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NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS

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November 5, 2003

The Honorable Tommy G. Thompson
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C., 20201

Dear Secretary Thompson:

As part of its responsibilities under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the National Committee on Vital and Health Statistics (NCVHS) was called upon to "study the issues related to the adoption of uniform data standards for patient medical record information (PMRI) and the electronic exchange of such information." NCVHS studied these issues, prepared a comprehensive Report on PMRI Standards and presented it to the HHS Data Council on August 9th, 2000. This Report provided a framework for PMRI standards and a set of guiding principles for the selection of these standards. The NCVHS then used these guiding principles to evaluate and select PMRI Message Format Standards. The PMRI message format standards became the first set of specific PMRI standards and were recommended to you on February 27, 2002. You subsequently adopted these standards on March 21, 2003 as part of the Consolidated Health Informatics (CHI) initiative.

This letter recommends the second set of specific PMRI standards based on the guiding principles mentioned above. This second set addresses PMRI terminology standards and will complement the recommendations made for PMRI Message Format Standards.

Adoption and use of standards for PMRI message formats and terminologies are important because this will facilitate significant improvements in the quality of patient care, promote patient safety, control rising healthcare costs, enhance the productivity of clinical research and strengthen the nation's ability to identify and respond to health emergencies. They are critical to the creation of a National Health Information Infrastructure. Additionally, use of PMRI standards will enable government to provide higher quality and more efficient healthcare within its own delivery systems through the Consolidated Health Informatics initiative.

Background Information

Process to Select PMRI Terminology Standards

The NCVHS commenced the process of selecting PMRI terminology standards in August 2002 by soliciting input from *medical terminology experts* on the appropriate scope and criteria for selection of PMRI terminologies. Based on the input received and assessed by the NCVHS Subcommittee on Standards and Security, a working document was prepared that specified the scope of the terminology-selection activity and the criteria that would be applied in the selection process[1]. In January 2003, the *developers* of 46 candidate healthcare terminologies were invited to complete a comprehensive

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questionnaire describing various aspects of their terminologies, including (1) content and technical features, (2) extent of usage and market acceptance, and (3) matters of licensing and intellectual property. Rigorous analyses of these data with respect to the previously agreed-upon selection criteria were included in the initial version of the NCVHS PMRI terminology analysis report. This report narrowed the pool of candidate terminologies to ten. Several versions of this analysis were prepared, progressively incorporating data from the questionnaires, comments from members of the NCVHS, and feedback from the terminology developers themselves[2]. Written and oral testimony was then provided to the NCVHS by *users* of the candidate terminologies in May 2003 to ascertain the utility and limitations of the terminologies in practice. This testimony was assembled and analyzed in a companion NCVHS PMRI terminology-user report[3]. Finally, in August 2003, testimony was provided to the NCVHS on the specific topic of terminology standards for *medications* and *medical devices*, and this information was summarized in a separate document[4]. The sum of the information collected through all of these activities was employed by the NCVHS to arrive at the recommendations presented herein.

Guiding Principles Used as Criteria for Selection

As in its previous recommendations on message format standards, the Committee used the following general criteria (derived from the PMRI guiding principles) in formulating recommendations for the PMRI terminology standards: (1) the extent to which the standard enables interoperability between information systems; (2) the ability of the standard to facilitate the comparability of data; (3) the aspects of the standard that support data quality, accountability and integrity; and (4) the degree of market acceptance of the standard. The criterion of "market acceptance" was broadly interpreted to include widespread use and/or strong user support for a new PMRI terminology during NCVHS hearings. This allowed for the appropriate consideration of recently developed terminologies.

Recommendations Encourage HHS Guidance and Incentives Rather Than Mandates

NCVHS recommends that HHS set forth guidance for industry use of PMRI terminology standards, rather than create new federal regulations. NCVHS also recommends that you direct government agencies to follow this guidance by becoming early adopters of PMRI terminology standards and by accelerating the process envisioned for the incorporation of standard terminology by the Consolidated Health Informatics initiative. These actions will serve as an example and incentive to the entire healthcare industry.

