pam Grosze, Board Chair The Cooperative Exchange, Vice President, Product Manager Lead PNC Healthcare

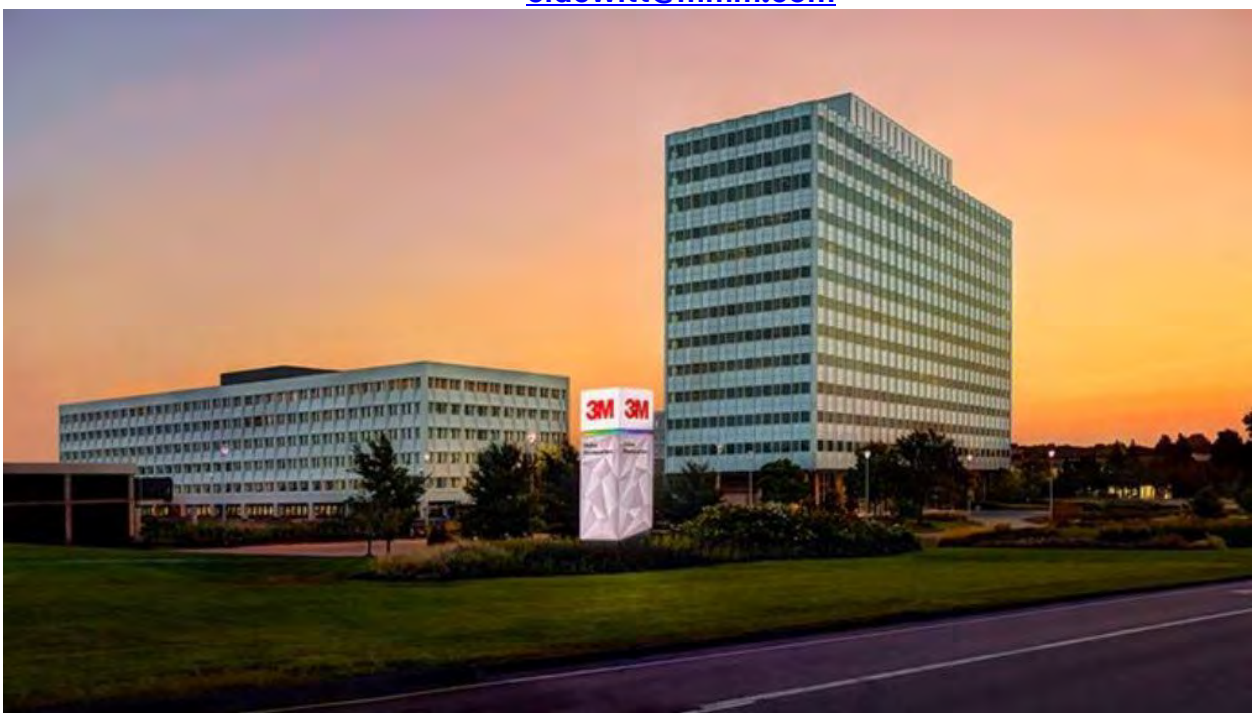
9	Haskell Memorial Hospital	Elizabeth A. Miller, CPA Consulting Chief Financial Officer Haskell County Hospital District
10	Intelligent Medical Objects	June Bronnert, MHI, RHIA, CCS, CCS-P Vice President, Global Clinical Services Theresa Rihanek, MHA, RHIA, CCS Mapping Informaticist
11	Kaiser Permanente	Jamie Ferguson Vice President, Health IT Strategy & Policy Kaiser Foundation Health Plan, Inc.
12	KG Consulting, LLC	Kathy Giannangelo, MA, RHIA, CCS, FAHIMA
13	Massachusetts Health Data Consortium MHDC) and its Data Governance Collaborative (DGC)	Janice Karin Director of Policy, Technology, and Innovation
14	Minnesota Department of Health	Zora Radosevich Director Office of Rural Health and Primary Care
15	National Council for Prescription Drug Programs (NCPDP)	Lee Ann C. Stember President & CEO
16	Seymour Hospital Texas	Leslie Hardin
17	Texas Department of Agriculture	Trenton Engledow Director, Texas State Office of Rural Health
18	United Health Group	Neil de Crescenzo CEO, Optum Insight
19	WEDI	Ed Hafner Chair, WEDI

Response to Request for Information for ICD-11

Prepared for Department of Health and Human Services

Due: 6/30/2023

3M Contacts for RFI:
Michelle Badore & Eric DeWitt
mbadore@mmm.com
eldewitt@mmm.com



Cover Letter

Department of Health and Human Services
Centers for Disease Control and Prevention
National Committee on Vital and Health Statistics
NCVHSmail@cdc.gov

RE: Response from 3M HIS regarding ICD-11 RFI

3M Health Information Systems (3M HIS) kindly submits the following comment to the national Committee on Vital and Health Statistics (NCVHS)'s ICD-11 RFI, which originated from the Meeting of the Workgroup on Timely and Strategic Action to Inform ICD-11.

We understand that the purpose of the ICD-11 Workgroup is to gather information and identify gaps in currently available information and research essential for analysis and policy decision on the U.S. approach to support adoption and implementation of ICD-11 for morbidity. In addition, the Workgroup hopes to enable coordination of public and private entities that may affect ICD-11 integration into U.S. health information environments by obtaining broad stakeholder input on studies or assessments that HHS should undertake to information the transition and its timeline.

We appreciate the latitude that NCVHS has provided the industry to share not only input on those questions raised in the RFI but to also comment on any aspect of ICD-11.

If you have any questions about our comment herein, please do not hesitate to reach out to us using the contact information below.

Michelle Badore
Global Clinical & Nosology Content Manager
mbadore@mmm.com

Eric DeWitt
RFP Manager
eldewitt@mmm.com

Executive Summary

3M Health Information Systems (3M HIS), a wholly owned subsidiary of 3M Company, is in a unique position to comment on this RFI. 3M HIS designed and developed the ICD-10 Procedure Coding System (ICD-10 PCS) and the General Equivalence Mappings (GEMs),under contract with the Centers for Medicare and Medicaid Services (CMS). 3M HIS also completed the initial version of the CMS MS-DRGs to ICD-10. As such, we are well acquainted with the benefits and potential risks associated with the adoption and implementation of an updated procedure coding system.

3M HIS has chosen to respond to a subset of the questions provided in the RFI where we feel we can rely on our experience and expertise can provide valuable insights to HHS.

3M HIS Background

Since 1983,[1] 3M HIS has been driven by a mission to build viable data compilation resources and capabilities, empowering the healthcare industry to understand how to adapt and apply their data most effectively to design and execute strategies and programs that serve as the catalyst for change in the total cost of care, health equity, and member outcomes. To this end, we work closely with both providers and payers of healthcare.

From our roots working with CMS on Medicare payment transformation, 3M HIS has become the world leader for innovating the language of health and delivers comprehensive software and consulting services to our clients and partners. Within the United States, 3M methodologies and products are being used by more than 5,000 provider organizations, the Centers for Medicare and Medicaid Services (CMS), the Department of Defense, the Veteran's Administration, 30 State Medicaid Agencies, and over 200 private payers. Globally, 3M HIS works with 8,000+ healthcare organizations, including providers, government agencies, and payers in more than 20 countries to deliver software and services that help them succeed in an ever-changing healthcare world. 3M HIS also provides the most widely used medical coding software in the world, with more than 300 active industry and technology partnerships. Our 360 Encompass System sits at the center of more than 3,000 hospitals and processes more than 320 million unique healthcare records per month. Because of broad footprint, we can uniquely speak to the impact that the adoption of ICD-11 will have on the industry.

[1] With the 3M Methodology, MS-DRGs, CMS and 3M transformed the Medicare cost reimbursement model from a percentage of bill charges model to a prospective payment model, where flat fees were paid per admission based on the patient's diagnosis.

Questions

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

2. What information or research will your organization need in order to inform assessments of cost, benefits, implementation approaches, communications, and outreach regarding the transition to ICD–11? Respondents may choose to refer to NCVHS' most recent recommendations to HHS for proposed research questions, many of which HHS has not yet addressed.

Necessary information to make accurate assessments of the level of effort needed for ICD-11 implementation and associated costs include:

- Notice of the proposed year of implementation, at least 12 months in advance of implementation.
- A decision on whether the implementation will include only ICD-11 MMS diagnosis coding or whether CMS will also include procedure coding in the implementation. If one is to follow the other, information regarding the timeline would be beneficial.
- Advance notice on whether NCVHS will implement a linearization of the WHO ICD-11 within the WHO Foundation framework or whether NCVHS plans to implement a clinical modification that diverges from or does not participate in the WHO-provided update process or operate within the WHO Foundation framework.
- Information regarding whether NCVHS plans to develop publicly available mapping software that links its linearization/clinical modification to ICD-10-CM/PCS.

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

Regarding impacts to future coding platforms and services, from a technology and ICD-11 content implementation perspective as well as the end user application, all ICD-11 coding specifications related to compliant and complete code generation, display, reporting, and interfacing for billing purposes will be needed to assess implementation efficiencies, internal tools and platform needs. For example, the new structural components of ICD-11 such as combining stem codes and extension codes, and ordering these in a complex code cluster must be reviewed in context of existing capabilities as well as any potential upgraded capabilities to efficiently generate the content creation and to provide the end user an optimal experience with ICD-11.

This will be a comprehensive assessment that will cover all related application features including annotation of patient documentation, encoder coding paths, autosuggestion, automation, and final code generation for an encounter. Training, education, and support for hospital IT teams to address the transition will facilitate the technical implementation. In

addition, any information that may forecast the impact to coders, change management, and transition would be nice to have for planning purposes.

3M HIS also has expertise in ICD-11 considerations that impact MS-DRGs. We would like to provide comments on this aspect after NCVHS provides direction regarding the form of ICD-11 that is planned for implementation.

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)?

The industry has a clear need for a standardized coding system across both inpatient and outpatient facility claims/events. 3M HIS recommends expanding the procedure coding system to encompass not only inpatient hospital but also outpatient facility for ICD10PCS (or potentially ICD11PCS) for both inpatient and outpatient facility coding.

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

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?

3M HIS appreciates the coordination between NCVHS and CMS regarding ICD-10 diagnosis and procedure coding. We recommend extending the continued increase coordination regarding the implementation of ICD-11. 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?

The current framework for ICD updates is owned by NCVHS/CMS, with shared ownership of the process through the ICD-10 Coordination and Maintenance (C&M) Committee's biannual public meetings. While NCVHS has lead responsibility for ICD-10-CM maintenance and updates, CMS has lead responsibility for ICD-10-PCS. It is logical that these two agencies would continue to share the responsibility under ICD-11. As for management of the process, we recommend that the United States have a defined linearization of ICD-11. As such, there would need to be a forum for proposing, discussing, and adopting changes to the US ICD-11 linearization. Further, there may be some benefit to more frequent updates under ICD-11. However, whether the industry can absorb more frequent updates than the current two per year depends on what other digital infrastructure changes are contemplated for the move to ICD-11. 3M HIS

recommends that NCVHS provide guidance regarding digital infrastructure improvements planned for ICD-11.

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

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

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

.

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

3M HIS developed and maintained the General Equivalence Mappings (GEMs) as an industry tool to assist in converting payment methodologies, quality measures, and other coding from ICD-9 to ICD-10. A similar crosswalk will likely be necessary for the ICD-11 adoption, but we cannot yet speculate regarding the industry's needed specifications of such a mapping tool until we know more regarding the extent and method that the U.S. is planning for the ICD-11 adoption and implementation. We can, however, anticipate that the ICD-10 to ICD-11 mapping tool will be software that gives probabilistic matches rather than simple correspondences between a fully specified code in ICD-11 and a fully specified code or codes in ICD-10.

Probabilistic matching is critical where there are no fully specified codes in ICD-11, as there are in ICD-10-CM, where all the detail for a given diagnostic condition is contained in a single code of 4-7 characters in length. ICD-11, rather, contains stem codes and a panoply of possible extension codes added on to those stem codes. In other words, there is no finite list of codes in ICD-11 but rather a potentially infinite set of combinations. A simple crosswalk cannot account for a potentially infinite number of possible combinations of stem and extension(s), as such probabilistic matching will be necessary.

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

AMERICAN CLINICAL LABORATORY ASSOCIATION

June 23, 2023

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: American Clinical Laboratory Association Request for a 30-day Extension on the ICD–11 RFI

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

On behalf of the American Clinical Laboratory Association (ACLA), **I write to you today to request a 30-day extension for the Department of Health and Human Services request for information (RFI) related to the National Committee on Vital and Health Statistics (NCVHS) and the adoption of the International Classification of Diseases (ICD-11) for morbidity coding in the United States.** 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.

In the past, ACLA took a leading role in providing education to clinical laboratories and ordering providers regarding the transition from the ICD-9-CM to the current ICD-10-CM code system. The impact on the laboratory system during the last transition was significant and our members look to provide valuable insight to help inform the next transition to the ICD-11-CM system. An extension would allow ACLA and our member organizations to review the questions in depth and develop responses to help guide the committee.

Thank you for your consideration of our request and we look forward to connecting to discuss a potential ICD-11-CM transition in more detail.

Please do not hesitate to contact Joan Kegerize at jkegerize@acla.com if you have questions or would like additional information.

Sincerely,

Adam Borden
Senior Vice President, Policy & Strategy, ACLA

AMERICAN CLINICAL LABORATORY ASSOCIATION

July 27, 2023

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 Recording in the U.S.

Dear Ms. Monson,

The American Clinical Laboratory Association (ACLA) is pleased to submit our comments in response to the National Committee on Vital and Health Statistics (NCVHS) Request for Information (RFI) on the adoption of the International Classification of Diseases (ICD-11) for morbidity coding in the United States.[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.

ACLA member laboratories appreciate the opportunity to comment on the ICD-11 RFI and provide information to the NCVHS Workgroup on their efforts to inform ICD-11 policy. ACLA member laboratories anticipate that the eventual implementation of ICD-11 in the U.S. will be a complex and costly undertaking. The lessons learned in the transition from ICD-9 to ICD-10 less than a decade ago should serve as a guide when the U.S. does commence the transition.

ACLA recommends the following.

I. The Department of Health and Human Services (HHS) should plan for a multi-year preparation and transition period to solicit stakeholder feedback prior to implementation and involve stakeholders in the preparation steps. 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

[1] National Committee on Vital and Health Statistics; Meeting and Request for Information, 88 Fed. Reg. 38519 (Jun. 13, 2023).

information systems, and conduct end-to-end testing.

II. **Stakeholders should be afforded adequate resources, tools, and support for ICD-11 implementation.** 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. Educational resources on the structure of ICD-11, general equivalency mapping/crosswalks between ICD-10 and ICD-11, testing tools, and technical guidance are among the support laboratories will need for implementation.

III. **HHS should organize a designated testing period for all federal health care programs prior to the implementation of ICD-11.** 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 to stakeholders, as warranted.

IV. **The ICD-11 implementation should be overseen by the same entity that oversaw implementation of ICD-10, the National Committee on Vital and Health Statistics.** The NCVHS has expertise to provide advice and assistance to HHS and serve as a forum for interaction with interested stakeholders on health data issues.

V. **HHS should resolve the regulatory gap between ordering providers and laboratories**. HHS should clarify and enforce a requirement that at the time of ordering a laboratory test, an ordering provider must submit to the laboratory appropriate diagnosis codes at the highest level of specificity, whether or not the ordered tests are covered by a national coverage decision (NCD) or local coverage decision (LCD).

These recommendations and others are addressed more fully in our responses to the RFI questions, below.

RFI Questions

Question3: What considerations affect the impact of ICD-11 on clinical documentation, payment processes (including risk adjustment), public health, population health, or research?

ICD diagnosis codes are essential to many aspects of the lifecycle of a laboratory test, including coverage by a health plan, marketing, and education about the test, ordering by clinicians, result reporting, claim preparation and submission, claim adjudication, and appeal of denials.

Many health plans include in coverage policies for laboratory tests the diagnosis codes for which they consider a test reasonable and medically necessary, and this is done through inclusion of ICD codes in the coverage policies. 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 about their test menus and how to order tests, including the ICD codes that are in major health plans' coverage policies. 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.

A laboratory must plan for and implement changes from ICD-10 codes to ICD-11 codes 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.

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

ACLA does not support HHS implementing ICD-11 at this time. We expect that the transition from ICD-10 to ICD-11 will be similar to the transition from ICD-9 to ICD-10 in terms of the tremendous capital and human resource needs. This type of coding transition requires significant updating, education, and reprogramming in countless areas of a laboratory's operations, including test ordering, payors' coverage policies, laboratory information system (LIS) interfaces with electronic health records (EHRs), billing systems, and test menus, to name a few areas. Additionally, if health plan coverage policies are not fully updated prior to ICD-11 implementation, health care providers will have their claims denied or payment will be delayed. It is too soon for HHS to implement a new coding system that burdens health care providers and puts their reimbursement at risk.

ACLA recommends that HHS plan for a multi-year preparation and transition period so that it may solicit stakeholder feedback prior to implementation and involve stakeholders in the preparation steps. For example, stakeholders can advise HHS on the types of education that have value for a variety of stakeholders, participate in end-to-end testing, and alert the agency to issues that may cause problems after implementation. The plan for the preparation period should include a timeline with measurable goals so that HHS 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 HHS does implement ICD-11, there should be a 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 was not used. This type of flexibility was afforded to health care providers by the Centers for Medicare & Medicaid Services (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 – such flexibility will be needed again.

Question 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?

It would be reasonable for ICD-11 implementation to be overseen by the same entity that oversaw implementation of ICD-10, the National Committee on Vital and Health Statistics. We expect that NCVHS has adequate resources and expertise to bring to bear and that it will use its experience and "lessons learned" to ensure that the transition to ICD-11 is as seamless and efficient as possible. We also would expect that NCVHS once again would collaborate and coordinate with partners such as CMS, the American Medical Association, the American Health Information Management Association, and the American Hospital Association on aspects of development and implementation coordination.

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

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 providers, payors, referring laboratories, IT vendors, clearinghouses)
- General equivalency mapping/crosswalks between ICD-10 and ICD-11
- Testing tools
- 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 NCVHS about issues and problems with implementation

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

HHS must provide active leadership in the transition to ICD-11 for it to be successful. The department will have a vital role to play in developing, promoting, and updating educational resources about ICD-11 and the plan for the transition from ICD-10 to ICD-11. This includes webinars, fact sheets, FAQs, live and asynchronous presentations, and different versions that are tailored to different stakeholders (*e.g.*, clinicians, EHR vendors, health plans). HHS also should be responsible for issuing policy guidance on different aspects of implementation and for ensuring that a variety of guidance resources are readily available on a central ICD-11 website. HHS itself should distribute and promote all such education and guidance resources, and it also should work

with key provider groups and industry trade associations to disseminate them and publicize their availability.

