September 26, 2007

Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

Revisions to HIPAA transaction standards urgently needed

Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the National Committee on Vital and Health Statistics (NCVHS) studies and recommends healthcare information standards. To fulfill this responsibility, NCVHS' Subcommittee on Standards and Security held hearings on proposed new versions of the HIPAA transaction standards on July 30 and 31, 2007. The purpose of this letter is to summarize those hearings and make recommendations.

Background

The original HIPAA transaction standards were adopted in 2000 and amended in 2002. Since that time, hundreds of requests for changes have been submitted to the National Council for Prescription Drug Programs (NCPDP) and the Accredited Standards Committee (ASC) X12N, the Standards Development Organizations (SDOs) responsible for maintaining the transaction standards. Both have developed and approved new versions of the existing HIPAA transaction standards. The NCPDP has also developed and approved a new transaction.

The HIPAA regulation process for reviewing and adopting proposals for modifications and additions to the transaction standards flows through the Designated Standards Maintenance Organizations (DSMOs), consisting of SDOs and content committees (e.g. the National Uniform Claim Committee). They review the proposed standards after SDO approval, and make recommendations to the NCVHS regarding adoption. On July 30 and 31, 2007, the Subcommittee on Standards and Security heard testimony from providers, health plans, vendors, SDOs and others on the need to implement the new standards forwarded in May 2007, the impact on industry, and implementation issues.

ASC X12N Standards

ASC X12N has developed a modified version of their standards, Version 5010, to replace the current HIPAA standards, Version 4010 (as modified by Version 4010A1) for the following transactions:

- ASC X 12 834, health plan enrollment;
- ASC X12 820, premium payments;
- ASC X12 270/271, eligibility inquiry and response;
- ASC X12 278, health care services – request authorization;
- ASC X12 837, health care claims/encounters (institutional, professional and dental);
- ASC X12 276/277, health care claim status request and response; and
- ASC X12 835, health care claim payment/remittance advice.

There are four basic types of changes in Version 5010: structural, front matter, technical improvements and data content changes. Structural changes involve the physical components and either add new data elements; modify length of existing elements, data type, optional status; or remove data elements. Front matter changes are organizational revisions to ensure that each technical report covers the same topics in the same location, and that the standardization of topics is clear, more instructional and accurate. Technical improvements better accommodate the data collected and transmitted. Specifications for Implementation Guides reduce ambiguities from the same data having multiple codes or qualifiers, or from appearing in different segments. Loop and segment repeat counts that were not always logical and sometimes excessive were reduced or removed. Unnecessary data content was removed and redundancies lessened. Needed additions of new information occurred, as in the ASC X12N 278 health care services-request authorization transaction, where a lack of data content for medical decisions about authorizations limited significant industry implementation.

New Version 5010 functions, added in response to industry requests, include: additional audit controls in enrollment transactions; qualifiers when adding or deleting dependents; support of ICD-10-CM for reporting diagnoses and other health conditions and support of ICD-10-PCS for reporting inpatient procedures; privacy issues, such as drop-off locations for other than home residences; a place to report additional deductions to payments; indications of the remittance method used by health plans; added support for 38 patient service type codes; support for reconsideration requests, made prior to a formal appeal; present on admission indicators; ambulance pick-up and drop-off locations; remaining patient liability; national health plan ID (when an identifier is adopted) ; alternate search options; requirements for the health care eligibility response that improve the value of the transaction and tighten situation rules; and information on the patient's portion of payment responsibility. Certain functions such as "purchased service provider" and "referring provider specialty" were removed.

NCPDP Standards

The NCPDP HIPAA standards currently in place are the Telecommunications message format standard, Version 5.1 and its equivalent NCPDP Batch Standard Batch Implementation Guide,

Version 1.1, used for transactions involving pharmacy providers or their authorized billing agents for pharmacy drug claims. These are the main transactions between pharmacies, payers, pharmacy benefit managers (PBMs), and clearinghouses/switches. NCPDP has developed a revised Telecommunications Standard, Version D.0, to replace Version 5.1, and an equivalent batch standard, Version 1.2, to continue support for eligibility verification, claim, service, information report and prior authorization transactions.