NCVHS Recommendations for PMRI Terminology Standards

A "Core Set" of PMRI Terminology Standards

NCVHS recommends that the federal government recognize a "core set" of PMRI Terminologies as a national standard. This core set should comprise the minimal set of terminologies that (1) are required to adequately cover the domain of patient medical record information and (2) meet essential technical criteria to serve as *reference terminologies*[5]. Furthermore, the NCVHS recommends that these terminologies be

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organized into a coherent, internally consistent, minimally redundant, cross-referenced core terminology set. Also, the NCVHS recommends that you designate the National Library of Medicine (NLM) as a central coordinating body to manage this terminology resource and coordinate its ongoing maintenance and distribution.

The initial terminologies recommended for the core set of PMRI terminology standards are:

- SNOMED CT (as licensed by the National Library of Medicine)
- Logical Observation Identifiers Names and Codes (laboratory subset)
- Federal Drug Terminologies:
  - RxNorm;
  - The representations of the mechanism of action and physiologic effect of drugs from NDF-RT; and
  - Ingredient name, manufactured dosage form and package type from the FDA

SNOMED CT

NCVHS, through the terminology-evaluation process described above, has identified SNOMED CT as the general terminology for the core set of PMRI terminologies. The breadth of content, sound terminology model, and widely recognized value of SNOMED CT qualify it as a general-purpose terminology for the exchange, aggregation, and analysis of patient medical information. The broad scope of SNOMED CT itself and the inclusion within it of concepts from other important healthcare terminologies (including the following terminologies developed to support nursing practice: *HHCC, NANDA, NOC, NIC, Omaha System, and PNDS*[6]) allow SNOMED CT to encompass much of the patient medical record information domain. The license agreement between the College of American Pathologists and the National Library of Medicine makes the use of SNOMED CT free of charge in the United States.

Logical Observation Identifiers Names and Codes (LOINC) – Laboratory Subset

NCVHS also determined that the laboratory subset of LOINC ("Lab LOINC") is a useful, soundly constructed, and widely employed terminology for the representation of individual laboratory tests. Lab LOINC is already used in many systems for ordering laboratory tests and reporting laboratory test results. Please note that you already designated Lab LOINC for PMRI standards in your announcement of March 21, 2003.

Federal Drug Terminologies

In its July 2000 report "Uniform Data Standards for Patient Medical Record Information," NCVHS recommended "improvement of drug data capture and use through:

1. requiring the Food and Drug Administration (FDA) to make publicly available in an easily accessible format its National Drug Codes (NDC) database registry information
2. requiring the FDA to develop a drug classification system based on active ingredients so that all drugs that fall into a given category can be identified by the name of that category.

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3. encouraging the FDA to participate in private sector development and ongoing maintenance of a reference terminology for drugs and biologics that promotes the ability to share clinically specific information for patient care purposes."

The NCVHS notes today that HHS has made great strides in implementing these recommendations through cross-agency partnerships that can serve as an example for future efforts. Because the Food and Drug Administration (FDA) has regulatory responsibility for approving safe and effective drug products in the US and has engaged in efforts to harmonize drug-related terminologies nationally and internationally, it serves as the basic source for terminology and information about drug products. Since our July 2000 recommendations, the FDA has been working in partnership with the National Library of Medicine (NLM) and the Department of Veterans Affairs (VA) and in open collaboration within the Health Level 7 (HL7) standards development organization to address the substance of the above recommendations by:

1. NLM creation of RxNorm, a non-proprietary vocabulary that represents drugs at the level of granularity needed to support clinical practice;
2. VA creation of NDF-RT, a non-proprietary terminology that classifies drugs by mechanism of action and physiologic effect;
3. Linking the above to FDA drug terminologies[1] that represent medication information required for regulation, formulation, linkage to commercial drug information services and other special instances of clinical practice; and
4. Taking initial steps to improve the quality and low cost electronic dissemination of all the linked, federal supported drug terminologies.

Versions of RxNorm have been available quarterly for several years through the NLM's Unified Medical Language System (UMLS). It is our understanding that full documentation for RxNorm will be available by January 2004. NDF-RT, currently used in the VA and now available directly from them, will be released in the UMLS in April 2004. RxNorm also facilitates the clinical use of associated drug-product information in electronic form from the FDA. RxNorm, NDF-RT and the linked FDA terminologies have also been proposed as target US government standards by the Consolidated Health Informatics (CHI) initiative.

