



NCVHS

National Committee on Vital and Health Statistics

February 13, 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 Criteria for Adoption and Implementation of Health Terminology and Vocabulary Standards, and Guidelines for Curation and Dissemination of these Standards

Dear Secretary Azar:

This letter conveys two recommendations for revisions to criteria for adoption of health terminology and vocabulary standards/systems and new guidelines for curation and update of already adopted standards. Health terminology and vocabulary systems, such as the International Classification of Diseases (ICD), are the backbone of interoperable health information, health statistics, and research. These recommended criteria and guidelines will be useful to HHS when considering the adoption of standards. They also will inform the health industry of the characteristics for contemporary standards and their maintenance.

This letter also conveys two reports developed by the National Committee on Vital and Health Statistics (NCVHS) that support adoption of the criteria and guidelines - *Health Terminologies and Vocabularies Environmental Scan*¹ and the *Health Terminologies and Vocabularies Expert Roundtable Meeting Summary*.²

Background

Standardized naming and coding of complex health concepts has been the focus of international collaboration for more than a century. In the U.S., the 1996 Health Insurance Portability and Accountability Act (HIPAA) authorized the Secretary to facilitate administrative simplification through the adoption of standards for transactions, and data elements for such transactions, and enabled the electronic exchange of health information. Health terminology and vocabulary standards define data elements and ensure consistency of meaning as data are

¹ 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>

² NCVHS, *Health Terminologies and Vocabularies Expert Roundtable Meeting Summary*, 2018. <https://ncvhs.hhs.gov/wp-content/uploads/2018/09/Report-Health-Terminologies-and-Vocabularies-Expert-Roundtable-Report.pdf>

exchanged and used for a broad range of essential purposes. They are the content foundation for administrative transactions and for use by electronic health record and other health information systems.

HIPAA directed NCVHS to “study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information.”³ As your advisory committee on health data, statistics, privacy, national health information policy, and HIPAA, NCVHS is also charged with advising the “Department on health data collection needs and strategies; review and monitor the Department's data and information systems to identify needs, opportunities, and problems.”⁴

The Environmental Scan report describes the complexity and variation of the health vocabulary and terminology domain in terms of the number of systems, their purposes and uses, ownership and governance, and ways in which systems are maintained and disseminated. These complexities impact the timely adoption and cost-effective use of uniform standards and the validity and reliability of data to support the range of uses including interoperability and exchange of health information, clinical innovation, public health, vital and health statistics, and biomedical research.

A limited number of terminology and vocabulary systems are referred to as “named standards” defined as “terminology and vocabulary standards that are specifically identified in federal regulations requiring their implementation by the parties set forth in the regulation for purposes or circumstances denoted in the regulation.”⁵ With enactment of HIPAA in 1996, the U.S. government’s role in the collection, exchange, and protection of health data according to nationally established standards was explicitly recognized. NCVHS Guiding Principles for Selecting Patient Medical Record Information Standards were conveyed to the Secretary in July, 2000.⁶

After nearly two decades’ experience with named standards, and based on a comprehensive environmental scan involving HHS agencies and industry experts, **NCVHS recommends approval of updated criteria and guidelines for HHS to use as it guides health terminology and vocabulary initiatives in the coming years.** These will guide evaluation of new standards and version updates for existing named standards. They also serve as a reference to raise the bar for development, curation and implementation of health terminology and vocabulary systems that are not named standards.

³ Health Insurance Portability and Accountability Act (HIPAA) of 1996 [Internet], Pub. L. 104-191, 110 Stat 1936 (Aug 21, 1996) [cited 2018 Aug]. Available from: <https://www.gpo.gov/fdsys/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf>

⁴ NCVHS 2018 Charter. Available from: <https://ncvhs.hhs.gov/about/charter/>

⁵ 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>, p.6.

⁶ National Committee on Vital and Health Statistics. Report to the Secretary of the U.S. Department of Health and Human Services on Uniform Data Standards for Patient Medical Record Information as Required by the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act of 1996 [Internet]. Washington (DC): National Committee on Vital and Health Statistics (U.S.); 2000 Jul [cited 2018 Aug]. 65 p. Available from: <https://www.ncvhs.hhs.gov/wp-content/uploads/2014/08/hipaa000706.pdf>

Recommendations

1. The Secretary of HHS should approve the *Criteria for Adoption and Implementation of Health Terminology and Vocabulary Standards* as delineated in Attachment A.

This set of criteria replaces “Guiding Principles for Selecting PMRI Standards” approved by NCVHS on July 6, 2000, which were designed to support the initial selection of named terminology and vocabulary standards under HIPAA. The new criteria reflect what has been learned in working with named terminology and vocabulary standards over the past two decades. The word “adoption” is used instead of selection, and is defined as “formally establishing a terminology or vocabulary standard through the regulatory process, into effect, practice, or use as a named standard.”⁷ Implementation is defined as “incorporation of terminology and vocabulary standards into operational systems by the industry.”⁸ These recommended criteria reflect the experience and advice of experts who participated in the Roundtable meeting described above.

2. The Secretary of HHS should approve the *Guidelines for Curation and Dissemination of Health Terminology and Vocabulary Standards* recommended as delineated in Attachment B.

These are new guidelines as the issues of terminology and vocabulary maintenance, or curation, and their dissemination were beyond the scope of issues dealt with by the Committee during HIPAA implementation. Curation is the process for managing the semantic content of a terminology or vocabulary, and dissemination refers to the processes supporting wide-scale availability of standard terminologies and vocabularies. As described in the Environmental Scan report, the processes for curation and dissemination are not uniform across named standards and may not be appropriate to the scale and scope of curation and dissemination required to enable interoperable health information, health statistics, and research. Adoption of these guidelines will advance transparency and support migration to improved approaches.