In consultation with stakeholders, HHS also should organize a designated testing period for all federal health care programs prior to the implementation of ICD-11. Additionally, HHS should coordinate testing by state Medicaid programs and make monetary and technical resources available to those programs to facilitate the testing. This is essential to ensuring that health care providers' claims for services furnished to federal health care program beneficiaries continue to be paid promptly and seamlessly after implementation.

Furthermore, HHS should actively monitor progress towards milestones prior to implementation (*e.g.*, participation in educational sessions, end-to-end testing, federal health care programs' readiness to process claims bearing ICD-11 codes accurately) and delay implementation, if warranted.

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

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.

Question 11: What other operational impacts of ICD-11 adoption and implementation should HHS consider?

HHS should resolve the regulatory gap between ordering providers and laboratories. ACLA member laboratories strongly urge HHS to clarify and enforce a requirement that at the time of ordering a laboratory test, an ordering provider must submit to the laboratory appropriate diagnosis codes at the highest level of specificity, whether or not the ordered tests are covered by a national coverage decision (NCD) or local coverage decision (LCD).

As covered entities under HIPAA, clinical laboratories are required to submit diagnosis codes in standard transactions where such codes are required. Medicare contractors and private payers typically require such codes through coverage decisions, but also edit claims for diagnosis codes at the highest level of specificity regardless of whether the test is subject to an NCD or LCD. A clinical laboratory depends upon referring providers to provide the diagnosis codes that the laboratory must submit in HIPAA standard transactions, such as claims for reimbursement. Unfortunately, for various reasons, clinical laboratories are required to submit diagnosis codes in HIPAA standard transactions when there is no currently enforced requirement for referring providers to provide such codes to the laboratory. The act of requesting a laboratory test is not a standard transaction under HIPAA, and therefore the HIPAA requirements pertaining to diagnosis

codes applicable to the claim, which is a standard transaction, do not apply to test orders, which are not.

Laboratory test orders for which diagnosis codes are required for payment to the laboratory may lack diagnosis data altogether or contain diagnosis data that is deficient in some manner. Laboratories that receive test orders with insufficient diagnosis data must contact the ordering provider to obtain the missing or deficient data, resulting in significant inefficiencies. This regulatory gap is problematic for clinical laboratories, providers, health plans and patients today, using the ICD-10-CM code set with which the healthcare industry is familiar. If not resolved, the failure to provide diagnosis codes could become a much greater problem as the industry transitions to the new ICD-11-CM code set, which is a much larger set of codes that most physicians are not familiar with. ACLA is requesting your help in resolving this issue so that our transition to ICD-11-CM can be as effective as possible.

There is a Medicare requirement for submission of diagnosis data by referring providers to clinical laboratories in test orders, but it has been narrowly interpreted by CMS to apply only to tests covered by NCDs or LCDs and has been rarely if ever enforced. In Section 4317(b) of the Balanced Budget Act of 1997 (BBA, 105 P.L. 33), Congress amended Section 1842(p) of the Social Security Act (42 U.S.C. § 1395u(p)), the statutory provisions relating to the administration of Medicare Part B, by adding the following new paragraph: "In the case of an item or service defined in paragraph (3), (6), (8), or (9) of subsection 1861(s) [42 U.S.C § 1395x(s)] ordered by a physician or a practitioner specified in subsection (b)(18)(C), but furnished by another entity, if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the item or service to provide diagnostic or other medical information in order for payment to be made to the entity, the physician or practitioner shall provide that information to the entity at the time that the item or service is ordered by the physician or practitioner."[2]

Diagnostic laboratory tests are among the items and services defined in paragraph (3) of subsection 1861(s) of the Social Security Act [42 U.S.C. § 1395x(s)]. Since CMS and its contractors require clinical laboratories to submit diagnosis codes at the highest level of specificity in all claims in order for payment to be made, whether or not the service is subject to an NCD or LCD, it is the position of ACLA that this statute should be interpreted to mean that referring providers are required to provide diagnosis codes at the highest level of specificity in all test orders for Medicare Part B beneficiaries. Requiring CMS to interpret the statute as we have described, to educate ordering providers about the requirement, and to identify and apply an enforcement mechanism to ensure ordering provider compliance would help to resolve this issue as it relates to Medicare transactions, and if CMS were to encourage private payers to do likewise, we believe they would follow.

* * * * *

We thank NCVHS for the consideration of our comments on the ICD-11 RFI. Please

[2] 42 U.S.C. § 1395u(p)(4) (emphasis added).

contact me at 202-637-9466 or jkegerize@acla.com with any questions.

Sincerely,

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

601 Pennsylvania Avenue, NW
South Building, Suite 500
Washington, D.C. 20004

T 202.778.3200
F 202.331.7487
ahip.org

June 30, 2023

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: 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 to the National Committee on Vital and Health Statistics (NCVHS) in response to the request for information (RFI) on ICD-11.

AHIP appreciates NCVHS' efforts in support of ICD-11 adoption and implementation, including its engagement of stakeholders and solicitation of industry input to inform meetings, such as the upcoming expert roundtable event on August 3, 2023. Below we provide input on specific responses where we have recommendations, concerns, or considerations that we ask NCVHS to take into consideration as it develops recommendations to the Secretary.

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

AHIP members are committed to establishing strong foundations that enable health care providers and health insurance providers to identify and report conditions and medical treatments in more specific ways, ultimately leading to more effective measurements of quality, health outcomes, and equity.

Our member health insurance providers have voiced general support regarding the move to ICD-11. Anticipated advantages of ICD-11 include enhanced alignment and integration with EHR systems and with richer clinical terminology and vocabulary standards, such as SNOMED, increased flexibility of application and the ability to describe health conditions in greater detail through the combination of codes. More research will be needed to identify and document the benefits that moving to ICD-11 will bring to various stakeholders (e.g., providers, health plans, public health, others). We look forward to sharing more information with NCVHS as we progress toward ICD-11 adoption.

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?

Health insurance providers process millions of eligibility, coverage, prior authorization, payment, and other transactions daily. The migration to ICD-11 code sets will have a major impact on business and administrative operations and require significant financial and human resources for successful implementation.

Given that ICD-11 takes a somewhat novel approach to its coding structure compared to ICD-10, AHIP anticipates that the cost and burden associated with adoption and implementation will be substantial and much larger than the transition from ICD-9 to ICD-10. More detailed information 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; the pathway and transition process between versions; timelines for implementation; and adoption by government, payers, regulators, and accrediting bodies will assist organizations in assessing and preparing for implementation costs. Moreover, additional clarity is warranted around potential changes in governance processes in terms of whether and if so, how, the U.S. will continue to deviate from the World Health Organization (WHO).

Research around the possible impact of the adoption and use of ICD-11 on payment, reimbursement, and other administrative processes compared to the current ICD-10 CM and PCS standards will be important in defining the benefits of the change. Particularly, how the use of the proposed ICD-11 can be cost-neutral, when compared to the current use of ICD-10: A similar issue that the industry faced when transitioning from ICD-9 to ICD-10. It will also be valuable to understand the benefit of adopting ICD-11 in new payment models such as value-based payments.

Communication and outreach 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. Advance notice with reasonable timeframes for implementation is pivotal to ensure organizations have adequate budget and staff for these activities. In addition, widely disseminated, clear implementation guidance will help avoid unintended consequences such as negative impacts on clinical care, coverage, and payment for services.

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

Given that ICD codes are used throughout health care, such as to inform claims adjudication and processing, identify areas where patients may need further supports, aid clinical decision making, assist with public health efforts, and inform research, the impact of moving to ICD-11 is substantial. We provide a general overview of potential implications throughout our RFI responses.

4. What unique U.S. coding or terminology considerations are essential? For example, coding or terminology related to community health, social determinants of health (SDOH), 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)?

AHIP and its health insurance provider members are committed to reducing health care disparities and promoting health equity. However, reducing disparities requires that the industry first identify and document them. To advance health equity, AHIP and its members believe key investments in standardizing the documentation of sociodemographic characteristics and health-related social needs will allow for the identification of disparities in care, promote equitable care, and advance recognition of the role of SDOH. AHIP believes it is important to understand the impact that structural and socioeconomic factors have on outcomes and disparities and work to address these structural and socioeconomic barriers to health.

Unfortunately, limitations in existing clinical terminologies and code sets complicate the ability to define and identify the SDOH and health-related social needs of patients and collaborate across sectors to provide the necessary support and interventions. There is a clear need to understand the mapping and transitioning from current Z-codes in ICD-10 to the health-related social needs and SDOH codes in ICD-11, and to refine and augment existing SDOH codes to gather more data in a standardized way across payers and providers. Better data will foster a greater understanding of patients' needs as well as the quality of health care provided and how it may differ by population. In turn, this will empower quality improvement activities and patient engagement.

ICD-11 should strive to overcome existing barriers in SDOH data collection by filling in gaps in coding, refining the language of existing codes, and by addressing terminology vagueness. ICD-11 should also strive to align with the coding and vocabulary standards identified by the consensus-driven Gravity Project and in the USCDI Version 3 for SDOH Diagnosis.

Filling in Gaps in Codes

Gaps remain in existing interoperable codes to appropriately document different social needs. For example, new Z codes for food insecurity and education were just created in 2021, and codes for transportation insecurity and financial security were just created in 2022. Remaining gaps and recommended additions to fill these gaps include:

- **Loneliness and Lack of Social Support Inclusion Terms**: ICD-11 should add a "loneliness" inclusion term under R45.89 (Other symptoms and signs involving emotional state) and "lack of emotional support" under Z60.8 (Other problems related to social environment) to fill in gaps in missing concepts that are different from "social isolation." There are important and distinct nuances between the different needs

associated with social isolation, loneliness, and inadequate social support, but currently there are only ICD-10 Z codes for "problems related to living alone," "social exclusion and rejection," "other problems related to social environment," and "other specified problems related to primary support group." There are no Z codes to appropriately document "loneliness."

- **Material Hardship:** ICD-11 should revise Z59.87 to "material hardship due to limited financial resources" to clarify economics as the driver. This could include "unable to obtain adequate clothing and/or utilities and/or childcare due to limited financial resources." Furthermore, ICD-11 should include a new code and term under Z58 to cover basic necessities unavailable in the environment: Z58.81 Material hardship, inadequate physical environment. This could include "unable to obtain internet service and/or electricity due to inadequate physical environment." This distinction between Z58 and Z59 is important to inform community-level need for economic support.

- **Intimate Partner Violence and Abuse**: ICD-11 should add codes for intimate partner violence and abuse that are applicable to all ages—whether physical abuse, sexual abuse, or psychological abuse. This will help ensure that abuse that occurs between minors is not coded as "child abuse." ICD-11 should also include a new subcategory for "financial abuse."

- **Personal History of Military Service and Deployment**: ICD-11 should add a unique code Z91.85 (Personal history of military service) to clarify the distinction from Z91.82 (Personal history of military deployment). The risks of deployment and service are distinct and need to be independently identified.

- **Digital Equity Needs:** ICD-11 should include the capability of identifying digital access and digital literacy needs of consumers, a new domain in the SDOH ecosystem.

- **No Identified Needs:** ICD-11 should also include new codes to track when patient SDOH assessments were administered but no needs were identified.

<u>Refine Language of Existing Codes</u>

In addition to filling in coding gaps, there may be a need to revise the language associated with existing codes to ensure it is neutral and not judgmental, such as inferring blame on the individual for structural or societal barriers. This will help ensure individuals feel comfortable responding and clinicians feel comfortable asking the necessary questions. This challenge is made more acute by the recent enforcement of Cures Act Final Rule,[1] which requires providers to make information available to individuals through Application Programming Interfaces (APIs). As such, clinicians may be hesitant to add a code that includes potentially sensitive

[1] "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program;" 85 Fed. Reg. 25642 (May 1, 2020).

language if there is a chance that code could be seen by the individual when they access their records through APIs.

Address Terminology Vagueness

Minimizing variation in data collection should include efforts to address terminology vagueness and linguistic ambiguity among specific codes or code sets. 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. Such concepts should be tied to objective definitions linked to quantifiable, measurable outcomes (e.g., 4th grade reading level). Another example are the nuanced differences between "social isolation," "loneliness," and "inadequate social support." Each of these needs requires a nuanced understanding of their subtle yet distinct differences for appropriate and accurate documentation of existing ICD-10 Z codes for "problems related to living alone," "social exclusion and rejection," "other problems related to social environment," and "other specified problems related to primary support group." As mentioned above, new code(s) should be created to appropriately document "loneliness" as it is distinctly different than existing codes.

For these reasons, AHIP has supported the Gravity Project's efforts to develop consensus-based data standards in ICD-10 to facilitate documenting and exchanging SDOH data within health care and other sectors. We have written several letters to the ICD-CM Committee in support of the Gravity Project's proposed codes.

In addition to striving for clear, easy to understand and apply terminology at the outset of ICD-11 adoption, HHS must also engage in extensive education campaigns, including to facilitate understanding of any nuanced differences between codes that cannot be captured by clearer code language. Provider use of SDOH Z codes has been low for several reasons, including lack of awareness. Increasing awareness through education campaigns will take time, effort, and communication. AHIP has previously shared barriers to Z code reporting that we believe should be addressed in future iterations of codes, such as:

- Technological and information sharing (e.g., many EHRs do not have easy pathways to add a Z code to the problem or diagnostic list, which hinders providers' ability to report them);
- Billing systems (e.g., electronic billing systems currently constrain the number of diagnosis codes that can be placed on a claim; the 837i permits 25 diagnoses, but payers often truncate this at 10 or 15); and
- Patient hesitancy (e.g., patients who are unhoused and have children may be hesitant to share this information due to concern about being unfairly targeted by child protective services).

To overcome these identified issues, HHS should work with relevant agencies that oversee other aspects of health care operations, plans and providers to increase awareness, consider developing provider incentives to increase reporting, and evaluate ways to encourage EHR system changes to facilitate the use of SDOH codes.

All coding and terminology standards currently accepted in the U.S. should be assessed for uniqueness as compared to ICD-11. As a recommendation for coding, a governance model should be established to prepare specifications for coordinated coding solutions and, where possible, consolidate terminology in consultation with entities that have published clinical practice guidelines for areas of high or increasing prevalence morbidity and mortality (e.g., dementia, obesity, heart disease) and new areas of focus as predictors of healthcare costs (e.g., SDOH, behavioral health).

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

HHS should leverage lessons learned from the adoption of ICD-10 to avoid compliance concerns and delays.

HHS should develop a detailed roadmap and transition plan for adopting and implementing a change to ICD-11, including templates for health care organizations (e.g., providers, payers, public health, EHR/health information technology vendors, and others) to appropriately prepare, plan, transition, and fully implement the new coding standard.

HHS should also provide a comprehensive set of crosswalks along with standard terminologies and other classifications that provide the common medical language necessary for interoperability and the effective sharing of data facilitate seamless transition to ICD-11. Alignment across impacted organizations, sponsor communication and training, and sufficient time for complete implementation is critical.

HHS should establish budget neutral application of ICD-11 codes to ensure that the transition from ICD-10 to ICD-11 does not result in unintended increases or decreases in reimbursement for providers and payers. HHS should also seek alignment across agencies and government programs.

We encourage HHS to establish a dedicated transitional period where both ICD-10 and ICD-11 codes will be permitted. During this time, guidance and flexibility regarding reporting requirements will be critical to prevent confusion and unnecessary burden.

HHS must consider the many programs, priorities, and policies being implemented across the Department when planning a roadmap for ICD-11 adoption and implementation. This merits careful consideration of other administrative priorities and any associated implementation timelines and requirements. Overlapping implementation requirements across health care programs not only creates significant administrative burden and drives up costs, but it has the potential to create significant confusion and problems down the road if the intersection if ICD-11 coding and other programs is not considered and sufficiently addressed.

Programs that involve use of ICD codes must consider the transition to ICD-11 and provide sufficient guidance and appropriate flexibility. These considerations will be particularly important during the phase where ICD-10 and ICD-11 coding overlaps. One of many examples of salient programs that entail consideration of ICD transitions include Transparency in Coverage (TiC) and No Surprises Act requirements, which entail billing and diagnostic code level reporting and requirements associated with certain visits or requests. It is critical that ICD-11 implementation involve coordination across all authoritative agencies and entities involved in health care provider and health insurance provider regulation in order to prevent significant disruption due to unintended misalignment of code sets or associated policies.

Relatedly, AHIP strongly encourages HHS to work with Standards Developing Organizations (SDOs) on coordination; for example, for ICD-11 SNOMED codes to be integrated into the Fast Healthcare Interoperability Resource (FHIR®) Implementation Guides (IGs). This will require significant thought and attention around how to determine incorporation of ICD-11 codes and manage ICD-10 and ICD-11 coding overlap.

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

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. Specific resources identified include:

- SDO whitepapers outlining the difference between ICD-10 and ICD-11;
- Resources to understand alignment with state mandates;
- Understanding of clearing house and vendors ability to accept new ICD-11;
- Extensive coding mapping and crosswalks between ICD-10 and ICD-11;
- A plan and approach for managing mapping overlap;
- Testing tools; and
- An industry portal to submit issues and questions.

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

Implementation resources and needs will vary across entities. We encourage the USG to strive for timely release of policy and operational guidance and to continually engage with the industry through interactive education opportunities, including collaborative meetings and partnerships with payers, providers, and others.

As noted in the previous question, having a detailed roadmap, a transition plan and a series of templates for health care organizations to best prepare, plan, transition, and fully implement the new coding standard will be quite valuable, along with comprehensive crosswalks between the various coding standards, including ICD-11, ICD-10, CPT, SNOMED, LOINC, and HCPCS.

We recommend that the USG provide support for SDOs to collaborate with industry stakeholders on the creation of materials, crosswalks, and recommendations, including on how to manage overlap between ICD-10 and ICD-11 and how ICD-11 will be incorporated into existing standards such as FHIR.

To underscore and highlight changes, AHIP encourages the USG to enumerate the specific deleted codes or areas and provide possible replacement codes or code ranges. This allows for standardization, efficiency, and time/cost savings across all organizations particularly when coupled with nationally created change management tools (e.g., awareness, adoption, training materials).

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

As noted, HHS should map ICD-11 as closely as possible to ICD-10 and other standards, such as SNOMED. This is important to encourage seamless health information exchange and efficiency for all stakeholders. HHS should leverage the multi-cross-coding mapping resource – the Convergent Medical Terminology - maintained by the National Library of Medicine.

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

Health insurance providers use diagnosis codes in many different areas such as benefits and exclusions, processing logic of many kinds, policies and procedures, clinical policies, claims editing logic, diagnosis related groups (DRGs), and contracts. The translation of ICD-10 to ICD-11 may be more easily implemented for some of these processes compared to others, which may merit different approaches and resources. HHS should regularly check-in and engage with industry stakeholders to understand ICD-11 adoption and implementation progression.