NCVHS Recommendations for PMRI Drug Terminologies: Based on these developments NCVHS recommends that RxNorm, the representations of the mechanism of action and physiologic effect of drugs from NDF-RT, and ingredient name, manufactured dosage form and package type from the FDA be part of the core set of PMRI terminologies.

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[1] FDA supported terminologies include :

- ingredient name;
- Unique Ingredient Identifier [UNII] (initial version expected to be published in 2004);
- product name and code (first two segments of the National Drug Code);
- packaged product name and code (the complete National Drug Code);
- manufactured dosage form and package type (from the FDA/CDER Data Standards Manual);
- and electronic product label (under development).

The FDA terminology set is recommended, by the CHI initiative, for federal agency exchange of drug information and when appropriate may be used as PMRI terminology.

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These portions of NDF-RT complement, rather than compete with, the capabilities of drug knowledge bases that have been developed within the private sector.

Further Recommendations related to PMRI Drug Terminologies: The NCVHS recommends that the federal government increase funding to the NLM for the RxNorm project to accelerate the development of terminology content and to enable more frequent updates. The NCVHS also recommends increased funding for the FDA's efforts to improve the timeliness and efficiency with which it collects and distributes drug-product information. The success of these efforts will streamline the maintenance of RxNorm and NDF-RT, enhance their value as national standards for coding medications, facilitate patient safety activities and improve information dissemination to private sector drug information suppliers.

Integration of Core Set of PMRI Standard Terminologies

To form a cohesive, internally consistent terminology resource, the core set of PMRI terminologies must be integrated. The terminologies should be integrated by creating relationships within the UMLS. The relationships should be maintained in concert with changes to the constituent terminologies.

Mappings to Important Related Terminologies

NCVHS also recommends that the federal government recognize an additional group of terminologies as "important related terminologies," and that the government promote the creation and maintenance of mappings between these terminologies and the core set of PMRI terminologies specified above. Although these terminologies did not meet the NCVHS criteria for inclusion in the core PMRI terminology standards, their use in important administrative and clinical processes will continue and should be compatible with the recommended PMRI standard. The NCVHS asserts that compatibility of the core set of PMRI terminologies with these important related terminologies (specifically in the form of mappings) will enhance the value and accelerate the adoption of the PMRI terminology standards.

The NCVHS recommends that mapping to the important related terminologies be prioritized as follows:

Priority 1: Terminologies previously designated as HIPAA medical code sets:

- CPT-4 (Current Procedural Terminology)
- CDT (Current Dental Terminology)
- Level II HCPCS (Healthcare Common Procedure Coding System)
- ICD-9-CM (International Classification of Diseases – Clinical Modification)
- NDC (National Drug Codes)

Priority 2: Terminologies in common use as enablers of important healthcare functions. These terminologies include but are not necessarily limited to:

- DSM-IV (diagnosis codes for mental disorders)

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- Terminologies in private sector drug information databases (e.g., FirstDatabank NDDF Plus, Medi-Span, Micromedex, Multum Lexicon)
- ISBT 128 (coding system for describing blood products and tissues)
- Medcin (codes for structured entry of clinical notes)
- MedDRA (international code set for use by drug regulatory agencies)
- Nursing terminologies not otherwise included in SNOMED CT

Designation of a Central Coordinating Body for PMRI Terminologies

The NCVHS recommends that you designate the National Library of Medicine (NLM) as the central coordinating body for the PMRI terminology standards. As such, the NLM would (1) be the official repository and distribution center for the core set of PMRI terminologies, (2) be the organization responsible for integrating the core set of PMRI terminologies into a cohesive, internally consistent whole within the UMLS, (3) provide a mechanism for extraction of the individual PMRI Terminologies from the core set, and (4) be the organization responsible for funding, coordinating, and/or performing mapping between the core set of PMRI terminologies and the important related terminologies. The NCVHS recommends that the federal government increase funding to the NLM so that they can adequately perform these tasks in an expeditious fashion.