Version D.0 modified field and segment defined situations to be "not used", "required if", "required" or "optional", addressing the situational versus optional data requirements from the HIPAA privacy regulations. Segment usage matrices now clarify which segments and fields are sent for each transaction type, and segments and fields within each transaction type. Enhancements to accommodate Medicare Part D include the addition of a "facilitator" entity and eligibility transaction, to provide coded patient eligibility information for Medicare Part D; and enhancements to identify and process Medicare Part D long term care claims. Medicare Part B enhancements include additional segments for processing of Medicare certificates of medical necessity and new data elements for processing those transactions and assistance in the crossover of claims from Medicare to Medicaid.

Version D.0 also supports coordination of benefits (COB) and collection of rebates for compounded claims; clarification for pricing guidelines; the addition of new data elements that give more specificity to the COB process; a new section on prior authorization added to the implementation guide; a prescription/service reference number increase to 12 digits; and transaction codes for service billings.

A new Medicaid Subrogation Standard Implementation Guide, Version 3.0, addresses the business need for a standard that addresses the process whereby a Medicaid agency has reimbursed a pharmacy provider for a covered claim, and is pursuing reimbursement from other payers for these claims. Some states may choose to "pay" all claims in full, through a federal waiver at the point of receipt, and "chase" reimbursements from responsible third parties after the fact. In the absence of such a standard, a proprietary interpretation of the Batch standard or other proprietary standards often are used. This is a new HIPAA transaction.

Observations and Recommendations

Observation 1: Industry urges and supports transition to X12N Version 5010 and NCPDP Version D.0, and adoption of NCPDP Medicaid Subrogation Standard Version 3.0.

Based on the testimony to the Subcommittee from providers, vendors, clearinghouses, pharmacies and other industry segments, testifiers supported the move from X12N Version 4010A1 and NCPDP Version 5.1 to Version 5010 and Version D.0, respectively. The majority of the changes and modifications to these updated standards are a direct result of requests by industry to address demonstrated business needs and, in their totality, reflect a long list of positive changes. There appears to be widespread consensus on the business case for adopting D.0. While there needs to be more work to further quantify the overall business case for adopting Version 5010, there was general industry support for the move. Moreover, there are specific and urgent business drivers (e.g., the need to accommodate ICD-10 codes) that justify its

adoption. There is support for adopting the new Medicaid subrogation transaction, which will standardize the subrogation process across states.

Recommendation 1.1: The Secretary should expedite the development and issuance of a Notice of Proposed Rule Making (NPRM) to adopt NCPDP D.0 and its equivalent batch standard as modifications.

Recommendation 1.2: The Secretary should expedite the development and issuance of a Notice of Proposed Rule Making (NPRM) to adopt the ASC X12N Version 5010 suite of transactions.

Recommendation 1.3: The Secretary should expedite the development and issuance of a Notice of Proposed Rule Making (NPRM) to adopt the NCPDP Medicaid Subrogation Standard Version 3.0 as a new HIPAA transaction.

Observation 2: The timing of standards implementation is complex, and critical to success.

Testifiers acknowledged that there were no implementation issues with NCPCP Version D.0, but there was a need to test Version 5010 in real-life settings to ensure its interoperability and ability to support the transactions for which its adoption is proposed. The process for pilot testing and the parameters of that testing remain to be resolved. Three types of testing needs were identified: 1) testing of the standards themselves for workability; 2) conformance testing of products and applications that send and/or receive the transactions; and 3) end-to-end testing to assure interoperability among trading partners. NCVHS has observed that in previous HIPAA transaction implementation these three types of testing occurred unevenly, resulting in delays. These delays may be minimized or avoided by staging the various types of testing.

Testifiers expressed the need to test and verify Version 5010 before the implementation of ICD-10 code sets. Stakeholders testified that concurrent implementation of the Version 5010 standard with the changeover to ICD-10 would be burdensome to industry and result in errors, escalating system change costs and other barriers.

Because implementation of the ICD-10 code sets is dependent on the implementation of Version 5010, it is critical that the industry is afforded the opportunity to test and verify Version 5010 up to two years prior to the adoption of ICD-10. In addition, the compliance date for the new Claim Attachment standards, for which a Final Rule has not yet been published, will also necessitate significant system changes, and should not be done at the same time as Version 5010 or ICD-10.