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

Danielle A. Lloyd

Senior Vice President, Private Market Innovations & Quality Initiatives

James L. Madara, MD
CEO, EXECUTIVE VICE PRESIDENT

June 30, 2023

Jackie Monson, JD
Chair
National Committee on Vital and Health Statistics
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

RE: ICD-11 Request for Information

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) Request for Information (RFI) on the International Classification of Diseases, Eleventh Revision (ICD-11).

The AMA has long advocated for the use of standard code sets and terminologies to support the interoperability of health information. While uniform communication between physicians, other qualified health care professionals, and health plans is critical for reducing administrative burdens, the wide-scale upheaval and significant cost that will occur with the implementation of ICD-11 needs to be closely considered against any expected benefits. 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 appreciate the opportunity to provide the physician perspective on ICD-11. More broadly, the AMA prides itself in actively participating in cross-industry, multi-stakeholder efforts to advance health information technology (health IT) to meet unmet business needs and build consensus on the best path forward for adopting these innovations in real-world settings.

Unfortunately, the short period in which to provide comments on this RFI precluded us from doing outreach to our members, thus limiting the detail of our responses.

RFI Questions

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

The benefits of ICD-11 for physicians in any practice setting are 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 that will happen with the implementation of ICD-11 and what benefits could be gained.

[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.
[2] Shanafelt TD et al. Relationship between clerical burden and characteristics of the electronic environment with physician burnout and professional satisfaction. *Mayo Clin Proc*. 2016;91:836-848.

Additionally, physicians are still waiting to realize the benefits of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). The U.S. Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), and other organizations proclaimed there would be considerable benefits and savings from ICD-10-CM for physicians because of the higher level of specificity in the diagnosis codes. The purported benefits included:

- Improved claims adjudication and reimbursement, e.g., fewer rejected claims and more accurate payment.
- Fewer requests for additional clinical information for claims or prior authorizations.
- Increased efficiency, increased productivity, and decreased costs associated with administrative activities, i.e., submitting claims, checking eligibility, reconciling claim payments, etc.
- Decreased manual review of health records.
- Improved management of patients' diseases.

To date, physicians have not seen measurable ROI or benefits from the implementation of ICD-10-CM. Instead, physicians have experienced increases in rejected claims, multiple requests for additional information from public and private sector payers, and higher costs associated with increased administrative activities. Moreover, an overwhelming majority (84 percent) of physicians report that the number of prior authorizations required for medical services has *increased* over the last five years.[3]

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? Respondents may choose to refer to NCVHS' most recent recommendations to HHS for proposed research questions, many of which HHS has not yet addressed.

Physicians will, at a minimum, need the following:

- Details about the anticipated U.S. ICD-11 implementation timeline with major milestones and key deliverables.
- Proposed and expected nationwide ICD-11 education and training programs.
- Impacts on relevant federal and state programs and reporting requirements.
- A comprehensive understanding of the structural and content differences between ICD-10-CM and ICD-11.
- Expected changes to administrative transactions and workflows.
- Expected software changes to accommodate ICD-11 in the electronic health record (EHR) and practice management systems and estimated vendor implementation timelines and costs.
- Expected costs for staff training and necessary resources to support coding in ICD-11.
- Expected changes to current data management, i.e., data storage, mapping, etc.
- Expected changes to data collection and reporting, including quality measures, value-based programs, clinical research, and other clinical programs.

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

[3] 2021 Update: Measuring progress in improving prior authorization. Available at: https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf.

The potential effects of ICD-11 on clinical documentation, payment, public health, research, and other needs for diagnosis reporting are currently unknown. Additional information is needed to understand the differences between ICD-10-CM and ICD-11 and the requirements that will be associated with ICD-11. Physicians are facing a staggering number of technological and reporting requirements, including multiple, overlapping federal mandates, which place significant financial and operational burdens on practices, especially smaller practices. The impacts of implementing ICD-11 must be clearly identified and ROI must be established before moving forward.

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)?

The essential considerations for coding are the ability to identify the patient's diagnosis and additional relevant factors clearly and precisely for many purposes, including delivering coordinated care, addressing related health care and health-related social needs, billing for services rendered, receiving payment, and managing population and public health needs. Implementation of ICD-11 in the U.S. needs to consider the requirements and timelines of other mandated regulatory changes and updates, including interoperability standards, No Surprises Act, Health Insurance Portability and Accountability Act (HIPAA) standards and operating rules, and Trusted Exchange Framework and Common Agreement (TEFCA), to name a few. ICD-11 should continue to build on efforts like the Gravity Project to enhance Z-codes related to health-related social needs. Given ongoing efforts to collect data across the care continuum and between health care and community-based organizations, the implementation of ICD-11 may have unintended consequences beyond traditional health care settings.

The Office of Management and Budget (OMB) recently proposed updates to race and ethnicity statistical standards, in part to address the increasing number of uncategorized responses due to respondents not feeling represented by the categories provided or being forced to choose only one category. Any update to coding should support granular categories and the ability to select more than one category, preparing for other likely OMB updates such as collapsing race and ethnicity into a single question and adding a category of Middle Eastern or North African.

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

HHS should conduct comprehensive outreach to the physician community, particularly those working in settings or with patients and communities with fewer resources. Physicians have diverse needs based on specialty, practice location, geography, and patient demographics. Outreach must be conducted at multiple levels to successfully address the specific and vast array of physicians' needs.

Implementation of ICD-11 will need to be done methodically, systematically, and comprehensively. Physicians and their administrative staff will need time to be educated on ICD-11 and the various steps and timing for implementation, including:

- EHR and practice management system updates;
- Changes to administrative transactions;
- Health plan and payer policy changes;
- Testing;
- Coding training; and
- Crossover period.

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?

CMS, as the federal body responsible for the enforcement of HIPAA code set standards, is the logical choice for the national center for ICD-11 implementation. Collaboration with public and private sector organizations will be necessary to help ensure a smooth and successful transition to ICD-11.

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?

The current ICD-10 Coordination and Maintenance Committee should take on the responsibility of receiving ICD-11 requests and managing their resolution, either through development of new codes, changes to existing codes, or changes to the code extensions. The U.S. should leverage current best practices (for updating ICD-10-CM) and lessons learned over the years of ICD-10-CM deployment.

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

Physicians will need, at a minimum, the following resources and tools:

- Educational materials for both the ICD-11 code set and implementation, including computer-based training, toolkits, virtual and in-person training sessions, articles, etc.;
- Processes and timelines for implementation and maintenance (especially given the electronic only nature of ICD-11);
- Clear updates to existing regulatory reporting requirements;
- CMS Open Door Forums where industry questions are addressed;
- Cross maps from ICD-10 to ICD-11 and ICD-11 to ICD-10;
- Testing tools; and
- Financial support.

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

All items listed in #8. Since the implementation of ICD-11 will be a federal mandate, resources and tools need to be made available for physicians at no cost.

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

Physicians and their administrative staff will need education on the ICD-11 code set and the processes for its implementation and ongoing maintenance.

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

While it is too early to know exactly what physicians' practice requirements will be, at a minimum, it can be anticipated that any current area where there is mapping from ICD-10 to other coding terminologies will need to be implemented for ICD-11.

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

HHS must consider the current epidemic of physician burnout. The most recent study in the national burnout survey series[4] co-authored by the AMA shows how the COVID-19 pandemic magnified long-standing issues that have accelerated the U.S. physician burnout rate. At the end of 2021, nearly 63 percent of physicians reported symptoms of burnout, up from 38 percent in 2020, with physicians who identify as Black or two or more races reporting the highest rates of burnout.[5] Research shows that large-scale change is needed to address the physician burnout crisis.

Another study of physicians, nurses, and other clinical and non-clinical staff, published in the *Journal of General Internal Medicine*,[6] found the perceived work overload was associated with burnout and intent to leave across all role types. This evaluation suggests that health care workers (especially nurses and other clinical staff) feel unable to meet what are at present unrealistic demands for productivity and efficiency, with downstream effects on well-being and work intentions.

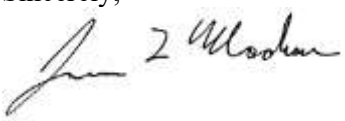
While many factors contribute to burnout, the burnout epidemic is often associated with system inefficiencies, administrative burdens, and increased regulation and technology requirements. Physicians and other clinical staff are tired from the immense administrative burdens being placed on them. The fact that they are retiring early or leaving the profession in large numbers cannot be overlooked.

HHS should consider other legislative and regulatory requirements and deadlines that will overlap with the implementation period for ICD-11. Physician practices have limited resources for updating their EHR and practice management systems, training staff, changing administrative workflows, and sustaining the loss of productivity through an implementation of this large scale.

Summary

Thank you for the opportunity to provide comments on ICD-11. We look forward to continuing our dialogue with NCVHS on how the health care industry 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 Vice President of Federal Affairs, at (202) 789-7409 or margaret.garikes@ama-assn.org.

Sincerely,



James L. Madara, MD

---

[4] Practice Transformation: Research. Available at: https://www.ama-assn.org/practice-management/sustainability/practice-transformation-research.

[5] 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.

[6] Rotenstein, L.S., Brown, R., Sinsky, C. *et al.* The Association of Work Overload with Burnout and Intent to Leave the Job Across the Healthcare Workforce During COVID-19. *J GEN INTERN MED* 38, 1920–1927 (2023). https://doi.org/10.1007/s11606-023-08153-z.

AMERICAN OSTEOPATHIC ASSOCIATION

511 2nd Street, NE
Washington, DC 20002
202.349.8750
osteopathic.org

June 29, 2023

Sharon B. Arnold, PhD
Executive Staff Director, NCVHS
Associate Deputy Secretary
ASPE, Science and Data Policy
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20024

Rebecca Hines, MHS
Designated Federal Officer, NCVHS
Health Scientist
CDC/National Center for Health Statistics
Office of Planning, Budget, and Legislation
3311 Toledo Rd
Hyattsville, MD 20782

Jacki Monson, JD
Chair, NCVHS
Senior Vice President, Chief Integration Officer
Sutter Health
2200 River Plaza Drive
Sacramento, CA 95833

Re: ICD-11 Request for Information

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

The American Osteopathic Association (AOA), on behalf of the more than 178,000 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. OMT employs a variety of techniques that allow physicians to use this therapy to treat a wide range of medical conditions, particularly to eliminate or alleviate somatic dysfunction and related disorders.

511 2nd Street, NE
Washington, DC 20002
202.349.8750
osteopathic.org

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.

Our responses to the questions within the RFI focus on this particular issue of eliminating "segmental and somatic dysfunction" codes for specific body regions. However, our physicians stand ready to assist with any other issues related to ICD-11 adoption and implementation as needed by the NCVHS.

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

The use of ICD codes is essential to the process of appropriate documentation of diagnoses, and the subsequent billing of services or treatments. 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.**

Questions 6 and 7: What entity should be responsible for coordinating overall national implementation of ICD–11 for morbidity coding, and how should the implementation be managed? And, what entity should be responsible for coordinating U.S. requests for updates or changes to ICD–11? How should this process be managed?

The AOA has supported HHS' historical approach of maintaining a federal interdepartmental committee comprised of representatives from the Centers for Medicare & Medicaid Services

511 2nd Street, NE
Washington, DC 20002
202.349.8750
osteopathic.org

(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, but we do not have input on where it should sit within the agency, especially in light of CDC's ongoing reorganization.

Conclusion

The AOA appreciates this opportunity to comment on ICD-11 RFI. 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 at any time.

Sincerely,

Ernest R. Gelb, DO, FACOFP
President, AOA

Kathleen Creason
Interim CEO, AOA

Brandeis UNIVERSITY

June 29, 2023

Dear Members of the ICD-11 Workgroup:

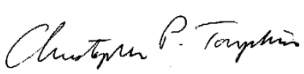
I am pleased to provide comments in response to your RFI published on June 13, 2023, addressing the potential use of ICD-11 for morbidity coding in the U.S. I have worked in health economics and payment reform for almost 40 years. Much of today's value-based payment is rooted in my work, notably the Medicare Shared Savings payment model and the concept for ACOs, and the Medicare Hospital Value-Based Payment (HVBP) program, which was introduced in a Report to Congress and included in the Affordable Care Act.

Between 2011 and 2016, I led the development of the Episode Grouper for Medicare (EGM) for CMMI, which was mandated in the ACA, and later the American College of Surgeons--Brandeis Advanced Alternative Payment Model. I supported CMS with the MIPS program for several years and have supported CMMI periodically regarding various payment models in their APM portfolio.

In many ways, the field has seen much investment in transformation toward higher value. However, in my 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. In the enclosure, I offer answers to many of the questions in the RFI and suggest a combination of strategic and tactical approaches that might expedite, facilitate, and optimize ICD-11 in the U.S.

By way of preview and emphasis, I want to offer a version (linearization) of ICD-11 that my colleagues and I believe would be suitable and practical as a starting point for the education, vetting, testing, and implementation of ICD-11 in the U.S. This version is almost fully drafted and is available for inspection and adoption by the ICD-11 workgroup and other agencies and stakeholders with interest in helping the U.S. move forward.

Sincerely,



Christopher P. Tompkins, Ph.D.
Associate Research Professor

Enclosure: Response to RFI 2023-12617

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

An overarching policy goal for the US is to have a sustainable, high-value (i.e., efficient and cost-effective) healthcare system. We need design and implementation plans that enable private and public healthcare delivery systems and stakeholders to understand and coordinate their respective roles in achieving that goal. Such a plan inevitably consists of many perspectives and interrelated activities, as shown in Figure 1. Some of these activities are undertaken by payers, such as performance report cards, payment systems, and identifying care improvement opportunities. Others are undertaken by clinicians and delivery systems, such as using clinical decision support tools and managing tasks and workflow. Respondents to this RFI are likely to represent each of these perspectives/activities depicted, and possibly others. There are many data needs and exchanges that occur simultaneously and interactively among these tasks and by various stakeholders.

The coding system is a starting point and key resource for all the activities shown in Figure 1, and thus greatly determines their capabilities and success toward our overarching goal. All of them benefit from the strengths and are hampered by the limitations in the ICD coding system. The transition from ICD-9 to ICD-10 was beneficial but marginal, adding considerable volume to the set of precoordinated codes that often consist of concatenated concepts reflecting separate conceptual dimensions. The transition to ICD-11 is likely to be much more impactful by shifting emphasis and capability to post-coordination (i.e., adding and joining codes to express more detail across conceptual dimensions) and thereby introducing new flexibility and clinical precision to patient records. For example, users can look forward to much richer information about separate dimensions of acuity, laterality, and severity, and the interrelations among clinical concepts describing a patient at once and over time.

With such important goals and so many related activities dependent on the coding system, it behooves the US to build it expeditiously and intentionally to answer the questions and solve the problems that are hindering the current system from achieving the overarching goal. The purpose should be redefining and not just enhancing administrative data to optimize the utility of the coding system. If we create the suitable core system once, then it will flow down and be available for multiple use cases all operating in alignment.

My work has focused primarily on Research (#5) and Payment Systems (#7) in Figure 1. Having bumped up against many limitations rooted in ICD-10-CM, I have collaborated over the past year with a team of like-minded academicians, clinicians, analysts, informaticists, and healthcare consultants. Collectively, we have created and utilized administrative and clinical databases to inform patients, providers, payers, researchers, administrators, and regulators about ways to improve the cost-effectiveness of healthcare services and value.

In our experience, the evaluation of comparative healthcare performance, the development and assessment of improved healthcare technology and practice, and the assessment of public policies, and clinical and health services research all currently suffer from the lack of a longitudinal patient perspective on care delivery, payment and reimbursement. Significant

information gaps exist on the onset and progression of clinical conditions and their response to therapeutic regimens.

Importantly, the adoption of ICD-11 can facilitate the creation of databases that can support a patient-centered information system that could subsequently support patient-, condition-, treatment-, and specialty-level analytics. This approach might help to mitigate significant tendencies toward fragmentation in care and dysfunctionalities arising from competing payer-, credential- or specialty-centered objectives. Embracing a principle of patient-centeredness could facilitate coding that optimizes total patient care over time and across all settings and specialties.

Figure 1: A Coding System to Drive a Sustainable, High-Value Healthcare System

For these reasons moving from ICD-10-CM to ICD-11 could be a game-changer for many of the applications and organizations with which we are involved. By integrating ICD-11 with electronic health records (EHRs) and healthcare IT systems, ICD-11 can become a universal translator of local data into a language that can facilitate digital data exchange (interoperability). By exploiting the ICD-11 architecture and syntax, clinically richer and more nuanced data could support many applications that are struggling, such as value-based care and payment.

Furthermore, by accessing important clinical data fields and social factors, patient records can be much more useful for coordinated care and related purposes such as monitoring care patterns, clinical outcomes, and resource use.

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? Respondents may choose to refer to NCVHS' most recent recommendations to HHS for proposed research questions, many of which HHS has not yet addressed.**

Because any such transition will impose administrative burdens on stakeholders who interact with the coding system, the default or common first response from many stakeholders might be to delay or avoid ICD-11 altogether. To overcome inertia or even resistance, NCVHS has presented a set of useful research questions, which generally fall into the major categories of "why" and "how." As such, the expected benefits should be spelled out or even quantified in some cases. Similarly, initial sites could work through the logic and mechanics of the implementation process and provide guidelines and lessons for others to follow.

- A key objective should be to optimize the utility of the new system to allow the benefits to flow down to stakeholders and use cases. This speaks again simply redoing or incrementally modernizing ICD-10-CM. ICD-11 offers many more benefits that should be exploited, which means to some extent, mandated.
- Notwithstanding the need to go far beyond ICD-10, we should minimize the burden of switching by making the transition seamless from ICD-10-CM. That means users should be able to code in ICD-10-CM with tools that automatically translate those into ICD-11, and vice versa: original coding in ICD-11 should automatically translate back to ICD-10-CM when needed.
- The government should provide or arrange for tools that automate coding and translation, such as those offered by WHO.
- The government should fund and/or disseminate results from case studies of pioneering ICD-11 installations. Ideally, some such installations might take the form of data laboratories that can illustrate side-by-side performance comparisons of clinical summaries and analytic results based on ICD-10-CM and ICD-11, respectively. For example, how would estimates of resource use or clinical performance change with better data?

We would benefit from the results of research and development (1) that links ICD-10-CM codes directly to the most appropriate ICD-11 cluster; (2) that relates ICD-11 clusters to their most faithful representation in ICD-10-CM; that substitutes a US-specific linearization for a new ICD-11 clinical modification; that relates ICD-11 stem and extension codes directly to fields in EHRs; and that expands the capabilities of the coding system by adding combinations of stem codes and extension that enable analysts to track the detailed course of a patient's health status, relate changes in a patient's health status to diagnostic and therapeutic interventions, assess the effect of alternative clinical interventions on a patient's health status, assess comparative risk-adjusted clinical outcomes and guide healthcare quality improvement initiatives. Extension of the WHO coding tool for MMS to support the US clinical linearization with its expanded capabilities would also be of particular value.