Relationship between PMRI Message Format Standards and PMRI Terminology Standards

In previous recommendations to you, the NCVHS identified a set of PMRI message format standards that included HL7 version 2.2+, HL7 version 3, DICOM, NCPDP SCRIPT, and IEEE 1073[7]. Each of these message format standards includes its own code sets, which are used to represent clinical and non-clinical information needed for standard message exchanges. These code sets, while not part of the PMRI terminology recommendations presented herein, remain essential elements of the message format standards and are in no way supplanted by the core set of PMRI terminologies described above. To the degree that there may be overlap in meaning between certain elements of these code sets and elements of the PMRI terminology standards, efforts should be made to achieve consistency.

This will require additional work and cooperation on the part of the standards development organizations and the terminology developers responsible for the various individual standards that comprise the PMRI standards suite.

Recommendations for Additional Research

The NCVHS recommends additional research to address outstanding content issues related to core set of PMRI terminology standards.

Dental Content: Standard terminology for dentistry is an element of the core set of PMRI terminology standards. However, the NCVHS must resolve a number of outstanding content issues before it can put forth recommendations in this specific area. The NCVHS is in the process of investigating and resolving these issues, and plans to make additional recommendations upon completion of this work.

Clinical LOINC: The NCVHS recommends further research into the need for and value of incorporating the clinical subset of LOINC ("Clinical LOINC") into the core set of PMRI terminology standards.

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Device Terminology: Standard terminology for medical devices is also an element of the core set of PMRI terminology standards. The NCVHS heard testimony from the FDA about the Global Medical Device Nomenclature (GMDN) and ECRI about the Universal Medical Device Nomenclature System (UMDNS). The NCVHS learned that the FDA and ECRI are exploring the possibility of merging these two terminologies. We support the merger of these two terminologies and will follow this activity and make recommendations as appropriate.

Content from Other Terminologies: The NCVHS recommends exploring the incorporation of content from terminologies other than those selected for the core set of PMRI terminologies. For example, the International Classification of Functioning, Disability and Health (ICF), which was highlighted in a previous NCVHS recommendation to you[8], may be a valuable source of concepts for encoding functional status. Similarly, concepts from terminologies specific to complementary and alternative medicine may also constitute useful additions.

NCVHS wishes to thank you for the opportunity to submit these recommendations within the framework of the Administrative Simplification Provisions of HIPAA.

Sincerely,

John Lumpkin, M.D., M.P.H.
Chair, National Committee on Vital and Health Statistics

Cc: HHS Data Council Co-Chairs
Enclosures

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[1] Scope and Criteria For Selection of PMRI Terminologies: A Report to the National Committee on Vital and Health Statistics Subcommittee on Standards and Security. Version 3. December 23, 2003. Report prepared by Walter Sujansky, MD PhD on behalf of the Subcommittee on Standards and Security of the NCVHS.

[2] Summary and Analysis of Responses to the NCVHS PMRI Terminology Questionnaire: A Report to the National Committee on Vital and Health Statistics Subcommittee on Standards and Security. Version 4. September 1, 2003. Report prepared by Walter Sujansky, MD on behalf of the Subcommittee on Standards and Security of the NCVHS.

[3] Summary and Analysis of User Testimony for PMRI Terminology Standards: Version 3. September 1, 2003. Report prepared by Walter Sujansky, MD on behalf of the Subcommittee on Standards and Security of the NCVHS.

[4] Summary and Analysis of Testimony on Drug and Device Terminologies for PMRI Terminology Standards: Version 1. September 1, 2003. Report prepared by Walter Sujansky, MD on behalf of the Subcommittee on Standards and Security of the NCVHS.

[5] Spackman KA, Campbell KE, Cote RA. 1997. SNOMED RT: A Reference Terminology for Health Care. Proceedings of the 1997 AMIA Fall Symposium. Philadelphia: Hanley & Belfus. 640 – 644.

[6] HHCC = Home Health Care Classification; NANDA = Nursing Diagnosis Definitions and Classification; NOC = Nursing Outcomes Classification; NIC = Nursing Interventions Classification; PNDS = Perioperative Nursing Data Set.

[7] Letter to Secretary of the Department of Health and Human Services from Chair of the National Committee on Vital and Health Statistics. February 27, 2002.

[8] Letter to Secretary of the Department of Health and Human Services from Chair of the National Committee on Vital and Health Statistics. July 16, 2001.