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.

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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,

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