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

ICD-11 has breakthrough potential in several respects. However, it must be implemented properly to better meet various needs, which among other considerations, means adopting and mandating a US version ("linearization") that is more capable than the WHO's Mortality and Morbidity System (MMS) alone, which is well suited to support cause-of-death statistics.

In distinction from mortality, the US should optimize measurement of morbidity with respect to patients' needs, changes in their clinical status over time, and their response to encounters with the healthcare system and therapeutic regimens. For example, tracking hypertension would help inform public health efforts, manage population health, and understand clinical progression and responsiveness to prescribed medications singly or in combination.

That speaks to the advantages for appropriate treatment and management of chronic conditions, post-marketing surveillance of pharmacologic therapeutics, and evidence to support clinical guidelines. Universal tracking of diagnosis and symptoms would greatly improve monitoring of public health and epidemiological patterns.

In a different example, coding the severity of osteoarthritis could support research and clinical practice regarding the appropriateness of costly procedures such as joint replacement. It would also help with risk adjustment to measure differential rates of procedures, complication rates, and efficiency comparisons. Moreover, as payment models require accurate predictions of resource use, their success will likely come only after transitioning to ICD-11 and reducing the bias in estimates. For example, the Medicare Advantage program could benefit from coding that is strictly linked to clinical databases to permit validation and is sufficiently precise to quantify measurable differences in resource needs for valid risk adjustment and performance evaluations.

The pursuit of value through value-based payment and performance comparisons is impeded by the lack of clinical precision and details. For example, there is substantial morbidity and costs associated with heart failure in the Medicare population. ICD-10-CM coding acknowledges heart failure but omits information that could be used to stratify patient cohorts according to severity or manifestations. Treatment requirements, functional limitations, risk of progression and death, and resource use are all highly variable and skewed within a heart failure cohort, and highly correlated with categorical designations such as the New York Heart Association Classification of I (No limitation or symptoms) through IV (Severe limitation or symptoms at rest or with any activity). Without the ability to observe or risk-adjust for such differences, then direct comparisons or measurements against benchmarks are suspect, and potentially worse, are gameable. Entire industries support "risk-bearing" organizations in defining clinician networks based on their profiles as observed against the expectations set by inadequate coding and risk-adjustment systems.

The result under status quo (ICD-10-CM) is not even a zero-sum game, but a negative sum game in which financial rewards flow mistakenly to winners who beat the expectations fortuitously or by carefully managing "who" is being evaluated against poorly informed reference standards. Value-based payment can become cost-increasing because it rewards "savings" that not only were not induced by the program but were actually not real. At the same time, clinicians who

treat sicker patients might be dinged for their falsely inferred "subpar performance," especially when programs are mandatory or there is little opportunity or motivation to game the system.

Using the previous example, a clinical group who is managing a patient cohort with heart failure, 20% of whom are NYHA Class IV (severe), will not exhibit "high value" when judged against reference standards that assume (but cannot verify) only 10% of patients are Class IV. However, other groups who happen to have, or who "manage" to have fewer than 10% of patients with Class IV could have an easy time exhibiting false signals of "high quality" and "efficiency."

The problem illustrated here with heart failure is more the rule than the exception. Clinical situations involving significant morbidity and resource use generally involve highly skewed inputs and outputs that will be unpredictable and gameable until we implement a better coding system. Until then, the billions of dollars being spent on driving high value have not been and will not be effective. However, they have established an infrastructure through which better data systems, unbiased performance inferences, and accurate value-based payment might eventually flow.

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)?**

Policymakers, clinicians, and program managers should specify their data needs, and ICD-11 should be configured and optimized to meet those needs. Many social and incidental factors have been available in current coding systems but underutilized. By making sure that data needs are met to an optimal degree, net benefits to society can be optimized. Regarding behavioral health, ICD-11 would capture granular and clinically important information about symptoms, manifestations, severity and etiology, which align with the approach taken in DSM-5.

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

With careful planning, the US could implement ICD-11 expeditiously and with optimal net benefits. First, the US should start with a version (linearization) of ICD-11 that can mimic ICD-10-CM. That would avoid the need to reinvent ICD-10-CM using ICD-11 codes just to meet current data needs and would permit a smooth transition of information systems to ICD-11. Second, the mandated version of ICD-11 in the US should facilitate access to all "Entities" (clinical concepts) available in the ICD-11 Foundation.

Third, compared to ICD-10, the linearization should provide better support to clinical care and other use cases and help the US achieve the overarching goal. In a phrase, we need a clinical linearization that captures the evolution of patients' health and their response to therapeutic regimens. We have nearly completed a linearization that captures that concept, which we call the Clinical Linearization, Evolution and Response (CLEAR). Additionally, it is comprehensive with respect to accessing all entities in the Foundation, and largely able to mimic ICD-10-CM through a combination of identical precoordinated stem codes and post-coordinated code clusters that include extension codes. We call this the Comprehensive CLEAR, or C-CLEAR.

Our wish is for C-CLEAR to be accessible in the public domain and for the US to study, test, vet, and modify C-CLEAR to the satisfaction of policymakers and interested stakeholder groups. This process can involve requests to the WHO for any additions to the Foundation or augmentations to coding or syntax. Starting with C-CLEAR should be particularly advantageous because it perfectly preserves the WHO's MMS version as a subset within. Meanwhile, modifications to C-CLEAR can occur while maintaining a stable crosswalk to all the contents, codes, and hierarchies comprising MMS.

We suggest that the result be implemented through rulemaking, specifically the requirements for Medicare, DHHS, and other relevant agencies. We tentatively call this future version CLEAR for the United States, or US-CLEAR. Other countries could follow the same pathway (e.g., KOREAN-CLEAR in 2028).

6. **The World Health Organization (WHO) recommends establishing a national center for ICD11 implementation. What entity should be responsible for coordinating overall national implementation of ICD-11 for morbidity coding, and how should the implementation be managed?**

Looking at the information available on its website, it appears that the NCVHS is best suited to coordinate overall implementation. Its charter to review proposals, stimulate and evaluation options, and connect to DHHS and Congress would facilitate careful action. Its existing connections to NCHS and CDC, as well as ASPE also could facilitate its coordinating role. Interactions can occur as needed with CMS to assist with program needs, and AHRQ and the National Library of Medicine for research topics and support for the healthcare community.

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?**

It is our understanding that the National Center for Health Statistics (NCHS) is heavily involved with the curation of ICD-10-CM. While the WHO has ended support for ICD-10, it solicits requests from around the world to help make ICD-11 better for all users. With development and refinement of US-CLEAR, the NCHS could work with the WHO to ensure the adoption of post-coordinated codes and clusters, and any new Foundation entities. As with the NCVHS for overall coordination, NCHS could work closely with "policymaking" agencies to ensure that refinements are timely and sufficient.

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

To answer this question, we assume that the US follows our suggestions in response to question 5., above and adopts a version of ICD-11 that mimics ICD-10-CM but is configured to better meet analytic and policy-related requirements. As described above, we would offer for the US to start with C-CLEAR (unlimited precoordinated detail) in the public domain rather than MMS, and eventually curate and mandate US-CLEAR. (Note that if entities in C-CLEAR that are not specifically included in MMS are removed, C-CLEAR reduces to an exact replica of MMS.)

Post-coordination details already standardized in MMS for conditions such as COPD (e.g., the Global Initiative for Lung Disease, or GOLD stages), congestive heart failure (NYHA classification), and cancer staging) could be utilized to provide important clinical details not currently available in ICD-10-CM. The NCVHS could coordinate an effort to select priority conditions in the US for which such standard definitions could be mandated (e.g., for Medicare claims and encounters), and NCHS could ensure that criteria and applicable thresholds are specified properly. Over time, the US could extend or modify the list of conditions and required details.

The data elements of standard reimbursement claim forms are not written in stone. Rethinking the required data elements for the new era of EHRs can help in several ways. Enhanced data would allow payment incentives to be better designed to optimize clinical outcomes and resource use and improve data collection as needed for analysis by mandating additional EHR-sourced data elements for claims and payment, thereby, among other things supporting analytics and progressively improved incentives. The additional fields could be based on test results, severity indicators, condition stages, etc.

Without altering either the current ICD-11 dictionary or architecture, US-CLEAR could provide an opportunity for clinicians to capture important information about the evolution of disease within a diagnostic category and responses to medical therapy. For example, a major improvement in the WHO operational recommendations would be to add post-coordination with extension codes for ‘medicaments’ to conditions that are being treated. Untreated moderately elevated blood pressure in essential hypertension (currently coded as BA00.Z in MMS) might be coded as BA00.Z&XS0T. If the same patient, now being treated with propranolol and furosemide, is seen with a mildly elevated blood pressure, this response to therapy could be captured with the code BA00.Z&XS5W&XM3HA9&XM8UE3. This degree of detail could potentially permit the creation of a credible representation of a patient’s clinical course directly from ICD-11 codes.

To better capitalize on these new capabilities, additional resources could include a framework or data model for linking US-CLEAR data elements to fields in EHRs. This would include a detailed data dictionary for US-CLEAR along with algorithms for properly specifying extension codes (i.e., modifiers) such as severity (e.g., mild, moderate, severe).

Going a step further, it would be very helpful to offer a user-friendly software coding tool for US-CLEAR expanding on the WHO offering for MMS. As such, clinicians and coders need only type or speak relevant clinical terms, and the coding tool can suggest the best precoordinated stem codes along with post-coordination code clusters.

From: Betsy Nicoletti
To: NCVHS Mail (CDC)
Subject: Transitioning to ICD-11
Date: Wednesday, July 5, 2023 1:14:05 PM

Good afternoon,

I am a coding consultant and trained medical practice groups during the transition from ICD-9 to ICD-10. I have worked in health care my entire life, and want to share my perspective:

- It was the biggest waste of health care dollars I've ever seen.
- The "this will improve quality" was an unfounded, unmerited claim.
- The clinical modification version added unnecessary and unneeded specificity, particularly in laterality and location. It did give payers another reason to deny claims.
- CMS's HCC model is only now starting to use ICD-10.

My input: don't do it. If you must do it, decrease the size of the clinical modification version to include only clinically relevant codes.

Respectfully,

Betsy Nicoletti, M.S., CPC

www.CodingIntel.com

August 2, 2023

To the National Committee on Vital and Health Statistics (NCVHS):

Re: Response from The Cooperative Exchange regarding ICD–11 RFI.

On behalf of The Cooperative Exchange[1], I am writing to provide comments in response to the Request for Information regarding ICD-11. The purpose of this RFI is to gather information and identify gaps in currently available information and research essential for analysis and policy decisions on the U.S. approach to support adoption and implementation of ICD–11 for morbidity.

The Cooperative Exchange Comments:

The Cooperative Exchange has reviewed the questions included in the RFI and provides the following comments:

Question 1 - What would be the benefits of implementing ICD–11 for morbidity in your setting or organization?
The Cooperative Exchange does not see benefits in implementing ICD-11 for morbidity from a clearinghouse perspective. Because the role of a clearinghouse is to facilitate the exchange of data between trading partners, potentially converting from a non-standard format to a standard format, the content of the data including ICD-11 information provides no benefit to clearinghouses.

Question 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?
Clearinghouses will need:

- Education on ICD-11, including differences in the structure of the codes and in the code set
- A detailed crosswalk from ICD-10 to ICD-11
- A detailed timeline with milestones outlined to ensure timely implementation
- Consistent testing approaches to be used across the industry
    - Certification opportunities, for example a process to confirm that a clearinghouse's ICD-11 work is syntactically correct. Certification could reduce the testing burden on all trading partners; however, there should not be a requirement to pay a fee to certify, and the certification process must not be burdensome. (for example, use of the existing ASETT tool is a potential option). Names of entities that have successfully tested with the ASETT tool could be made public.

Updates to a version of the mandated X12 transactions that supports ICD-11 must be in place prior to the ICD-11 implementation, along with updates to applicable operating rules. Due to the lengthy, burdensome process that must occur to update the versions of the standards used, any work to implement ICD-11 would reflect a timeline

[1] The Cooperative Exchange (CE) is comprised of 23 of the leading clearinghouses in the US. The views expressed herein are a compilation of the views gathered from our member constituents and reflect the directional feedback of the majority of its collective members. CE has synthesized member feedback and the views, opinions, and positions should not be attributed to any single member and an individual member could disagree with all or certain views, opinions, and positions expressed by CE.

of approximately 10 years for ICD-11. The Cooperative Exchange would like to remind the NCVHS of testimony provided at the NCVHS January 2023 hearing on updates to the X12 transactions, and the recommendations made regarding implementing a framework for regular, predictable updates to the transactions that would update transactions in a predictable cadence (for example every 3 years).

The Cooperative Exchange would also like to point out that only 35 countries have implemented ICD-11 worldwide as opposed to 117 that have implemented ICD-10, so globally we are early in the process of implementing ICD-11.

Question 3 - What considerations affect the impact of ICD–11 on clinical documentation, payment processes including risk adjustment, public health, population health, or research?
The Cooperative Exchange does not have a comment on this question.

Question 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)?
Updated versions of the mandated X12 transactions must accommodate all coding / terminology considerations included in the coding (e.g. sexual orientation, gender) before ICD-11 implementation commences.

Question 5 - How should HHS implement ICD–11 in the U.S. for morbidity coding?
The Cooperative Exchange strongly advocates for a hard cut over from ICD-10 to ICD-11 based on date of service. Not all trading partners will be ready at the same time, so clearinghouses will be required to support both versions and potentially reject transactions back to providers to code correctly. If clearinghouses do not reject transactions that include ICD-10, they would be considered out of compliance. Clearinghouses will also be required to track the capabilities of all trading partners with respect to ICD-11. An additional consideration - Provider Practice Management Systems / Accounts Receivable Systems must support the cutover to ICD-11 early in the implementation timeframe.

Additionally, ICD-11 should be implemented only after a clear return on investment is established to show that there is value in using the updated code set for morbidity, and that it outweighs the implementation costs.

Question 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?
The Cooperative Exchange recommends that CMS be the organization named to be responsible for the coordination. Their scope would need to cover all payers including commercial, not just the government payers.

Question 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?
The Cooperative Exchange does not have a comment on this question.

Question 8 - What resources, tools, or support will your organization need for implementation?
Clearinghouses will need:

- Education on ICD-11 and the differences between ICD-10 and ICD-11
- Crosswalks between ICD-10 and ICD-11
- Recommended industry milestones
- Testing tools
- Website that lists entities that are ready to test
- Industry portal to submit issues and questions
- Additional staffing / time and corresponding additional resources

Medicaid payers and small health plans will need additional funding to ensure they can meet the implementation deadlines. The clearinghouse experience is that these plans have historically had challenges meeting the mandated timelines resulting in outliers to the uniform implementation of standards and code sets.

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

- Timely release of policy guidance
- Development of a specific ICD-11 frequently asked question section on the CMS website
- Stakeholder-specific educational webinars (live and on demand)
- Regular review of industry readiness
- Include an ICD-11 support component into the ONC electronic health record certification program
- Incorporate ICD-11 into the provider Merit-based Incentive Payment System (MIPS)
- Work collaboratively with WEDI and other industry organizations to develop and disseminate implementation resources

Clearinghouses specifically will need:

- Crosswalks to map ICD-10 to ICD-11
- Testing Tools
- A portal reflecting testing readiness of industry stakeholders
- A standard industry tool to provide certification of clearinghouses ready for ICD-11 (for example the existing ASETT tool). A certification process may alleviate the need for end to end testing (note – most payers do not have a test system that can do end to end testing)

Question 10 - What workforce, workforce planning, or training will your organization need to support implementation?
Clearinghouses will need:

- Education on ICD-11 and the differences between ICD-10 and ICD-11

- Crosswalks between ICD-10 and ICD-11
- Recommended industry milestones
- Testing tools
- Website that lists entities that are ready to test
- Industry portal to submit issues and questions
- Additional staffing / time and corresponding additional resources
- Additional resources to correspond with direct trading partners to communicate their ICD-11 readiness

Medicaid payers and small health plans will need additional funding to ensure they can meet the implementation deadlines. The clearinghouse experience is that these plans have historically had challenges meeting the mandated timelines resulting in outliers to the uniform implementation of standards and code sets.

Question 11 - What are your organization's requirements for ICD–11 mapping to other coding systems and terminologies, including value sets?
Crosswalks will be needed for providers and medical coders.

Question 12 - What other operational impacts of ICD–11 adoption and implementation should HHS consider?
The Cooperative Exchange recommends that the ICD-11 implementation NOT occur simultaneously with an update to a version of the mandated X12 transactions that support ICD-11. Implementing an updated version of the mandated X12 transactions to a version that supports ICD-11 needs to happen before the implementation of ICD-11. We also recommend looking at lessons learned from the ICD-10 implementation to identify best practices for use with ICD-11.

Additional Comments – How Clearinghouses can assist in the implementation of ICD-11.

Clearinghouses are in a unique position to assist in the tracking and testing processes of implementation. We are the primary conduit for many providers and health plans in the exchange of transactions and can determine who may be ready to start testing and connect them with partners who are ready. In past transitions, clearinghouses have been able to survey their connections to determine readiness, and check transactions to assure that the correct version of the code set is being sent.

Additionally, clearinghouses can serve as educational resources to their customers, distributing industry approved guidance and collecting questions to forward to coding resources, CMS, and other partners. We would be pleased to discuss this further with the NCVHS Workgroup on Timely and Strategic Action to Inform ICD-11 Policy, either at the roundtable meeting in August or elsewhere.

Conclusion

In summary, The Cooperative Exchange strongly urges NCVHS to recommend updating the version of the mandated X12 transactions and corresponding operating rules prior to any implementation of ICD-11 to ensure

that the transactions support not only ICD-11, but also any coding / terminology considerations that must be included. Education and tools are needed for the industry, including a certification tool for clearinghouses to use to indicate ICD-11 readiness, which would eliminate the need for end to end testing between trading partners. The Cooperative Exchange appreciates the opportunity to comment, and we welcome the chance to discuss and elaborate on our comments if needed.

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.

