



# NCVHS

## National Committee on Vital and Health Statistics

February 21, 2019

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

### **Re: Recommendations on Regulatory Simplification of the International Classification of Diseases (ICD)**

Dear Secretary Azar:

This letter conveys recommendations for an approach to simplify the adoption of future versions of the International Classification of Diseases (ICD) and related health terminology and vocabulary standards. The National Committee on Vital and Health Statistics (NCVHS), your advisory committee responsible for advising the Secretary and the Congress on the status of the implementation of part C of title XI of the Social Security Act, identified the opportunity for regulatory simplification in its recent analysis of the U.S. health terminology and vocabulary environment. This work produced two reports referenced in this letter: *Health Terminologies and Vocabularies Environmental Scan*<sup>1</sup> and the *Health Terminologies and Vocabularies Expert Roundtable Meeting Summary*.<sup>2</sup>

HIPAA refers to these terminology and vocabulary sets as “Code Sets” defined as “any set of codes used to encode data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes. A code set includes the codes and the descriptors of the codes.”<sup>3</sup> A limited number of “named” terminology and vocabulary standards are identified in 2002 and 2003 HHS regulations implementing the Code Set provisions of HIPAA.<sup>4,5</sup> Section 1174 of the Act recognizes the unique challenges of maintaining dynamic

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<sup>1</sup> NCVHS, Health Terminologies and Vocabularies Environmental Scan, September 14, 2018.

<https://ncvhs.hhs.gov/wp-content/uploads/2018/10/Report-Health-Terminologies-and-Vocabularies-Environmental-Scan.pdf>

<sup>2</sup> NCVHS, Health Terminologies and Vocabularies Expert Roundtable Meeting Summary, September 14, 2018.

<https://ncvhs.hhs.gov/wp-content/uploads/2018/09/Report-Health-Terminologies-and-Vocabularies-Expert-Roundtable-Report.pdf>

<sup>3</sup> 45 CFR Part 162.103, Subpart A, Definitions.

<sup>4</sup> Federal Register Volume 65, Number 160. Thursday, August 17, 2000.

<sup>5</sup> Federal Register / Vol. 68, No. 34 / Thursday, February 20, 2003, [https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/Downloads/cms0003f\\_cms0005f.pdf](https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/Downloads/cms0003f_cms0005f.pdf)

medical and health code sets and “requires the Secretary to review the adopted standards and adopt modifications as appropriate, but not more frequently than once every 12 months in a manner which minimizes disruption and cost of compliance.”<sup>6</sup>

Having studied the current status of health terminologies and classifications including processes for adoption, curation, and dissemination, NCVHS offers three strategic recommendations relating to ICD and related code sets to reduce the burden and disruption of compliance as required by the Act:

**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.**

The World Health Organization (WHO) issues an updated version of ICD approximately every decade. The National Center for Health Statistics (NCHS), part of the Centers for Disease Control and Prevention, serves as the U.S. Collaborating Center for ICD and participates with the WHO in developing new versions. There has been one update to ICD since HIPAA Code Set standards were put in place. This was the 2015 transition from ICD-9 to ICD-10. The timeline and experience of this update illustrates why the process must be simplified. The WHO approved ICD-10 in 1990 and the U.S. began using it for mortality reporting in 1999. The U.S. then began building a clinical modification for morbidity classification. NCVHS recommended adoption in 2003.<sup>7</sup> HHS issued a notice of proposed rulemaking (NPRM) in 2008<sup>8</sup> and a final rule was published on January 15, 2009, calling for implementation on October 1, 2013.<sup>9</sup> This date was later revised to October 1, 2014 and finally to October 1, 2015. Protracted uncertainty around the effective date increased costs associated with planning for adoption and impeded progress in adoption of cost saving technologies.

In contrast to the regulatory approach used in moving from ICD-9 to ICD-10, for all other named code set standards HHS relies on the organizations responsible for maintaining the code set to release regular updates and specify effective dates. Update processes and timelines for each named standard are delineated in the Environmental Scan report.<sup>10</sup> While an annual update to ICD is issued each year through a coordination and maintenance process co-led by NCHS and CMS, the WHO-issued updates currently are adopted through regulation. Your authority to adopt administrative simplification standards through sub-regulatory processes appears broad so long as the standard is developed by a standards development organization, and there has

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<sup>6</sup> HIPAA Act, Subtitle F, Part C Administrative Simplification, Section 1174, Timetable for Adoption of Standards.