NCVHS is continuing to develop recommendations for the Department regarding health vocabularies and terminologies because other additional near term, mid-term and longer-term areas of opportunity were identified through the environmental scan, expert testimony and discussions with industry experts. For example, the Committee will recommend a path for adopting the next version of the International Classification of Diseases (ICD) in the U.S.

The Committee plans to continue to shape 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.

⁷NCVHS, Health Terminologies and Vocabularies Environmental Scan Report, September 14, 2018, p. 6.

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

⁸ Ibid., p.6.

Sincerely,

/s/

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

CC: HHS Data Council Co-Chairs

Attachments:

- 1) Criteria for Adoption and Implementation of Health Terminology and Vocabulary Standards.
- 2) Guidelines for Curation and Dissemination of Health Terminology and Vocabulary Standards.
- 3) NCVHS, [Health Terminologies and Vocabularies Environmental Scan](#), September 14, 2018.
- 4) NCVHS, [Health Terminologies and Vocabularies Expert Roundtable Meeting Summary](#), September 14, 2018.

Attachment A:

Criteria for Adoption and Implementation of Health Terminology and Vocabulary Standards^{9,10}

HHS will encourage its agencies and programs to use the following criteria to assess and make recommendations for adoption and implementation of standards for health terminologies and vocabularies for use in the U.S.

Health terminology and vocabulary standards should be:

1. Clear in purpose, expected outcomes, boundaries, and guidelines for use and designed to perform well for its stated purpose.
2. Supported by research confirming the benefits and estimates of cost, including burden of use, of adoption and implementation.
3. Sponsored by organizations such as ANSI (American National Standards Institute) or other ISO-accredited (International Organization for Standardization) standards development organizations, or other private or public organizations that will assure transparent practices, open well-documented processes for input and appeal, permitting broad participation from relevant communities of practice, resources, continuity and efficient maintenance and update of the standard over time.
4. Sponsored by an entity with sustainable resources sufficient to keep pace with advances in the medical and health science domain for which the new standard or an update to a named standard is designed and to support implemented standards.
5. Developed by the range of experts required to precisely and unambiguously define and represent the scope and detailed content of the standard using accepted content development practices that optimize data quality.
6. Designed to complement and integrate with related standards to minimize the unnecessary duplication and redundancy and reduce the burden of mapping.
7. Designed to be vendor- and technology independent with explicit semantics.
8. Designed to minimize the need for mapping and translation.

⁹ These Criteria replace the “Guiding Principles for Selecting PMRI Standards” approved by NCVHS on July 6, 2000. National Committee on Vital and Health Statistics, “Report to the Secretary of the U.S. Department of Health and Human Services on Uniform Data Standards for Patient Medical Record Information.” <https://www.ncvhs.hhs.gov/wp-content/uploads/2014/08/hipaa000706.pdf>

¹⁰ Terminology and vocabulary standards that are specifically identified in federal regulations or sub-regulatory guidance requiring their implementation by the parties set forth in the regulation for purposes or circumstances denoted in the regulation. The NCVHS Environmental Scan report lists the terminology and vocabulary standards designated in regulations under HIPAA (Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996) or Promoting Interoperability (“PI,” formerly the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, commonly known as Meaningful Use).

Implementation of adopted standards should be supported by:

1. Where mapping is essential to use, maps are tested and available.
2. No or low cost ways of obtaining standards, implementation guides and maps.
3. Documented lines of responsibility among stakeholders including terminology and vocabulary sponsor, regulators, vendors and end user organizations.
4. Plans and processes for implementation suitable for the terminology and vocabulary standard, considering vendor and user readiness and aligned with overall standards adoption roadmap.

Attachment B:

Guidelines for Curation and Dissemination of Health Terminology and Vocabulary Standards

HHS will encourage its agencies and programs to use the following guidelines to assess the curation and dissemination of standards for health terminologies and vocabularies used in the U.S.¹¹

Health terminology and vocabulary standards curation and dissemination should be:

1. Fully transparent and based on accepted curation practices carried out as a continuous process.
2. Curated by the range of experts required to precisely and unambiguously make modifications using accepted content development practices that optimize data quality.
3. Curated to assure backward compatibility and full and clear documentation regarding additions, changes, and deletions, preferably computer-processable and time stamped.
4. Maintained using open and timely processes for request and consideration of additions, changes and deletions with full disclosure of decisions and rationale.
5. Released according to a publicly available release process at a cadence that balances the importance of enhancements with update costs aligned with overall standards adoption roadmap.
6. Version updates to named standards accomplished through least costly and disruptive sub-regulatory processes.
7. Responsive to customer needs for support services and timely answers to questions about how to apply and use the standards guidelines, maps and other resources.
8. No or low cost ways to obtain updated standards, implementation guides and maps and other resources.
9. Use of electronic resource and dissemination methods that minimize cost and licensing barriers and advance seamless, consistent and predictable processes for accessing the then current versions of standards.

¹¹ Terminology and vocabulary standards that are specifically identified in federal regulations or sub-regulatory guidance requiring their implementation by the parties set forth in the regulation for purposes or circumstances denoted in the regulation. The NCVHS environmental scan lists the Terminology and vocabulary standards designated in regulations under HIPAA (Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996) or Promoting Interoperability ("PI": formerly the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, commonly known as Meaningful Use).