From: Elizabeth Miller
To: NCVHS Mail (CDC)
Subject: Response from Haskell Memorial Hospital regarding ICD–11 RFI.
Date: Saturday, July 1, 2023 1:30:50 PM
Attachments: image001.png

Elizabeth A. Miller, C.P.A.
Consulting Chief Financial Officer
Haskell County Hospital District
1 Avenue N
Haskell, TX 79521
Direct Phone: 940-228-3349
Main Phone: 940-228-4321
Cell: 325-669-7442 (please feel free to text)
emiller@hmhhealth.org
www.haskellmemorialhospital.com

From: Kimberly Hogan <khogan@hccscoding.com>
Sent: Friday, June 30, 2023 8:40 AM
To: Elizabeth Miller <emiller@hmhhealth.org>; Pam Snow <psnow@hmhhealth.org>; Michelle Stevens <mstevens@hmhhealth.org>; Mary Belle Olson <mbolson@hmhhealth.org>; Meghan Shelton <mshelton@hmhhealth.org>; Crystal Molina <cmolina@hmhhealth.org>; Kris Mitchell <kmitchell@hmhhealth.org>
Subject: RE: IMPORTANT: FORHP Notice and Request for Information Regarding ICD-11

Good Morning Elizabeth,

Thank you for the opportunity to provide valuable insights and address the questions outlined regarding the implementation of the International Classification of Diseases, 11th Revision (ICD-11) for morbidity coding. As a recognized leader in the healthcare industry, our organization is committed to enhancing patient care, improving data interoperability, and staying at the forefront of international health classification standards. With that, below are some of our insights regarding the benefits of implementing ICD-11, highlight key considerations and requirements specific to the U.S. healthcare landscape, and provide recommendations for a successful transition to ICD-11. We appreciate you allowing us to contribute to the dialogue surrounding this important initiative.

Benefits of implementing ICD–11 for morbidity:

- Enhanced clinical decision-making: During the planning phase, it is important to prioritize training and education programs to ensure healthcare professionals are equipped with the knowledge and skills to effectively utilize the new classification system.
- Improved accuracy and specificity in diagnoses: Consider implementing data validation processes and quality assurance measures to ensure accurate coding and documentation practices, which may involve the development of coding guidelines and documentation templates.
- Better patient outcomes: As part of the planning phase, it is crucial to establish mechanisms for monitoring and evaluating the impact of ICD-11 implementation on patient outcomes, allowing for the identification of any improvements or areas requiring further attention.
- Improved data interoperability: Evaluate the compatibility of existing health information systems with ICD-11 and plan for necessary system upgrades or integrations to ensure seamless data exchange and interoperability across different healthcare settings.
- Facilitated research collaboration: Foster collaborations with research institutions and establish frameworks for data sharing and research collaboration, considering the establishment of data standards and guidelines for

research studies using ICD-11.

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

- Assessing the costs and benefits: Conduct a comprehensive analysis of the potential costs associated with system upgrades, training, and implementation, while also identifying the expected benefits in terms of improved clinical outcomes, data quality, and research capabilities.
- Implementation approaches: Research and gather information on successful implementation approaches from similar organizations or healthcare systems to inform the planning and execution of the transition process.
- Communications and outreach: Identify the key stakeholders and develop communication strategies to effectively inform and engage them throughout the transition process, considering methods such as workshops, webinars, and targeted outreach campaigns.
- Research gaps and recommendations: Review the latest recommendations from organizations to identify research gaps and propose research questions that can inform the implementation process and assess its impact.

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

- Clinical documentation: Plan for training and education programs to ensure healthcare professionals understand the new documentation requirements and are able to accurately capture the necessary information using ICD-11 codes.
- Payment processes and risk adjustment: Assess the impact of ICD-11 on existing payment processes, including risk adjustment methodologies, to ensure appropriate reimbursement and financial sustainability during the transition period.
- Public health and population health: Consider the implications of ICD-11 for public health monitoring and disease surveillance and explore how the new classification system can enhance the collection and analysis of population health data.

Research: Evaluate the impact of ICD-11 on research studies and databases, considering the compatibility of data collected using ICD-10 with the new classification system and developing strategies for data migration and harmonization.

- Community health and social determinants of health: Ensure that the coding and terminology in ICD-11 adequately capture information related to community health and social determinants of health, allowing for better understanding and addressing of population health disparities.
- Obesity: Address the coding and documentation requirements related to obesity to better capture the impact of this health condition and enable appropriate management and resource allocation.
- External cause of injury: Ensure that the coding system accommodates detailed information regarding the external cause of injuries, facilitating accurate injury surveillance, prevention efforts, and resource planning.
- Mental, behavioral, or neurodevelopmental disorders: Align coding and terminology with the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) to support consistent and comprehensive classification and treatment of these disorders.

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

- Determine an implementation timeline and phased approach that allows for proper planning, testing, and stakeholder engagement.
- Assess the readiness of healthcare providers, payers, and health information systems to adopt ICD-11, and develop strategies to address potential barriers or challenges.
- Establish clear communication channels to disseminate guidelines, educational resources, and updates to stakeholders, ensuring a coordinated and well-informed transition process.
- Collaborate with relevant professional associations and organizations to develop implementation guidance, training programs, and support materials tailored to the specific needs of different healthcare settings.

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?

- Consider the creation of a national steering committee or task force composed of representatives from key stakeholders, including government agencies, professional associations, healthcare organizations, and academia, to oversee the overall implementation process.
- Define the roles, responsibilities, and decision-making authority of the coordinating entity, ensuring effective collaboration and representation of diverse perspectives.
- Develop a management framework that includes regular communication, progress monitoring, and feedback mechanisms to facilitate collaboration and address implementation challenges.

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?

- Establish a designated entity within the U.S., such as a national health agency or a specialized committee, responsible for coordinating and reviewing requests for updates or changes to ICD-11.
- Develop a structured and transparent process for submitting requests, involving the collection of relevant evidence, expert review, and stakeholder consultation to ensure the quality and validity of proposed modifications.
- Collaborate with the World Health Organization (WHO) and international stakeholders to align national requests with global updates and foster a consistent and harmonized approach to ICD-11 modifications.

In conclusion, the implementation of ICD-11 for morbidity coding presents significant opportunities for our organization and the U.S. healthcare system as a whole. By embracing this updated classification system, we can enhance clinical decision-making, improve data interoperability, and align with global standards. However, a successful transition requires careful planning, collaboration, and adequate support. We remain committed to working closely with all stakeholders to address the identified considerations, establish an effective implementation framework, and ensure a seamless adoption of ICD-11. Together, we can leverage the benefits of this advanced classification system to drive better healthcare outcomes, advance research and population health initiatives, and deliver improved care to the communities we serve.

Thank you again for considering our input, and we welcome the opportunity to further discuss our recommendations and contribute to the successful implementation of ICD-11.

HCCS Healthcare Coding & Consulting Services

Kimberly Hogan, RHIA, CHPS | Senior Client Services Manager
Direct: 806.236.1392 | Fax: 239.443.1484
khogan@hccscoding.com
www.hccscoding.com

From: Elizabeth Miller <emiller@hmhhealth.org>
Sent: Wednesday, June 28, 2023 4:59 PM
To: Kimberly Hogan <khogan@hccscoding.com>; Pam Snow <psnow@hmhhealth.org>; Michelle Stevens <mstevens@hmhhealth.org>; Mary Belle Olson <mbolson@hmhhealth.org>; Meghan Shelton <mshelton@hmhhealth.org>; Crystal Molina <cmolina@hmhhealth.org>; Kris Mitchell <kmitchell@hmhhealth.org>
Subject: RE: IMPORTANT: FORHP Notice and Request for Information Regarding ICD-11

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe. Please forward any suspicious emails to support@hccscoding.com

Intelligent Medical Objects
9600 W Bryn Mawr Avenue
Suite 100
Rosemont, IL 60018

P: 847-272-1242
F: 847-272-7968
jbronnert@imo-online.com
trihanek@imo-online.com

www.imohealth.com

June 29, 2023

ICD-11 RFI Comments

Dear National Committee on Vital and Health Statistics,

Thank you for the opportunity to provide information for the expert roundtable meeting being held August 3, 2023. Based upon the questions outlined in the request for information, IMO has the following comments.

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

- ICD-11 provides the needed flexibility to capture new discoveries in medicine. ICD-11 allows for the easy addition of extension codes to enhance existing disease and disorder concepts to provide additional granularity.
- As indicated by the World Health Organization (WHO), ICD-11 reflects medical and technologic advancements that ICD-10 is unable to leverage due to its fundamental structure. The ICD-10-CM/PCS Coordination and Committee must adhere to this structure when making new classification determinations. The clinically outdated structure presents challenges to classify disease states according to medical knowledge advances. Currently ICD-10-CM has difficulty in appropriately classifying rare disorders, genetic related disorders, etc. due to limitations within code categories and structure.
- ICD-11 is based upon an ontological structure. The flexibility of an ontological structure will help streamline the code update process. The additional granularity and postcoordination that is available in ICD-11, as well as the ability to store and leverage unique resource identifiers (URIs) will provide detailed information for a wide variety of use cases for coded data.
- Implementing ICD-11 in the United States (U.S.) would facilitate international data comparison as the U.S. data would be compatible with international standards and data structures.
- ICD-11 is designed to leverage health technology advancements thus eliminating the need for manual books.

© 2023 Intelligent Medical Objects, Inc. All rights reserved. IMO and INTELLIGENT MEDICAL OBJECTS are registered trademarks of Intelligent Medical Objects, Inc.
IMO confidential information, not to be shared with third party without IMO consent.

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? Respondents may choose to refer to NCVHS' most recent recommendations to HHS for proposed research questions, many of which HHS has not yet addressed.[5]

- IMO recommends the proposed research questions be addressed by NCVHS. The answers to those questions impact the cost, benefits, risks, and implementation approaches. For example, content evaluation which includes but is not limited to mandated post-coordinated extensions or semantic comparability studies will impact the answers to overall cost, return on investment and implementation strategy.
- Industry and organizational technology debt and stack costs to accommodate ICD-11 will need to be quantified. This includes technological changes necessary to effectively capture the full capacity of the system. Providing guidance on implementing ICD-11 across the ecosystem supports organizations being able to quantify and estimate the cost of the transition.
- How will post-coordination be used effectively throughout the healthcare ecosystem? What data infrastructure could be used to support post-coordination and how would it be developed? For example, will it be possible for the uniform resource identifier from the Foundation and Mortality and Morbidity Statistics (MMS) to be leveraged to provide the data necessary to support all aspects of healthcare?
- Definition of a complete ICD-11 code for reporting is necessary. What is the level to which stem and extension codes must be applied to be considered a complete code?

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

- Clinical documentation should remain independent of any coding system. Providers must be able to document clinical conditions which may or may not be represented in any code system. COVID-19 is a good example, as the disease state occurred before any industry standard code system created a code and code description.
- All systems and processes leveraging ICD-10-CM codes and descriptions will need to be evaluated for impact on transitioning to ICD-11. This includes payment systems, public health, social service entities addressing social determinant of health needs, population health and research.
- Will there be consistency across payers in the definitions as to a complete code? Will some payers only want to base payment off the stem code? What level of post-coordination is necessary to adjudicate a claim?

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)?

© 2023 Intelligent Medical Objects, Inc. All rights reserved. IMO and INTELLIGENT MEDICAL OBJECTS are registered trademarks of Intelligent Medical Objects, Inc.
IMO confidential information, not to be shared with third party without IMO consent.

- Is this question related to how the U.S. should use the current WHO links to other systems such as ICD-O or ontologies like MONDO etc.? Or is the question addressing if ICD-11 should represent concepts contained within other systems such as International Classification of Inherited Metabolic Disorders (ICIMD), or Orphanet uniquely?
- NCVHS must determine how the U.S. will address the need to capture conditions unique to the U.S. For example, is there is a need for a U.S. 'extension' without a complete modification or will an entire modification need to be established? The 'extension' model approach would be like the SNOMED approach to addressing country specific requirements.
- ICD-11's infrastructure presents new questions for implementing countries that were not considerations with prior ICD version implementations. For example, if the U.S. has unique ICD coding requirements that require either an extension or modification, will the U.S. create its own type of URI to align to the WHO's foundation/MMS?
- The trend of ICD-10-CM new code requests are for increased specificity especially in the area of rare diseases and genetic related conditions. Identifying how ICD-11 fits the industry's need to capture these types of conditions is an important consideration.

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

- Refer to lessons learned from the transition to ICD-10-CM along with the letters sent from NCVHS to HHS regarding future coding standard updates.
- Health and Human Services should evaluate the rule making process for updates to coding systems.
- Consideration for all types of organizations using ICD coded data must be evaluated for implementation of ICD-11. For example, will entities not covered under current HIPAA rules and regulations be required to implement ICD-11?
- The maintenance process must be evaluated to ensure the U.S. coding or terminology considerations are addressed. The current process of bi-annual code updates supports having new codes available for industry use after being vetted according to the established process.

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?

- National Center for Health Statistics (NCHS) should be named as the national implementation center with input from the Cooperating Parties, Office of National Coordinator (ONC), National Library of Medicine (NLM), Centers for Medicare and Medicaid (CMS), Centers for Disease Control (CDC), Office of Inspector General (OIG), other appropriate federal agencies, and industry experts.
- The fundamental principles used for ICD-10-CM implementation should be evaluated to determine which aspects should be leveraged for ICD-11 implementation.
- The established ICD code set management process should be evaluated to determine which aspects support ICD-11 implementation and ongoing maintenance of the system.

© 2023 Intelligent Medical Objects, Inc. All rights reserved. IMO and INTELLIGENT MEDICAL OBJECTS are registered trademarks of Intelligent Medical Objects, Inc.
IMO confidential information, not to be shared with third party without IMO consent.

- National implementation must consideration as to which linearization (MMS) will be leveraged or if other linearizations would be useful for specialties (i.e., mental health) and how the two different linearizations are harmonized.

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?

- As noted in #6, the NCHS should continue to coordinate U.S. requests for updates. The process, including the timing of requests/submissions should be evaluated to determine if the current ICD-10 Coordination and Maintenance meeting format supports ICD-11 maintenance process.
- The ICD-11 MMS appears to be much more fluid in update structure so versioning will be an important consideration for the U.S.

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

- Syntax that will be accepted for interoperability between other healthcare organizations, payers will need to be available for organizations to make necessary system modifications as necessary.
- The WHO ontology should be considered open source and shared publicly.
- Technical specifications need to be at an industry level. For example, what is a 'fully specified' ICD-11 code and how will it be reported across the ecosystem? In ICD-10-CM, it is clear from the guidelines, that a fully specified code may be between three (3) to seven (7) characters.
- The industry needs established coding guidelines for appropriate code assignment. For example, how many or which extension codes are required versus optional capture. Are there certain extension codes that should never be captured? If an extension code is considered 'optional', guidance is still necessary as organizations may choose to capture the optional codes.
- Resources outlining the desired state to maintain connections between the foundation and linearization is vital. Example, Aicardi syndrome has a unique URI in the Foundation, but the MMS uses a generic URI as it is classified as an 'other' condition in the MMS. Genetic conditions appear to follow a similar pattern. How will researchers be able to leverage the granularity of the Foundation URI, if it is not captured/stored and reported?

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

- The U.S. should have a browser (like current ICD-10-CM and/or WHO's) especially if the U.S. defines specific requirements of ICD-11 coding especially for extension reporting. If the U.S. does not use traditional medicine, do not make those selections available in a browser.
- Coordination of tools, resources and guidance across all government organizations as identified in question #6 is important to support the ICD-11 transition.

© 2023 Intelligent Medical Objects, Inc. All rights reserved. IMO and INTELLIGENT MEDICAL OBJECTS are registered trademarks of Intelligent Medical Objects, Inc.
IMO confidential information, not to be shared with third party without IMO consent.

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

- Reviewing workforce planning and training from ICD-10-CM implementation will facilitate identification of workforce needs to implement ICD-11. For example, education on what ICD-11 is and what it is not will be important. Coding specific guidelines for ICD-11 will require training.
- Technical infrastructure for appropriate ingestion of the system in order to leverage the richness of ICD-11 is another area to consider for the workforce.

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

- In general, many organizations will be interested in a forward and backward map between ICD-10-CM and ICD-11. The challenge of this cross map will be the post coordinated structure of the ICD-10-CM descriptions whereas ICD-11 may require multiple extensions. There will likely be several use cases to which a universal map may not fit.
- Organizations will also be interested in a map between ICD-11 and SNOMED.

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

- The transition to ICD-10-CM/PCS was delayed over several years. As the U.S. considers ICD-11, the timeline needed for healthcare organizations must be a primary consideration to avert prolonged delay.
- HHS should provide well developed and strong reasoning to assist the healthcare community in understanding the overall benefits of adopting ICD-11 and why it is in the best interest of the country and the individual organization to transition.

IMO is happy to further discuss our comments if NCHVS or the roundtable would like additional information. We appreciate NCVHS ‘s initiative to engage the community in evaluating the U.S. implementation of ICD-11 and look forward to roundtable discussions.

Best regards,

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

Theresa Rihanek, MHA, RHIA, CCS
Mapping Informaticist

© 2023 Intelligent Medical Objects, Inc. All rights reserved. IMO and INTELLIGENT MEDICAL OBJECTS are registered trademarks of Intelligent Medical Objects, Inc.
IMO confidential information, not to be shared with third party without IMO consent.

KAISER PERMANENTE®

June 30, 2023

National Committee on Vital and Health Statistics
National Center for Health Statistics
Centers for Disease Control and Prevention
Attention: ICD-11 RFI
311 Toledo Road
Hyattsville, MD 20782

Submitted electronically via NCVHSmail@cdc.gov

Re: National Committee on Vital and Health Statistics; Meeting and Request for Information

To Whom it May Concern:

Kaiser Permanente appreciates the opportunity to provide comments to the National Committee on Vital and Health Statistics (NCVHS) in response to the request for information (RFI) [1] soliciting public comment to inform analysis and policy decisions regarding adoption and implementation of the International Classification of Diseases, Eleventh Revision (ICD-11).

The Kaiser Permanente Medical Care Program[2] is the largest private integrated health care delivery system in the United States, with more than 12.7 million members in eight states and the District of Columbia. Kaiser Permanente's mission is to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve.

ICD-11 reflects critical advances in science and medicine to align classification with the latest knowledge of disease treatment and prevention. However, implementation for purposes of coding morbidity will be a significant undertaking with changes impacting nearly every aspect of health care, from clinical documentation and workflow processes to administrative transactions such as billing and quality reporting. We strongly urge HHS to work with industry stakeholders to identify issues and address concerns to facilitate implementation. Our high-level recommendations are summarized below, followed by more detailed comments.

- We recommend that HHS use lessons learned from the adoption of ICD-10 to avoid delays and known issues.

- We recommend that HHS provide more detailed information regarding the nature and scope of the expected changes, including a mapping between ICD-10 and ICD-11 and mapping to key international standards, including the systemized nomenclature of

[1] 88 Fed. Reg. 38519 (June 13, 2023).
[2] 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 39 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.

One Kaiser Plaza
Oakland, CA 94612

medicine clinical terms (SNOMED-CT) and logical observation identifiers names and codes (LOINC).

- We recommend that HHS assess all currently accepted and federally adopted coding and terminology standards for uniqueness compared to ICD-11.

- We recommend that HHS consider the possible impact of the transition to and use of ICD-11 on payment, reimbursement and other administrative processes, compared to the current use of ICD-10-CM and PCS.

- We recommend that HHS ensure alignment across all impacted agencies and organizations and allow sufficient time for implementation.

We appreciate HHS' consideration of the following comments.

