NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS SUBCOMMITTEE ON STANDARDS AND SECURITY

PROPOSAL FOR THE MODIFICATION OF THE HIPAA TRANSACTION IMPLEMENTATION SPECIFICATIONS ADOPTION PROCESS

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My name is Tom Wilder and I am providing testimony today on behalf of America's Health Insurance Plans (AHIP) regarding the white paper, "*Proposal for the Modification of the HIPAA Transaction Implementation Specifications Adoption Process.*" The white paper was prepared by representatives from the Accredited Standards Committee (ASC) X12, Health Level Seven (HL7), and the National Council for Prescription Drug Programs (NCPDP) and outlines a proposal to shorten the timeframe for modifying standards for electronic health care transactions used by health care providers, health plans, and health care clearinghouses.

I want to thank the Standards and Security Subcommittee of the National Committee on Vital and Health Statistics (NCVHS) for the opportunity to discuss the process used to modify electronic transactions standards as defined by the Health Insurance Portability and Accountability Act (HIPAA). AHIP is the national trade association representing the private sector in health care and our nearly 1,300 member companies provide health, long-term care, dental, vision, disability, and supplemental coverage to more than 200 million Americans.

AHIP's members use electronic transactions to process millions of claims, eligibility requests, payments, and other business operations on a daily basis. As a result, we strongly support the development of HIPAA standards to bring a streamlined, uniform process to these transactions. The change from "paper" to "electronic" transactions has the potential to promote more effective and efficient health care. We agree, however,

with NCVHS' statement in its June 22, 2006 letter to Secretary Michael Leavitt that "the process for changing versions or updating versions of HIPAA standards is slow and cumbersome." The issues with the HIPAA standards process are well-documented in prior testimony to this Subcommittee by representatives of the health care industry and in the white paper.

My testimony will focus on recommendations for streamlining the HIPAA standards process.

Inform the Industry Regarding the SDO Process

The white paper identifies a lack of understanding of the cyclical process of the standards development organizations (SDOs) as a complication with the existing implementation process for creation and modification of HIPAA standards. Many entities within the health care industry as a whole are not fully aware of how standards are created or modified. As a result, the policies and procedures used by ANSI X12, HL7, and NCPDP to develop HIPAA standards represent a "black box" that most health care providers and health plans do not fully understand. Clear guidance is needed to inform the health care industry about the HIPAA standards process and its importance. AHIP recommends that the SDOs collaborate with CMS to develop a publication that describes the standards processes including information about submitting change requests, filing public comments and ballots, and the applicable deadlines for SDO decision making.

Create a Uniform Process for Standards Development

Each standards organization follows a slightly different process for developing HIPAA standards in terms of when change requests must be submitted, how the requests are considered by each organization, when requests are released for public comment, and what are the deadlines for consideration. The SDO white paper recognizes the lack of predictability in the HIPAA standards process which negatively affects the budgeting and planning process for entities that must comply with the standards when they are implemented. Greater uniformity between the SDOs with clear deadlines for the steps needed to approve standards modifications would assist the health care industry in its budgeting and planning process. AHIP recommends that the SDOs work together to develop a uniform process and consistent deadlines for submitting and considering standards changes and that this uniform set of policies and procedures be included in the SDO publication discussed above.

Recognize the Importance of Pilot Testing

Pilot tests allow proposed HIPAA standards to be subject to real world conditions. The importance of pilot testing has been illustrated by recent experience with the proposed claim attachments standard. The claim attachments pilot test provided valuable insight into the use of claim attachments by health care providers and health insurance plans in adjudicating claims.

Pilot testing may not, however, be appropriate for all situations. Greater clarity is needed regarding the need for and the use of pilot testing as part of the HIPAA standards process.

AHIP recommends that the SDOs, CMS, and other industry stakeholders develop a common framework to define when a new standard or a modification of an existing standard would benefit from pilot testing. This framework should describe the procedures that should be used and the timelines for pilot testing.

Preserve the Ability for Public Comments within the HIPAA Rulemaking Process

The SDO white paper recommends a streamlined process for modifications of HIPAA standards. Included in the SDO proposal is a suggestion that public comments on proposed changes be limited to testimony before the NCVHS. With the proposed model, after a public hearing, the NCVHS would submit a recommendation letter to the Department of Health and Human Services (HHS) regarding the proposed change. HHS would subsequently accept or reject the NCVHS recommendation. The white paper concludes that discussion of any proposed HIPAA standards modification should take place during the SDO balloting/approval process and the NCVHS hearings.

We believe public comments on proposed changes to the HIPAA standards must be part of the HHS rulemaking process. The Administrative Procedures Act (5 U.S.C. §551 *et seq.*) requires federal agencies to provide full opportunity for public comment on any proposed regulations, even if the requested changes are considered to be "minor" in nature. This opportunity to provide input is important because comments can be made by any individual or organization and there are no membership requirements placed on those wanting to participate in the comment process. Public input on proposed agency regulations also creates a record in the event that a judicial review of the rulemaking is

needed.

The current SDO process for adopting modifications to the HIPAA standards used by ANSI X12, HL7, and NCPDP does include opportunity for industry input, however, these discussions typically focus on the technical aspects of the standards. In addition, access to discussion materials, the ability to participate in the debate, and the right to vote on any changes are often based on membership in the individual standards organization. The HHS regulatory public comment period is an open process giving the industry and public at large the opportunity to comment on the business operations and policy implications of the HIPAA standards. This forum is a necessary part of the HIPAA standards process and should not be omitted. AHIP recommends that HHS continue to allow public comment at the agency level for any proposed modifications to the HIPAA standards.

Conclusion

AHIP and its member health insurance plans support industry efforts to streamline and improve the HIPAA standards process. The health care industry would benefit from a better understanding of that process and how entities can play a role in making changes to the standards. Health care entities also need a clearer picture of how standards impact their own business operations and budget and planning processes. Critical components of the process are pilot testing of standards changes and the ability for the industry and public to comment at each stage as changes are considered. We look forward to working with NCVHS on this issue going forward.