Testifiers discussed lessons learned from prior HIPAA implementations, and identified potential barriers and resource issues. The importance of vendor compliance was stressed, as practice management system vendors are key to provider compliance, and delays in vendor rollouts of compliant products have delayed end-to-end testing. The resource-intensive nature of testing, particularly end-to-end testing, was also noted.

A variety of options for staggering the implementation of the Version 5010 and D.0 modifications were offered. For example, the compliance date for plans and clearinghouses

could be a year before the date for providers in order to facilitate end-to-end testing. Alternatively, different compliance dates could be assigned to different transactions (e.g., implement the claim and related transactions first.) Testifiers also attested to the importance of allowing dual processing (old plus new versions) for a sufficient period to allow end-to-end testing to occur.

Testifiers indicated that it is important to engage industry in end-to-end testing as soon as possible. It was noted that widespread use of compliance testing services, which allow entities to test products and applications to assure they can create and accept compliant transactions, could simplify end-to-end testing by assuring that individual products are compliant in advance. An alternative to staggering implementation would be to phase in compliance by establishing consecutive periods for compliance testing and end-to-end testing.

Recommendation 2.1: HHS should consider establishing two different levels of compliance for the implementation of HIPAA transaction and code sets. Level 1 compliance would mean that the covered entity could demonstrate that it could create and receive compliant transactions. Level 2 compliance would demonstrate that covered entities had completed end-to-end testing with all of their partners.

Recommendation 2.2: The implementations of Version 5010, ICD-10 and claims attachments should be sequenced so that no more than one implementation is in Level 1 at any time. HHS should also take under consideration testifier feedback indicating that for Version 5010, two years will be needed to achieve Level 1 compliance.

Observation 3: Various types of testing are needed.

NCVHS recognizes the value of compliance testing services as a precursor to end-to-end testing of system changes, and the need to pilot the use of the standards within organizations, as well as between partners as was done with the claims attachment transaction standards. We also recommend that CMS and industry stakeholders work to standardize commonly used terms such as “pilot testing” and “compliance testing” so that all entities can make decisions based on universally-accepted definitions.

Recommendation 3.1: HHS should develop a plan to work with the industry and the standards organizations to collect and analyze requirements related to testing (including defining the process of pilot testing), determine under what conditions pilots should be conducted, and when this testing should take place.

Recommendation 3.2: HHS should advocate the use of compliance testing services for software and/or applications that would demonstrate a covered entity’s ability to create and receive compliant transactions.

Observation 4: Outreach to all stakeholders is critical.

The Subcommittee heard from stakeholders that the need is great for education and outreach regarding the adoption and implementation of Version 5010. Taking lessons learned from its

experience with the National Provider Identifier (NPI), testifiers reiterated the need to cast a wide net to better inform and educate all industry segments as to how Version 5010 will impact their workflows, operations and other aspects of their respective businesses, as well as critical implementation dates. Special initiatives, such as a joint CMS/SDO/stakeholder Version 5010 education summit, may be needed to target small software vendors and other hard-to-reach groups.

Testifiers proposed that HHS should undertake steps to collect and analyze data about the Version 5010 process, business impacts (both cost and benefit), return on investment and other information and make it available for dissemination. As this is the first update of HIPAA standards and NCVHS also has heard testimony in favor of streamlining the process to adopt modifications to the standards, possible changes to the modification process could be examined.

Recommendation 4.1: HHS should identify communication approaches and strategies to educate and inform interested constituencies by partnering with responsible persons and organizations.

Recommendation 4.2: HHS should develop materials to educate the industry regarding these standards, and in particular Version 5010, to enable industry and stakeholder implementation efforts.

Recommendation 4.3: HHS should consider a summit or other similar event for gathering input regarding the adoption of these standards. A "lessons learned" exercise at the conclusion of this implementation process is recommended to identify best practices as well as issues/concerns to be applied to future standards adoption efforts, which also could include ways to streamline the adoption process for modifications to the standards

The NCVHS appreciates the opportunity to provide these recommendations.

Sincerely,

/s/

Simon P. Cohn, M. D., M.P.H.
Chairman, National Committee
On Vital and Health Statistics

Cc: HHS Data Council Co-chairs