Information Necessary to Inform ICD-11 Transition Cost, Benefits, Implementation

Kaiser Permanente agrees that the questions[3] NCVHS sent to HHS for consideration are appropriate research questions for HHS to evaluate in advance of ICD-11 implementation. We emphasize the importance of conducting an analysis to understand impacts of ICD-11 implementation on other adopted code sets, such as the Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), SNOMED-CT, and LOINC. More detailed information about the nature and scope of changes between ICD-10 and ICD-11 will help inform this analysis. We also emphasize the importance of an assessment to determine whether ICD-11 can fully support morbidity classification in the U.S. without development of a U.S. Clinical Modification (CM), including consideration of alternatives to U.S. CM such as post-coordination or a U.S. linearization or U.S.-specific extension codes. Development of a U.S. CM would increase costs, extend the time needed for implementation and impact other implementation activities. We recommend that HHS consider whether the level of granularity in ICD-11 matches clinical, public health or administrative needs or whether additional modifications are needed.

We recommend that HHS research and document the benefits and costs associated with the adoption of ICD-11 for morbidity coding and its corresponding use in clinical and administrative processes and transactions, particularly the impact on payment and reimbursement for health care services. It will also be valuable to understand the benefit of adopting ICD-11 in new payment models such as value-based care.

We also recommend HHS investigate instances of deprecated or deleted codes and provide recommended alternatives to promote standardization and efficiency among implementing organizations. It is important to understand what requirements will be needed for electronic health record (EHR) vendors to implement ICD-11 along with timelines for implementation for all impacted stakeholders including government agencies, health plans, health care providers and accrediting bodies to identify and account for interdependencies.

[3] NCVHS Letter to HHS Secretary, Updated Recommendations for Immediate Action on ICD–11 (Sept. 10, 2021): *https://ncvhs.hhs.gov/wp-content/uploads/2021/09/NCVHS-ICD-11-recommendations-for-HHS-Sept-10-2021-Final-508.pdf*.

Unique U.S. Coding or Terminology Considerations

We recommend that all currently accepted coding and terminology standards be assessed for uniqueness as compared to ICD-11. A governance model should be established to prepare specifications for coordinated coding solutions and consolidate terminology in consultation with entities that have published clinical practice guidelines for areas that have a high or increasing prevalence of morbidity and mortality (e.g., dementia, obesity, heart disease) and new areas of focus as predictors of health care costs (e.g., social determinants of health and behavioral health).

HHS should review any differences between U.S. SNOMED extension and the ICD-11 set to find potential areas that are unique to the U.S. Disabilities, genomic and pharmacogenomic attributes should also be explored for any unique U.S. considerations along with timing, revisions and chronicity of patient reported statuses or conditions.

Implementation of ICD-11 for Morbidity Coding

We recommend that HHS use lessons learned from the adoption of ICD-10 to avoid delays and known compliance issues such as the persistent use of older, more generic codes when newer, more specific codes were available. We recommend that HHS ensure the application of ICD-11 codes is budget-neutral so that the transition from ICD-10 to ICD-11 does not result in unintended increases or decreases in reimbursement for providers and payers. HHS should also ensure alignment across agencies and government programs.

HHS should develop a transition plan that might include allowing use of both coding systems for a period as entities update impacted systems and workflows. There will be multiple changes needed to implement ICD-11 with both upstream and downstream dependencies, and sufficient time is needed for testing. We recommend that HHS provide entities with at least 36 months after publication of a final rule to implement changes following adoption of ICD-11.

Resources, Tools, or Support Needed for ICD-11 Implementation

We recommend that HHS develop a detailed roadmap and transition plan for adopting and implementing ICD-11, including templates for health care organizations (providers, payers, public health, EHR/Health IT vendors, and others) to appropriately prepare to implement the new coding standard. We also recommend that HHS provide a comprehensive set of crosswalks along with standard terminologies and other classifications that provide the common medical language necessary for interoperability and the effective data sharing to facilitate a seamless transition.

Specific tools and resources include:

- EHR implementation standards and tools to support ICD-11 code sets including and data model development and replacement tools such as decision support builds, preference lists, documentation tools and dynamically suggested replacements for end-users.
- EHR integration playbooks and official industry transition guidebooks such as the ICD-10 Implementation Guide for Large Practices.
- Frequently asked questions (FAQ) documents for coders and providers.
- Communication reference materials

- Impact assessments for health plans, providers and EHR vendors.
- Gap analysis of ICD-10 to ICD-11 including a code set crosswalk between the two revisions.
- Guidance and publications on the use of U.S. specific ICD-11 post-coordination, extension codes, or linearizations.
- Mapping between ICD-11 and key international standards, such as SNOMED-CT.
- Educational material and trainings for end-users.
- Modification of Health Insurance Portability and Accountability (HIPAA) code sets and standards for electronic health care transactions to accommodate ICD-11.

As implementing ICD-11 will be a significant undertaking for all stakeholders, we urge HHS to ensure entities have sufficient lead time before use is necessary. We believe at least 36 months after publication of a final rule adopting ICD-11 as a HIPAA code set will be necessary to implement all the steps in a roadmap and transition plan.

* * *

Kaiser Permanente appreciates HHS' consideration of our comments, and we look forward to continued collaboration. Please feel free to contact me at Jamie.Ferguson@kp.org or Megan Lane at Megan.A.Lane@kp.org with questions or if we can provide additional information.

Sincerely,

Jamie Ferguson
Vice President, Health IT Strategy and Policy
Kaiser Foundation Health Plan, Inc

June 30, 2023

National Committee on Vital and Health Statistics

RE: Response from Kathy Giannangelo Consulting, LLC regarding ICD-11 RFI

Dear NCVHS,

This letter is in response to the ICD-11 request for information.

Kathy Giannangelo Consulting, LLC, specializes in clinical data transformation through terminology feasibility assessment, adoption methodology appraisal, and implementation support. Consulting services include evaluation of terminologies based on desired use case, requirements analysis and documentation, concept mapping to standard terminologies (e.g., SNOMED CT, ICD-10, ICD-11, CPT), legacy data conversion, and data standard migration strategies. Additional services offered are clinical terminologies and classifications education and training. I am a member of the World Health Organization Family of Classifications Network Informatics and Terminology and Family Development Committees. Examples of ICD-11 work include co-presenter at AMIA22 on "Making a Case for Adoption of ICD-11 Morbidity Reporting in the US: Multiple Perspectives" and AHIMA21 on "Extracting the Value of ICD-11 MMS in the US Through Use Case Analysis." In addition, I authored AHIMA's on-demand webinar series "The Evolution of ICD-11" and the three-module course "Introduction to ICD-11 Coding."

Following are my comments on the RFI.

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

The regulatory process as it stands is a major consideration affecting the impact of ICD-11 on all uses. I support Recommendation 1, HHS should use sub-regulatory processes to make version updates to the International Classification for Diseases (ICD) in the same way it handles updates to all the other named HIPAA code set standards.[1] HHS should make this a priority under CMS's Office of Burden Reduction & Health Informatics whose focus is to reduce administrative burden and advance interoperability and national standards.

Question 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

[1] NCHVS February 21, 2019 Recommendations on Regulatory Simplification of the International Classification of Diseases (ICD); https://ncvhs.hhs.gov/wp-content/uploads/2019/03/Recommendation-Letter-Regulatory-Simplification-of-ICD.pdf

including alignment with the Diagnostic And Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)?

It is of my opinion any unique U.S. coding or terminology considerations can be addressed with the new ICD-11 structure and the World Health Organization's (WHO) proposal platform.

ICD-11's new structure, i.e., the Foundation, is an ontological database containing all ICD entities. These entities classify what has been a staple for ICD such as signs, findings, symptoms, diseases and disorders, injuries, external cause of injury but also what has been added to ICD-11 such as medicaments, anatomy, severity scales, course of condition, histopathology, diagnosis code descriptors such as diagnosis timing, e.g., present on admission, and diagnosis certainty, e.g., provisional diagnosis.

Regarding the list of entities in question, most are already in the ICD-11 Morbidity and Mortality Statistics linearization or the ICD-11 Foundation. To illustrate, an analysis of the 395 ICD-10-CM code additions for FY 2024 showed for example, IgG4-related disease: ICD-10-CM code D89.84 and ICD-11 MMS code 4A43.0 and Inappropriate sinus tachycardia: ICD-10-CM code I47.11 and ICD-11 MMS BC81.6. In instances where a condition is not in ICD-11 MMS, it can be found in the ICD-11 Foundation. For example, Proliferative sickle-cell retinopathy has a specific uniform resource identifier (URI) of http://id.who.int/icd/entity/2007271012 and the URI for Insulin resistance syndrome, Type A is http://id.who.int/icd/entity/343459534. In very few cases, such as resistant hypertension, ICD-10-CM code I1A0, neither ICD-11 MMS nor the Foundation contains the concept. In those cases, a proposal could be submitted via the WHO's open and transparent online maintenance platform for inclusion in the Foundation.

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

My recommendation for the next step is for HHS to organize a stakeholder consultation workshop with the aim of discussing ideas, considerations and consultation requirements to develop a case for the adoption of ICD-11 in the U.S. The Australian Institute of Health and Welfare (AIHW) was commissioned by Australian Government Commonwealth Department of Health to undertake such a review which serves as way forward for them. [2]

Question 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?

My recommendation is the National Library of Medicine's (NLM) Office of Health Data Standards and Terminologies (HDST), which is in the Division of Library Operations (LO), be designated as the national center for ICD-11 implementation. This Office would be responsible for coordinating and managing the overall national implementation of ICD-11. NLM is legislatively mandated to support the essential work of acquiring, organizing, preserving, and disseminating biomedical information. The LO Division already provides key health data standards and

[2] ICD-11 Review stakeholder consultation report. https://www.aihw.gov.au/reports/international-comparisons/icd-11-review-stakeholder-consultation-report/summary

terminology services such as those for SNOMED CT which would serve as a blueprint for managing ICD-11 implementation.

Question 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?

My recommendation is the NLM's HDST be the responsible party for coordinating U.S. requests for updates or changes to ICD-11. The process should emulate what NLM's has in place as the U.S. National Release Center for SNOMED CT.

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

To assist with transition and longitudinal data analysis, ICD-10-CM to ICD-11 and ICD-11 to ICD-10-CM maps are essential. My recommendation would be the NLM's HDST be responsible for the coordination and/or develop and dissemination of the mappings and be guided by the mapping project assumptions[3]

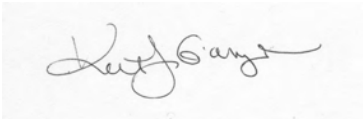
The U.S. may need to develop standards or guidelines around how specific features of ICD-11 should be used to ensure consistency in morbidity such as the use of extension codes.

Question 12: What other operational impacts of ICD-11 adoption and implementation should HHS consider?

ICD-11 has the potential to decrease costs associated with ICD-10-CM if the U.S. takes advantage of the new ICD-11 structure and utilizes the WHO's implementation package (the Classification System, the Coding Tool, Browser and all supporting documents including the Reference Guide and Implementation Guide, and a set of tools such as the application programming interface service). Centralizing the implementation, management, and maintenance of ICD-11 to the HDST would also result in efficiencies and improved stakeholder relationships.

If I can provide any further information, or if there are any questions regarding this letter, please feel free to contact me at kathy.giannangelo@gmail.com.

Sincerely,



Kathy Giannangelo, MA, RHIA, CCS, FAHIMA
www.linkedin.com/in/KathyGiannangelo

[3] Basic Mapping Project Assumptions.
https://www.nlm.nih.gov/research/umls/mapping_projects/mapping_assumptions.html

Massachusetts Health Data Consortium

NCVHS ICD-11 RFI Comment

This document is submitted by the Massachusetts Health Data Consortium (MHDC) and its Data Governance Collaborative (DGC) in response to the ICD-11 RFI posted in the Federal Register on June 13, 2023 and found here: https://www.federalregister.gov/documents/2023/06/13/2023-12617/national-committee-on-vital-and-health-statistics-meeting-and-request-for-information

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

Timeframe for Comment

We urge NCVHS to provide a longer response window for future RFIs and other regulatory requests for comment. 17 days is not a sufficient time period for a comprehensive response, particularly when it overlaps with existing healthcare-related regulatory deadlines such as the deadlines for comment on ONC's HTI-1 NPRM (June 20) and USCDI+ for Quality (June 30).

MHDC facilitated the transition from ICD-9 to ICD-10 in Massachusetts and, had there been sufficient time, would have provided a detailed and (hopefully) useful response based on lessons learned from the previous transition. We hope to be able to engage further in later stages of the regulatory process.

Code Mapping Considerations

We urge NCVHS and any other relevant entities to consider that moving to ICD-11 affects more than existing ICD-10 usage. There are other ways to represent the same data and direct, consistent, repeatable, idempotent mappings between ICD-11 and other code sets (such as SNOMED CT) are an important part of the transition, particularly for data exchange and interoperability requirements. We understand the biggest lift is the replacement of ICD-10 with ICD-11, but please consider these ancillary needs as well in your deliberations.

Timeline for ICD-11 Adoption

We urge NCVHS to consider the proper timing for ICD-11 adoption. There are a great number of existing health data and health IT requirements in the pipeline related to interoperability, data standardization, and data access. Many of these already involve significant modifications to how systems and processes work by requiring use or support of FHIR. While we understand the need to progress in all areas and to adopt standards that are starting to be used internationally here in the United States, we also note that healthcare entities have a limited amount of resources to devote to health data and IT projects and believe that there might be benefits to waiting to move from ICD-10 to ICD-11 until after more payers, providers, vendors, and others are further along in the process of complying with existing ONC and CMS rules, perhaps until after the current set of deadlines pass in January 2026.

Regardless of the exact timing chosen, we urge careful coordination of various regulatory deadlines with changes requiring extensive data and/or IT updates.

June 30, 2023

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

To the Centers for Disease Control and Prevention, HHS:

The Minnesota Small Rural Hospital Improvement Program (SHIP) receives funding from the Health Resources and Services Administration's Federal Office of Rural Health Policy to fund small, rural hospital investments in hardware, software, or training related to value-based purchasing. In the 2023 – 2028 funding cycle, activities for ICD-11 readiness are a funding priority for all grant recipients. On behalf of our grantees, the MN 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 hospitals. The responses we received are summarized below.

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

MN SHIP hospitals shared that ICD-11 morbidity coding would improve accuracy and standardization across the country; however, many are concerned that they do not have the staff capacity to effectively utilize the additional information that would be made available from these codes.

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?**

Implementation cost was the primary concern for MN's SHIP hospitals. This includes the cost of software, electronic health record upgrades, and other technology updates. Cost of staff training is another consideration, as well as the potential loss of revenue incurred when staff are less productive while they learn new systems. Trainings and educational materials should include materials specific to small, resource limited organizations.

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

It will be a challenge to fully realize the impacts of ICD-11 to a rural hospital until rural hospitals are given more information on the supports and timeline to implement ICD-11. If given the

necessary time and resources (financial and educational), MN SHIP hospitals believe ICD-11 will help with reimbursement, and that it will provide better information related to population health and improve their ability to provide outreach to underserved, rural populations.

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

Essential coding or terminology shared by SHIP hospitals includes mental or behavioral health terminology, external cause of injury, social determinants of health, sexual orientation, and gender identity. Coding for behavioral health is important to track the growing needs for mental health and behavioral health services in the United States. It was also shared that providers and nurses would benefit from additional education for SDOH coding, as well as expanded opportunities for reimbursement for these codes.

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

Hospitals requested that educational and training resources be made available well in advance of implementation in order to ensure small facilities with limited staff have ample opportunity to update systems and train their staff appropriately.

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?

A federal organization such as the Department of Health and Human Services, Centers for Medicare and Medicaid Services, or Centers for Disease Control and Prevention.

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?

Responses for the entity to manage updates were mixed. Some SHIP hospitals believed changes should be coordinated by the same organization that manages the implementation, while others believed an independent task force or other non-governmental agency would be more appropriate.

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

Small rural hospitals requested the following resources, tools, and support: training and education, manuals and training materials, software, hardware, clinical technology and payer platform updates, and funding to implement updates to software, electronic health records, and related technology.

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

In addition to the resources listed in question 8, MN SHIP hospitals suggested access to a digital code set once it is approved with live workflow, software updates, and a crosswalk identifying changes between ICD-10 and ICD-11 for facilities that rely on outside vendors to ensure their systems are up to date.

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

The top need to support ICD-11 implementation was staff training materials and funding to support staff who work on the revenue cycle and billing, coding, and informatics, as well as providers and other clinical staff. The Small Rural Hospital Improvement Program Grant allowable expenses should be updated to include ICD-11 implementation and training as allowable uses of grant dollars.

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

Most respondents were unsure of the organizational requirements for ICD-11 mapping. Others noted that they would require software updates to their electronic health record and related software systems. A crosswalk between ICD-10 and ICD-11 would be a useful mapping resource.

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

MN SHIP hospitals restated the importance of considering the amount of time it will take rural providers and other staff to learn the new system, which will impact their productivity and revenue in facilities that are already struggling financially.

Thank you again for the opportunity for Minnesota SHIP program hospitals to respond to the Request for Information on the potential use of ICD-11 morbidity coding in the United States.

Sincerely,

Zora Radosevich
Director, Office of Rural Health and Primary Care
Health Policy Division
Minnesota Department of Health
www.health.state.mn.us

June 30, 2023

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

Submitted to: NCVHSmail@cdc.gov

Re: ICD-11 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 on its Request for Information (RFI) regarding timely and strategic action to inform ICD-11 policy. To our knowledge, there has been no analysis on how the transition from ICD-10 to ICD-11 will impact the pharmacy industry; however, the ICD-11 architecture is profoundly more granular than ICD-10. As such, the transition from ICD-10 to ICD-11 will likely have an impact on the pharmacy industry and would 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. 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.

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. 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)

From: belliott@seymourtexas.net
To: NCVHS Mail (CDC)
Cc: Leslie Hardin
Subject: Response from Seymour Hospital
Date: Friday, June 30, 2023 12:51:44 PM

We are not well acquainted with ICD-11 but, can tell this is not just a change in codes or coding platform, it is truly changing coding as we now know it. Even our encoder assist programs will be useless without massive training on the search terms alone, much less trying to interpret the code, based on the provider documentation. I reached out to some of the on-line training programs to inquire about training and they were not, as of this date, scheduling ICD-11 training.

If physicians are not getting trained on the concepts for ICD-11 coding, we will get the same diagnosis, generalized and nonspecific, that we get with ICD-10. When we changed from ICD-9 to ICD-10, the nonspecific codes were supposed to be used less, however, the rural hospitals experienced very little change with the physician's nonspecific diagnoses.

With the CPT 2023 change in Evaluation and Management CPT codes for in-patient and observation billing, we had insurances that could not get their systems to recognize the E&M codes billed for an observation (outpatient) because they had not updated their program to receive E&M codes as outpatient billing that was inpatient only service before the change. This small change caused delay in payments and repeated billing for greater than 6 months after the change went into effect, imagine what ICD-11 will do!!