<sup>7</sup> NCVHS, Letter to the Secretary on ICD-10, <https://ncvhs.hhs.gov/wp-content/uploads/2018/05/november-5-2003-letter-to-the-secretary-icd-10-recommendations.html-charsetutf-8>

<sup>8</sup> Federal Register, 45 CFR Parts 160 and 162 HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards To Adopt ICD-10-CM and ICD-10-PCS; Proposed Rule, August 22, 2008. <https://www.govinfo.gov/content/pkg/FR-2008-08-22/pdf/E8-19298.pdf>

<sup>9</sup> Federal Register, HIPAA Administrative Simplification: Modifications to Medical Data Code Set Standards To Adopt ICD-10-CM and ICD-10-PCS <https://www.govinfo.gov/content/pkg/FR-2009-01-16/pdf/E9-743.pdf>

<sup>10</sup> NCVHS, Health Terminologies and Vocabularies Environmental Scan, September 14, 2018, pages 22-26.

been consultation with government and specified industry organizations and consultation with NCVHS as outlined in the Act.<sup>11</sup>

The Act calls for updating standards according to schedules and processes that are clear and understood by stakeholders. It relies on the organization responsible for maintaining the code set to specify the valid dates of versions.<sup>12</sup> This recommendation aligns the process for ICD updates with that of other code set standards. This approach will help those who must adopt the standards to better understand the intent and the relationship of ICD to the other code set standards.

**2. HHS should invest now in a project to evaluate ICD-11 and develop a plan that will enable a smooth and transparent transition from ICD-10 to ICD-11 at the optimal time.**

The U.S. recently adopted ICD-10, but in May 2019 the WHO will adopt ICD-11 for worldwide use. This in turn starts the clock ticking on a series of critical decisions for the U.S., such as when ICD-11 should replace ICD-10 for cause of death coding, whether ICD-11 includes sufficient detail to meet the U.S. needs for morbidity classification without a clinical modification, the cost-benefit of a version update, and an assessment of optimal timing considering other standards updates. With this recommendation, NCVHS urges the Secretary to provide the leadership and resources needed to begin this complex evaluation sooner rather than later.

In a separate letter, NCVHS has put forth updated Criteria for Adoption of Health Terminology and Vocabulary Standards.<sup>13</sup> The Committee believes that this ICD-11 evaluation project would be an ideal test for these new criteria. A rigorous evaluation and a transparent process will begin engaging and informing stakeholders and paving the way for a sub-regulatory adoption action at some appropriate time in the future.

NCVHS believes that this recommendation is in line with provisions of Section 1174 of the Act that require the Secretary to ensure “that procedures exist for the routine maintenance, testing, enhancement, and expansion of code sets, along with instructions on how data elements encoded before any modification may be converted or translated to preserve the information value of any pre-existing data elements.”<sup>14</sup>

**3. HHS should clarify that ICD-10-PCS is completely separate from ICD-10 and will not be updated with the transition of ICD-10 to ICD-11.**

ICD-10-PCS is a procedure classification system designed by CMS for coding hospital-based procedures. This development was undertaken because the WHO retired its procedure coding system with the 10<sup>th</sup> revision of ICD. The ICD rubric was attached to the new U.S. system

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<sup>11</sup> HIPAA Act, Subtitle F, Part C Administrative Simplification, Section 1172, General Requirements for Adoption of Standards.

<sup>12</sup> Federal Register Volume 65, Number 160 (Thursday, August 17, 2000).

<sup>13</sup> NCVHS Letter to the Secretary: Recommendations on Selection Criteria for Adoption of Health Terminology and Vocabulary Standards, and Guidelines for Curation and Dissemination of these Standards (February 13, 2019).

<sup>14</sup> HIPAA Act, Subtitle F, Part C Administrative Simplification, Section 1174, Timetable for Adoption of Standards.

presumably to make it clear that this system replaced the earlier ICD version. However, it is not a WHO-developed or maintained vocabulary. Updates to the U.S. procedure classification system do not need to be tied to updates to ICD and vice versa.

NCVHS believes that taken together these three recommendation address important near term administrative simplification code set issues. Initiating an ICD evaluation and adoption plan will avoid the costly and highly disruptive migration which occurred in the transition from ICD-9 to ICD-10, the impact of which was experienced across the industry for several critical years. The Committee is eager to avoid this from occurring in the future and to support you as you move these issues forward.

In addition, NCVHS is continuing to advance recommendations for the Department regarding health vocabularies and terminologies. For example, there are certain redundancies and gaps in code set standards that require additional focused research. Also, it is essential that bridges between clinical and administrative data standards are aligned to achieve synergy in advancing interoperability and administrative simplification. The Committee plans to continue contributing to the development of health terminology and vocabulary policy and science to advance the accurate capture of medical and health information to more fully support health and healthcare transformation.

Sincerely,

/s/

William W. Stead, M.D., Chair  
National Committee on Vital and Health Statistics

CC: HHS Data Council Co-Chairs  
Director, National Library of Medicine