Unfortunately, ICD-11 will take years to change systems with coding and billing and substantial education for both coders and physicians. This immense expense will, once again, fall on the healthcare providers to carry the heavy burden of expensive negligible reimbursements. Coders will be expected to do more, with less time and resources.

The driving factor for implementing ICD-11 is mortality reporting and data sharing. However, the burdensomeness of changing to ICD-11 could effect smaller facilities ability to timely bill and receive payments for services provided to the patients . CMS was very
slow converting their LCD and NCD from ICD-9 to ICD-10 for medical necessity. Now, other insurances have similar medical necessity challenges that will require conversion to ICD-11.

If you think patient care is not in some way effected by these unnecessary, expensive billing and coding conversions; then you have never considered the ever decreasing budgets medical facilities have for medical equipment upgrading, the hiring of qualified staff providing those services. It is my opinion that the CDC can use our reported ICD-10 codes and convert them to ICD-11 for their data gathering and reporting. After all, in ICD-9 (410.71); ICD-10 (I21.4); or ICD-11 (BA41.1); they all report the same Acute Non-ST elevation infarction (NSTEMI).

TEXAS DEPARTMENT OF AGRICULTURE
COMMISSIONER SID MILLER

June 30, 2023

Re: Response from Texas Department of Agriculture (Texas State Office of Rural Health) Regarding ICD-11 RFI

The Texas State Office of Rural Health (SORH), located within the Texas Department of Agriculture (TDA), appreciates the opportunity to provide the United States Department of Health and Human Services National Committee on Vital and Health Statistics (NCVHS) with information regarding the adoption of ICD-11 by Texas rural hospitals. The Texas SORH applauds the NCVHS outreach efforts to obtain feedback and concerns regarding the implementation of ICD-11 from rural hospitals. Obtaining this information may reduce the transition costs, financial burden, and disruption to the US healthcare system that was seen in the recent transition from ICD-9 to ICD-10.

The Texas SORH realizes that the NCVHS has formulated a comprehensive outline of research areas and questions to evaluate the benefits, costs, and burden to the US healthcare system in the transition to ICD-11. Through this extensive process, the NCVHS will determine the burden and estimated costs associated with the conversion to ICD-11 from the health care sector and from EHR companies and health information coding software vendors/developers. Once the estimated ICD-11 implementation costs are determined for small rural hospitals (CAHs, PPSs, and REHs) the Texas SORH recommends that NCVHS determine ways to provide adequate federal grant funding to small rural hospitals before mandating the implementation of ICD-11 on these financially vulnerable rural healthcare entities.

The Federal Office of Rural Health Policy's (FORHP) Small Rural Hospital Improvement Program (SHIP) is one program that has provided priority funding for ICD-10 software and training and beginning in 2023, is now focused on ICD-11 software and training readiness and implementation. While this federal grant program is very beneficial to small rural hospitals, the annual grant funding (around $10,000 a year for each eligible rural Texas hospital) is inadequate to support the full cost of implementing ICD-11. The Texas SORH recommends the SHIP federal grant funds be increased to support the full implementation of ICD-11 by small rural hospitals if the NCVHS determines that these small rural healthcare entities be required to convert to ICD-11.

Thank you again for this opportunity to provide information regarding ICD-11 and the impact it will undoubtedly have on Texas small rural hospitals. If you should have any questions, please contact our office at any time.

Sincerely,

Sincerely,

Trenton Engledow

Trenton Engledow
Director, Texas State Office of Rural Health

P.O. Box 12847
Austin, Texas 78711

TexasAgriculture.gov

(512) 463-7476
Fax: (888) 223-8861

UNITEDHEALTH GROUP

9900 Bren Road East, MN000-T000, Minnetonka, MN 55343

June 30, 2023

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

Submitted Electronically: NCVHSmail@cdc.gov

Re: International Classification of Diseases (ICD-11) Request For Information

Dear Dr. Arnold:

UnitedHealth Group (UHG) is writing in response to a Request for Information (RFI) from the National Committee on Vital and Health Statistics (NCVHS) regarding the adoption and use of ICD-11 for morbidity. The RFI was published in the Federal Register on June 11, 2023 (88 FR 38519).

UnitedHealth Group is a mission-driven organization that is dedicated to helping people live healthier lives and helping our health care system work better for everyone through two distinct business platforms – UnitedHealthcare, our health benefits business, and Optum, our health services business. Our workforce of 380,000 people serves the health care needs of 149 million people worldwide, funding and arranging health care on behalf of individuals, employers, and the government. We not only serve as one of the nation's most progressive health care delivery organizations, but we also serve people within many of the country's largest and most respected employers; in Medicare, serving nearly one in five seniors nationwide; and in Medicaid, supporting underserved communities in 32 states and the District of Columbia.

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

UHG uses health data in a variety of settings including claims processing, patient care, pharmacy management, and support of public health activities. Adoption of ICD-11 will allow our organization to be more precise in analytics and predictive models. In addition, this change will have the potential to make it easier for clinicians to increase specificity with respect to coding resulting in better patient care and health outcomes.

We would note that there may be a potential approach for stakeholders working directly with the World Health Organization (WHO) in real time to request code updates that could eliminate the need for a periodic revamping of the entire ICD coding system, which potentially allows health plans and health care provider to more quickly correct where there are clinical and coding conflicts.

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? Respondents may choose to refer to NCVHS' most recent recommendations to HHS for proposed research questions, many of which HHS has not yet addressed.

UHG has not engaged in an analysis of the potential costs of implementing a transition to ICD-11 and is unaware of the range of impact or corresponding operational challenges or costs. There are a number of factors that need to be addressed such as timelines for implementation, level of federal agency and other stakeholder support, and assessment of the impact of ICD-11 coding on operational systems including information technology, patient management, administrative systems, and internal and external reporting.

An important consideration is assessing the time commitment for physicians and coders to adopt and utilize ICD-11. For example, coding tools and electronic medical records must be updated and tested to ensure ICD-11 is mapped correctly.

It is also critically important is understanding the range of new codes and coding changes between ICD-10 and ICD-11 and the need to create cross-maps between the two iterations. In addition, we will need to understand any plans by the Centers for Medicare & Medicaid Services (CMS) to create a Hieratical Condition Category model that is aligned with the ICD-11 coding system.

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

Adoption of ICD-11 will affect a range of clinical documentation and health data interoperability systems including FHIR US Core condition codes (currently supporting the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) and ICD-10) which would presumably need to be updated to reflect the ICD-11 value set. Changes to payment systems will need to be adopted such as adjudication systems and prior authorization. In addition, the change may allow a minor improvement in risk assessment adjustment by providing more granularity in coding.

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)?

The Department of Health and Human Services (HHS) should work with stakeholders to assess the potential impact of ICD-11 adoption on health care delivery systems. For example, review of the impact of ICD-10 to ICD-11 coding Z codes on assessing and tracking social determinants of health and a similar cross walk to the Systematized Nomenclature of Medicine (SNOMED) terminology.

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

The transition from ICD-10 to ICD-11 will be challenging. It is difficult to provide a full assessment of implementation without better understanding the impact on clinical and operational systems across the health care community. In addition, stakeholders need better insight into steps HHS and others will take to cross walk ICD-11 coding changes to other impacted systems (e.g., Z-codes and SNOMED CT) and when any necessary updates to those systems will be completed.

6. The World Health Organization (WHO) recommends establishing a national center for ICD11 implementation. What entity should be responsible for coordinating overall national implementation of ICD-11 for morbidity coding, and how should the implementation be managed?

Regardless of the entity that will coordinate ICD-11 implementation, it is critical to have engagement of all impacted stakeholders. For example, medical organizations such as the American Medical Association and other entities with clinical insight should be involved in the process.

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?

As discussed above, both government and public stakeholders should be engaged in the process. We recommend the National Library of Medicine as the central point of contact for requesting that WHO make updates and changes (e.g., request for new codes) with engagement by the Centers for Disease Control and Prevention (which currently manages ICD-10) along with other stakeholders to provide clinical and operational perspectives on any proposed changes.

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

As noted, further analysis will be needed to determine the impact of ICD-11 adoption. Resources will include training for physicians, coders, and administrative personnel, updates to operational systems, and changes to health care data systems.

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

At a minimum, crosswalks from ICD-10 and SNOMED CT will be needed. We also recommend a strong educational component (e.g., CMS webinars and educational events).

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

Assessment and implementation will include a number of activities including:

- Project and scope analysis
- Budget planning and capital funding allocations
- Updates to clinical systems.
- Changes to claims processing and other operational systems
- Updates to consumer facing capabilities (e.g., call centers, nurse support)
- Education and training of staff (physicians, coders, etc.)

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

As discussed above, HHS should work with other stake holders including standards organizations to develop cross maps to health data standards that rely on ICD-10 (e.g., SNOMED CT).

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

As noted, we believe the migration from ICD-10 to ICD-11 raises a number of challenges. For example, all claims adjudication platforms will need to be updated, administrative and operational systems will be impacted, and record systems and other health care standards will need to be modified. HHS will also need to implement changes to regulatory requirements and internal systems and must provide sufficient timeframes for adoption across all components of the health care system.

HHS should work with the appropriate standards organizations such as HL7 and X12 to ensure standards and implementation guides which currently depending on ICD-10 codes are updated to include ICD-11 well in advance of any implementation deadlines.

UHG appreciates the opportunity to provide comments and looks forward to continued collaboration with NCVHS on this important issue.

Sincerely,

Neil de Crescenzo
CEO
Optum Insight

Jacki Monson, JD
Chair
National Committee on Vital and Health Statistics
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

June 30, 2023

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 June 13, 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 plans, 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).

International Classification of Diseases, Eleventh Revision (ICD-11) is expected to present a significant challenge for health care stakeholders. We anticipate that this new code set will impact billing processes, clinical documentation, quality reporting and other administrative transactions. Also, many organizations are expected to have to modify workflow processes and undertake extensive staff training.

The adoption of ICD-11 should not be undertaken without taking the steps necessary for success. These include:

(i) Ensuring Medicare and Medicaid readiness for accepting ICD-11 codes and transparency of that readiness;

(ii) Supporting expedited and comprehensive testing for all impacted stakeholders; and
(iii) Developing industry education and support resources, with emphasis on smaller, less resourced organizations as well as non-covered entities.

Failure to complete the anticipated adoption steps will impact the ability of the industry to realize a smooth transition to ICD-11. It is also critical that the government and industry stakeholders work together to identify and address concerns and agree on a more appropriate implementation approach.

WEDI Member Input

To address the NCVHS RFI, WEDI leveraged our Member Position Advisory (MPA) process. Our MPA process engaged the WEDI membership through a survey asking RFI questions specific to implementation issues and feedback from WEDI workgroups.

Survey

WEDI conducted a survey between June 16 and June 22, 2023. We received a total of 74 responses on a select group of RFI questions. The following table outlines the number of respondents who completed the surveys and the stakeholder groups they represent:

Answer Choices	Responses (%)	Responses (Number)
Provider	21.6%	16
Health Plan	25.7%	19
Clearinghouse	6.8%	5
Vendor	29.7%	22
Other*	16.0%	12
Total		74

*" Other" included: Medical device industry, Academic institution, State Medicaid Program, Consulting, Medical Society, Government Health Plan (Medicaid), Revenue Cycle Management, Specialty Society, Consultant to Medicaid, Education, EDI Claim Scrubber, and Tribal Health Clinic.

Responses to the RFI Questions

RFI Question

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

WEDI Response

WEDI asked survey respondents "**What would be the benefits of implementing ICD–11 for morbidity in your setting or organization**? **Check all that apply."**

Responses

Answer Choices	Responses (%)	Responses (Number)
More accurate coding for billing and reimbursement	37.0%	27
More accurate coding in support of quality reporting and/or value-based care	38.4%	28
More accurate coding in support of health equity and/or collection of Social Determinants of Health Data	30.1%	22
More efficient comparison of international health data	17.8%	13
No benefits	13.7%	10
Unsure of the benefits	37.0%	27
Total Respondents		73

Supplemental Survey Respondent Comments

1	There has not been a lot of info or education on the clinical or administrative changes of ICD-10 to IDC-11 and any possible benefits to the change.
2	For Mental Health
3	Depends on the needs/benefits of our clients, who are the health plans. Keep in mind that a change to the code sets, benefits, transmission of data is a very time consuming and expensive process for software vendors and the health plans especially in the current environment where health plans use many vendors for business processes: payment processing, eligibility inquiry, claim inquiry, care management as well as delegated entities for benefits such as pharmacy, vision, hearing. For some commercial TPAs, they need to update as many as several hundred interfaces to incorporate a new code set with a different qualifier.
4	Unclear if the costs and burdens associated with another transition would outweigh the benefits. How would this benefit patients and physicians? Also, really who benefits-- payors and other third parties at the expense of physicians? More meaningful clinical content, accuracy of coding, new core chapters, etc. can all be achieved in the current ICD.10.
5	It's hard to say the level of tangible benefits that the industry would realize
6	This is a more informatics friendly data capture system
7	The benefit of migrating to ICD-11, compared to the resource commitment and operational impact, is difficult to estimate
8	Because of the post coordination will make recording a diagnosis much more cumbersome then with ICD-10-CM. Since not all physicians use professional coders, will result in more diagnoses that the insurance companies will refuse to cover. Will also make diagnosis coding with EHR much more difficult. This will be an unnecessary burden on the physician.

9	There is a belief that ICD-10 (and previous versions) in accordance with both APR and MS DRG reimbursement methodology understate the true acuity of large, academic, quaternary care health systems.
10	The SDOH codes are difficult to code and of some concern.

RFI Question

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? Respondents may choose to refer to NCVHS' most recent recommendations to HHS for proposed research questions, many of which HHS has not yet addressed.

We agree that the questions NCVHS sent to HHS for consideration are appropriate research questions for HHS to evaluate ICD-11 implementation. It is critical that ICD-11 be evaluated for its impact on: A

(i) Burden, efficiency, workflow, training and implications for documentation quality by use case and stakeholder (cost and benefits and human factors);
(ii) Interrelationships between ICD-11 and other HIPAA and Promoting Interoperability (PI) standards, specifically including but not limited to Current Procedural Terminology (CPT®), Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), Healthcare Common Procedure Coding System (HCPCS), Logical Observation Identifiers Names and Codes (LOINC®), RxNorm and SNOMED CT;
(iii) Adherence of ICD-11 to accepted terminology practices, especially regarding maintenance, such as concept permanence, non-ambiguity, maintaining consistency and backward compatibility;
(iv) Alternative approaches (methods & infrastructure platforms) to support semantic comparability studies;
(v) Technical and legal considerations, e.g., issues including validation of received ICD-11 value sets, and how systems implementation guides (IGs) can accommodate the 10-digit vs 11-digit codes in ICD-11;
(vi) ICD-11 coordination with detailed clinical documentation using nationally mandated clinical information interoperability content standards;
(vii) The extent to which ICD-11 coordinates with non-clinical national and state mandated information interoperability content standards, e.g., coding used for social services coordination, public health case or surveillance reporting, or quality measures or health equity assessments;
(viii) Fitness of ICD-11 for morbidity to contribute to convergence of clinical, social, and administrative health information standards;
(ix) Whether ICD coding can be implemented as a computable service on top of standardized clinical statements captured by the electronic health record (EHR) using the Promoting Interoperability (PI) standards to record clinical care;
(x) Whether interoperable representations of research and clinical terms/classification and nosology simplify distribution and deployment of health terminology and vocabulary standards;

(xi) The crosswalk agreement between ICD-11 and the ability of DSM-5 to capture behavioral, substance abuse and psychiatric disorder coding; and
(xii) The ICD-11 licensing agreement to ensure availability and usability for U.S. users without cost burden.

RFI Question

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

WEDI Response

We believe ICD-11 will impact many aspects of business operations 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 systems and EHR 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 the 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 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 diagnosis 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.

- *Public 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, 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 codes will need to be changed should the nation move to ICD-11.

<u>Testing</u>
It is expected that ICD-11 testing will not be a required action for covered entities. However, 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.

As we experienced with ICD-10, ICD-11 will impact how claims adjudicate in health plan systems. While CPT and HCPCS codes will still be the main determinant of how much providers will be paid, we expect ICD-11 codes will be used by health plans for some coverage and payment decisions. Performing testing will allow the industry to better understand any impact regarding how claims will be processed after ICD-11 implementation and reduce the risk of unanticipated claims issues.

Testing will benefit providers by helping minimize the following risks:

- Claim denials, claim delays and resulting administrative work and productivity loss associated with ICD-11 coding errors and other issues
- Cash flow disruption owing to claim denials and delays
- Confirmation of the EHR and associated application(s) ability to generate ICD-11 claims.

We anticipate ICD-11 testing will have challenges that include the following:

- Insufficient provider resources knowledgeable about and available for ICD-11 testing (e.g., coding, data collection/evaluation, testing facilitation, troubleshooting of test results)

- Insufficient training for staff on ICD-11 codes
- Insufficient testing opportunities with providers, health plans, clearinghouses and other partners
- Lack of clarity and expectations among testing partners (lack of consistency of testing environments drives some of the misaligned expectations)
- Lack of readiness from vendors and their systems
- Confusion resulting from varying testing criteria and instructions (e.g., test file acceptance dates, compliance date for testing purposes); much of this can be solved by knowing which questions to ask up front
- Lack of availability of health plans to test with and plan resources to contact about testing opportunities

Further, providing information on ICD-11 readiness will be a powerful component in creating the atmosphere of collaboration and transparency needed to succeed both in the testing and deployment of ICD-11. Testing internally and externally helps both vendors and their customers confirm the preparedness for the shift to ICD-11 by enabling them to validate updated business procedures and vendor system changes. 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.

RFI Question

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

WEDI Response

WEDI asked survey respondents **"How should HHS implement ICD–11 in the U.S. for morbidity coding? Check all that apply."**

Survey Results

Answer Choices	**Responses (%)**	**Responses (Number)**
Long glidepath where both ICD-10 and ICD-11 are permitted for a designated period of time	36.5%	27
Hard Cut Over from ICD-10 to ICD-11	29.7%	22
ICD-11 implemented after other high priority interoperability and administrative mandates are adopted	35.1%	26
ICD-11 implemented only after a clear return on investment is established	33.8%	25
HHS should not adopt ICD-11 at this point	14.9%	11
Unsure	6.7%	5
Total Respondents		74

Supplemental Survey Respondent Comments

1	More time is needed to compare the current ICD-10-CM codes with ICD-11 and determine whether current diagnosis needs are accommodated in ICD-11. The implementation of ICD-11 will require significant resources and that work cannot be overlapped with other high priority implementations. Providers need to know there will be some ROI with implementing ICD-11 in order to commit to this massive project
2	The healthcare industry is facing an enormous amount of regulations, workforce constraints, inflation and other economic issues, Medicaid rewinding, opioid and mental health epidemics, market changes (retail health, etc.) and the need to create new workflows around interoperability and transparency requirements and new technology (telehealth and remote HC, A.I.). There is simply no time or resources to consider ICD-11 at this point.
3	The ICD-11 implementation will involve significant cost and effort; industry participants will need to know benefits so that support will be there for the implementation.
4	The implementation of ICD-11 at this time comes with a lot of challenges for providers in clinical practice especially as practices are still trying to recover from the PHE. Also, there will be additional administrative burden and cost to providers and their practice
5	The Healthcare community is still recovering from the recently expired PHE. Many are facing resource limitations and budget pressure. A conversion from ICD-10 to ICD-11 will require significant system and staff readiness. This affects the entire healthcare life cycle and will require many years for implementation and readiness.
6	Assumes adoption of new EDI standards that support EDI
7	Keeping in mind that the investment to add a new code set with a new qualifier is an expensive endeavor for all of the interfaces as well as the new benefit configuration. New benefit summary documents would also have to be established and communicated to providers and care management systems since the covered benefits will have to be configured to connect to the new ICD-11 codes.
8	Assumes adoption of new EDI standards that support ICD-11
9	Stop changing the key tools used by physicians!!! There are already too many burdens associated with EHRs, cost to maintain and update EHRs, lack of interoperability, onerous payor policies, preauthorizations, utilization review, audits, MIPS, denials, advance notifications, etc. All of these issues need to be addressed and streamlined. Interoperability should be a top priority, reductions in administrative burdens that take physicians away from patient care need to be alleviated, and physicians and staff need relief from onerous activities that do not directly affect patient care in an efficient and effective manner.
10	A long glidepath will provide time for entities to update their claim payment systems
11	Conflicts and confusing overlap need to be minimized, therefore a hard cut over is best.

12	I'd like to see the industry implement Prior Authorization transaction changes as well as Attachment processing changes be implemented before the move to ICD-11
13	With the possibility of a hipaa ansi update from 5010 to 8020, or whatever next version is, it will take dedicated resources at every level to fulfill the tech needs
14	To ensure coding consistency across the industry, and concentrate the software revisions and Partner testing to a specific time frame, a hard cut-over date for all health care entities should be used. However, the implementation of Prior Authorization and Attachment transaction changes should be prioritized over migration to ICD-11, to allow the industry to take advantage of ROI benefits from those transaction reforms. A decision for migration to ICD-11 should be evaluated on its own merits
15	Unlike when ICD-10 came into play, many countries have not implemented ICD-11 so there isn't any tracking mismatch as there was with ICD-9/ICD-10. No need to move to ICD-11 until more countries implement it. The process for adding and modifying codes in ICD-11 will be much harder, especially since WHO is looking at forbidding local clinical modifications.
16	Although we realize ICD-11 coding will not work with standard versions of 5010, 6020, 7030, 8020, or 8030. What we need to do is what was done with 4010 to 5010. 4010 could not handle ICD-10, So 5010 was created with ICD-10 in mind. The Industry went to 5010 then the industry went to ICD-10. We realize that ICD-11 will not fit in any current (5010) or proposed X12 standard (6020 for 275 and 278) 8020 or 8030 (everything else). The industry needs either an X12 8040 or and X12 9010 standard that includes all the (changes, deletes and new segments, loops and data elements from previously proposed standards) that will be able to handle the ICD-11 variable length codes and cluster codes. We also we to realize that the industry needs to move the whole suite of transactions to that same standard at the same time.
17	Only one standard (whether that is X12 5010 vs. 8020; ICD-10 vs. ICD-11; etc.) should be in production use at any given time. The overall health care industry priority should be to first implement the remaining HIPAA transactions (specifically Prior Authorization 278 and the Attachment 275) BEFORE diverting attention and resources to work on ICD-11, X12 v8020, new CAQH Operating Rules, or any other initiative within the industry; in order to get all HIPAA transactions operational on a national level, and THEN move forward to new standards. We believe this to be the best approach for the industry to achieve a return on investment
18	Not fully informed on the totality of benefit. ICD-10 was a tremendous usurpation of resources, probably necessary, but has provided little in the way of global healthcare benefit
19	Another complete overhaul of ICD codes is unnecessary at this time
20	Having been through the ICD-9>10 transition, this seems a reasonable approach. Would be good to somehow incentivize early adoption.
21	It is time to catch up with the rest of the world. Set a date and make the transition. Otherwise, healthcare stakeholders have to maintain two different systems, which is a waste of money.
22	We cannot continue to burden our providers and trading partners with multiple high-priority initiatives at once.

23	Getting modernized is not the problem. Taking tons of time to implement a new solution is inefficient and why the government programs are deemed way too slow. No arguing, just do it.

RFI Question

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?

WEDI Response

We concur with the WHO when it recommends the U.S. establish a national center for ICD-11 implementation. We believe that the entity that should be responsible for coordinating overall national implementation of ICD–11 for morbidity coding is the Centers for Medicare & Medicaid Services.

RFI Question

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?

WEDI Response

We believe the entity that should be responsible for coordinating U.S. requests for updates or changes to ICD–11 is the Centers for Disease Control and Prevention's National Center for Health Statistics.

RFI Question

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

WEDI Response

ICD-11 will represent a significant impact to IT applications and business processes. Health care is currently facing many competing priorities, all which could affect an organization's ability to take steps necessary to successfully transition to ICD-11. The high level activities that will be will common to most organizations and listed in chronological order as follows:

- Plan, organize and assess
- Communication and outreach
- Remediate
- Test
- Train
- Transition

WEDI asked survey respondents **"What internal resources will your organization need for implementation? Check all that apply**"

Survey Results

Answer Choices	**Responses (%)**	**Responses (Number)**
Education on ICD-11 and the differences between ICD-10 and ICD-11	90.5%	67
Additional staffing	41.9%	31
Additional coding experts	40.5%	30
Financial resources	58.1%	43
Unsure	13.5%	10
Total Respondents		74

Supplemental Survey Respondent Comments

1	The above resources will be needed but it is uncertain what additional resources will be needed until more information is available about ICD-11. Other internal resources that will be needed include vendor support and coding tools.
2	Extensive coding mapping. Plan and approach for managing mapping overlap
3	System preparation and readiness
4	IT staff modify system
5	This list is insufficient to report all of the resources and costs of moving to a new coding system
6	We primarily support Payer organizations. They're going to need to invest in provider outreach and extensive testing with their trading partners in order to ensure a smooth transition.
7	From a Payer organization perspective: outreach, collaboration, and coordination with Trading Partners is critical to the success of the implementation and adoption of the new ICD coding and the differences between ICD-10 and ICD-11 Additional staffing Additional coding experts Financial resources Unsure WEDI Seeking Industry Input for the NCVHS ICD-11 RFI 9 / 16 standard. This will require expansion of Partner outreach and testing resources
8	We need time to establish funding approval and achieve an internal decision on moving forward. Each entity in the industry also needs time to assemble their team and prepare their people to work on ICD-11. We also need to set up a collaborative test environment for our Trading Partners well ahead of any mandated implementation date
9	Significant investments in moving intelligent documentation and coding to the next level. By the time ICD-11 is implemented, manual and mechanical coding by staff should be obsolete. That is the best way to take advantage of the purported benefits
10	We doubt that more staff would be needed. Current staff would need training, and we suspect ML/AI tools could be developed to leverage existing staff.

WEDI asked survey respondents **"What external resources, tools, or support will your organization need for implementation? Check all that apply."**

Survey Results

Answer Choices	**Responses (%)**	**Responses (Number)**
Education on ICD-11 and the differences between ICD-10 and ICD-11	89.2%	66
Crosswalks between ICD-10 and ICD-11	83.8%	62
Recommended industry milestones	51.4%	38
Testing tools	79.7%	59
Website that lists entities that are ready to test	43.2%	32
Industry portal to submit issues and questions	71.6%	53
Unsure	4.0%	3
Total Respondents		74

Supplemental Survey Respondent Comments

1	The above resources will be needed but it is uncertain what additional resources will be needed until more information is available about ICD-11. Other external resources that will be needed include coding tools, webinars, virtual learning tools, and project plans.
2	Resources to understand alignment with state mandates. Understanding of clearing house and vendors ability to accept new ICD-11. Whitepapers from Standards Development Organizations to include differences in ICD-10 and 11 and implementation information
3	Extensive implementation timeline to affect change throughout the entire healthcare lifecycle
4	Need to evaluate the downstream impact of code set change to different applications such as risk adjustments, metrics for quality, MIPSS, etc.
5	Need an industry recognized certification tool that proves compliance without the need to endto-end test the same data with thousands of different payer endpoints.
6	Free implementation and system reconfiguration, grants to offset the costs of transitioning, training, updating EMRs, forms, and other documents. Payors, labs, etc. need to be ready to accept the new codes at the onset to avoid problems with preauthorization requests, advance notifications, referrals, orders, prescriptions, etc.
7	The X12 TR3's currently in use (5010) cannot accommodate ICD-11. The migration to a version that allows for ICD-11 must be completed first
8	Understanding the "if desired" concept for post coordination especially in terms of coverage

9	A key requirement will be a mandated national hard cutover date for use of the ICD-11 code set
10	Lead time for payers and vendors to modify their software must be sufficient for us to both implement system changes, AND set up collaborative test environments for our Trading Partners, well in advance of any mandated implementation date
11	Grants to fund real time computer assisted/automated documentation and coding
12	The items marked could be of help, especially from CMS

RFI Question

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

WEDI Response

WEDI asked survey respondents **"What kinds of technical resources, guidance, or tools should the U.S. Federal Government make available? Check all that apply.**"

Survey Results

Answer Choices	**Responses (%)**	**Responses (Number)**
Timely release of policy guidance	89.2%	66
Development of a specific ICD-11 frequently asked question section on the CMS website	85.1%	63
Stakeholder-specific educational webinars (live and on demand)	71.7%	53
Regular review of industry readiness	67.6%	50
Include an ICD-11 support component into the ONC electronic health record certification program	33.8%	25
Incorporate ICD-11 into the provider Merit-based Incentive Payment System (MIPS)	35.1%	26
Establish a designated testing period for all federal government - controlled health plans	66.2%	49
Develop recommended industry milestones	59.5%	44
Work collaboratively with WEDI and other industry organizations to develop and disseminate implementation resources	70.3%	52
Unsure	4.0%	3
Total Respondents		74

Supplemental Survey Respondent Comments

1	It is too soon to know which of the above or other resources will be needed from the federal government to support the implementation of ICD-11.

2	Expenses related to ICD-11 implementation to be included in the MLR calculation for plans. 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
3	Provide education and training for medical associations to assist members.
4	All areas of regulatory bodies will need to coordinate updates to the code set and provide similar resources as needed.
5	We'd like to see a two-year advance notice, with lots of communication to the provider community, and a hard cutoff to allow for required system upgrades, training, and extensive B2B testing
6	There will be many resources needed and we have not even used ICD-10-CM for 10 years yet. It is too soon. We can't even get minor changes to accommodate ICD-10-CM claims
7	The ICD-11 implementation date should be established with sufficient lead time (at least two years) for Payers to renovate their systems, and to stand up tools for data-exchange testing with their Trading Partners
8	Close work with medical societies
9	Easy to access crosswalks
10	The conversion to ICD-11 is necessary. We have talked about it for years. Incentives are just another game we play. Set the dates and make the penalties for not complying big enough that healthcare stakeholders get on board.
11	Anything to speed up the time for faster implementation.

RFI Question

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

WEDI Response

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.

RFI Question

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

WEDI Response

WEDI asked survey respondents "**What other operational impacts of ICD–11 adoption and implementation should HHS consider?**

Responses

1	Pilot tests, recognition that vendor work must be done first before providers and plans implement, interim steps with deadlines for the industry, and a commitment to a firm implementation date
2	Support from agencies and SDOs for ICD-11 SNOWMED codes and how these codes are added to the FHIR Implementation Guides (IGs). Significant work effort needed to evaluate the FHIR resources and IGs to determine incorporation of ICD-11 codes and how to manage theICD10 and 11 coding overlaps. HHS should recognize that healthcare entities will have an overlapping time of collecting both codes and should provide information and flexibility in terms of data reporting requirements. 6/22/2023 1:54 PM 5 The financial impact of implementing a new code set and the relationship between ICD-11 MMS, SNOMED CT and LOINC.
3	Will impose a significant burden on everyone to accommodate both ICD-10 and ICD-11 for an indefinite period. If it's adopted for morbidity, that opens the door for additional uses, and we feel that it's not beneficial to implement this very complex codeset piecemeal
4	Be sure to provide GEMs mapping in the same/similar format. Also, early notification when GEMs will no longer be updated.
5	As an indirect provider, Independent Clinical Laboratories are dependent on the education and adoption of the ordering clinician/physician. Planning and readiness for ICD-10 extended beyond 5 years, required excessive planning, created financial burdens and system upfit was extensive. The work effort to prepare for ICD-11 adoption will not deliver the necessary return on investment for the health care industry
6	The disparity of Healthcare should be held I. The forefront of our minds and ensure that the ICD 11 does not make more of disparity in accessibility of services for BIPOC
7	Large provider impacts and financial impacts. Health plan/Payer policies that are related specifically to DXs will have a larger reach than might have been discussed previously. Clearinghouse/vendors/trading partners will need to complete crosswalks, validation testing, and user acceptance testing (UAT) before full implementation
8	HHS should consider downstream impact to risk adjustment and quality that utilize ICD and the needs of the industry in transitioning.
9	This may be very beneficial for the industry, but the transition can be very costly and time-consuming which competes with existing staff workload. Keep in mind that a change to the code sets, benefits, transmission of data is a very time consuming and expensive process for software vendors and the health plans especially in the current environment where health plans use many vendors for business processes: payment processing, eligibility inquiry, claim inquiry, care management as well as delegated entities for benefits such as pharmacy, vision, hearing. For some commercial TPAs, they need to update as many as several hundred interfaces to incorporate a new code set with a different qualifier. Even Medicare and Medicaid administrators have up to 10 interfaces that would be impacted. Some interfaces are standard X12, but the industry still has many proprietary formats used for communicating membership, claim status,

	accumulators, claim payments, care management data such as referrals and authorizations; which would need to be updated and tested
10	The transition should have minimal financial impact to providers. There should be ample time between the implementation of the next version of the standards and the implementation of ICD-11 to minimize impact to resources and reimbursement.
11	Mapping to/from SNOMED, LOINC and CPT
12	Direct impact to revenue cycle needs to be fully investigated and vetted in advance of any implementation timeline
13	Provider outreach and education
14	The X12 TR3's currently in use (5010) cannot accommodate ICD-11. The migration to a version that allows for ICD-11 must be completed first
15	Should not be adopted
16	My biggest concern is probably the impact of competing initiatives. I think there would be a big positive impact if we could get Prior Auth and Attachment updates implemented, as noted earlier. I'm also interested to see when the industry is going to move to an updated X12 standard, which would be another heavy lift.
17	Impact on financial resources to switch platforms in conjunction with other major initiatives such as Ansi changes.
18	Definitions could pose potential medicolegal issues as it could potentially remove the clinical judgement of the physician.
19	Prioritization of other initiatives facing the industry must be considered in relation to the need for the ICD-11 migration. We recommend implementation of the Prior Authorization and Attachment revisions, before an X12 standards migration or an ICD-11 implementation.
20	ICD-11 is more like Snomed. It may be great for the computers but it is not physician/provider friendly at all, especially with the layers of post-coordination. While there was a concern about drop in payments with the ICD-10-CM transition, which did not occur, the multiple layers required to code a diagnosis will give the insurance companies more reasons to deny services and payment. The EHR haven't made using ICD-10 easy. It will be an absolute nightmare with ICD-11.
21	All learning points from going from ICD-9 to ICD-10. So many of the HIPAA transactions have the ability, whether required or situational, to hold a diagnosis code. The industry needs to move at the same time, to one version of the X12 standard that will accommodate ICD-11 for all of the HIPAA transactions
22	Please recognize that the inter-related nature of 837 Claims, 837 Encounters, 275 Attachments, 278 PAs; and the response 999s and TA1s is such that they should all operate on the same standard at the same time.
23	Workforce investment grants. ICD-10 pushed some into retirement and others into higher salaries. If ICD-11 is that much more digital and capable of being updated more frequently, combined with the evolution of coding and documentation technology, it's entirely possible that coders are performing validation and audit functions in the future or working to better define the electronic health record. This will require an upskilled workforce
24	The difficulty and cost especially for small offices
25	Should not be implemented until after the next update to electronic transactions

26	HHS should be just one among many stakeholders of industry.
27	Offer training webinars with explanations of usage
28	Being new to this, it seems important to clearly communicate the benefits of the new system to each stakeholder group.
29	Regulatory compliance requirements, direct ties to quality, value-based payments and the transition of healthcare from a provider centered system to a consumer-centric and 21st century system... at a significantly lower cost
30	Need plenty of time to get the changes into the HIPAA data standards incorporated in the timelines
31	To me it's mostly the crosswalk and the implementation time of it.
32	How much more efficient it is. US has to get to where the rest of the high performing markets are. Stop healthcare as a for profit venture and take care of our people.
33	Financial
34	Burnout among clinical providers is at an all-time high. Providers are tired from the immense administrative burdens being placed on them. The fact that clinical providers are retiring early or leaving the profession in large numbers cannot be overlooked. The other big impact to providers is the overall cost they will incur from implementing ICD-11. Direct costs will include system upgrades, vendor support, staff training, resources and tools for coding, etc. Indirect costs will come from downtime for system upgrades and staff training, and decreases in productivity. HHS needs to seriously consider the real costs and the ROI expected from ICD-11. Close consideration must also be paid to other health IT priorities and the timing of those implementations. The focus must be on the changes that will deliver the most benefits for care delivery

Recommendations

Should HHS move forward with requiring adoption of ICD-11, we encourage the Department to take the following steps to minimize claims payment disruption and facilitate a smoother transition to ICD-11:

- Name an ICD-11 ombudsman and establish a dedicated webpage. Soon after release of an ICD-11 final rule, 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 organizations and HHS advisory groups. HHS should issue a report delineating the benefits to physician practices and other care settings.

  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 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 overlapping CMS initiatives. Existing federal health IT mandates on physicians, such as the prior authorization rule, attachments mandates, and interoperability requirements, 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 World Health Organization (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.

  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.

- 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 the Office of the National Coordinator for Health Information Technology (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 to 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.

- Work 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 solicit industry opinions on the potential impact the 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 the health care industry and reducing administrative burden for all stakeholders. As the collective voice of the health care industry on health IT issues, we are pleased to continue

our important partnership with the NCVHS and look forward to the ICD-11 Expert Roundtable on August 3, 2023, conducted by the Standards Subcommittee.

Sincerely,

/s/

Ed Hafner

Chair, WEDI

cc: WEDI Board of Directors