September 22, 2011

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

Dear Madam Secretary:

Re: Observations on the Standards and Operating Rules Development and Maintenance Process under HIPAA

The National Committee on Vital and Health Statistics (NCVHS) is the statutory advisory committee with responsibility for providing recommendations on health information policy and standards to the Secretary of the Department of Health and Human Services (HHS). Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), NCVHS is to advise the Secretary on the adoption of standards and code sets. Under the Patient Protection and Affordable Care Act of 2010 (ACA), NCVHS is also to advise the Secretary on the adoption of operating rules.

The NCVHS Subcommittee on Standards held a public hearing on April 27, 2011, to gain industry and stakeholder insight into the review and update process for standards, implementation specifications and operating rules[1]. In this letter, we provide a number of observations about the existing process which was established with the original HIPAA regulations in 2000. We will continue working with the industry to identify specific areas for improvement and expect to make recommendations in a subsequent letter later this year.

As relayed to you in our letter of September 30, 2010, there are a variety of issues with the current HIPAA standards review and update process. Among them, constraints from the regulatory process; length of time from industry approval to implementation of new transactions, versions, and modifications to approved and adopted versions; lack of predictability in the process; limited pilot testing of transactions prior to implementation; constraints, limitations and lack of industry-wide input in the standards development process. This last point was highlighted by statements from industry stakeholders who have said that they do not send many change requests to the Designated Standards Maintenance Organization (DSMO) because they do not believe the process works, or why it is necessary to use the DSMO when requests can be sent directly to the

[1] See glossary at end of letter for definitions of standards, implementation specifications and operating rules

standards maintenance organizations. Testimony indicated that there are misperceptions and lack of knowledge about the process; difficulty navigating the requirements of the submission process and insufficient or infrequent feedback.

General Observations

There are new entrants to the HIPAA field: The Affordable Care Act (ACA) requires that HHS adopt *operating rules* to support the adopted HIPAA standards. Therefore, there will be new "players" at the table alongside the existing standards development organizations (SDO) and code set maintainers. Similar to standards and code sets, the operating rules will be updated on a regular basis, and such updates will be made based on stakeholder input. The presence of new organizations creating operating rules and perhaps even new standards (e.g. the Electronic Funds Transfer standard) will require that a process be developed to ensure communication and coordination among all relevant entities.

The current change request process needs to evolve: For the standards currently adopted under HIPAA, the change request process has two paths. Change requests may be submitted to the Designated Standards Maintenance Organization[2] or to the individual Standards Development Organizations (SDOs) themselves. The DSMO, comprised of three standards organizations and three code content committees, meets quarterly to discuss the status of change requests and their disposition, and reports annually to the NCVHS standards subcommittee. Over the years, the number of change requests submitted to the DSMO has declined, but there are a steady number of change requests being submitted directly to the standards organizations. For example, between June 2010 and June 2011, the DSMO received 21 change requests, but according to an X12 representative, X12 has received "hundreds of requests" over the same period. Change requests that are processed and accepted by the DSMO are then submitted to the appropriate standards organization or content committee for processing. Changes processed are incorporated into the new version, but do not go into effect until the next version of the standard or code set is adopted through regulation.

The DSMO does not currently have a process or plan for reviewing operating rules, and the current author of the operating rules that NCVHS recommended to the Secretary (CAQH CORE), is not a participant in the DSMO and is under no obligation to have its rules subjected to the same process. Lastly, both CAQH CORE and members of the DSMO have indicated that they do not agree with our September 2010 recommendation that CAHQ CORE become a member of the DSMO.

HHS needs to clearly define differences between standards, implementation specifications and operating rules: Industry is not clear on the distinction between an

[2] Members of the DSMO include the named designated standards maintenance organizations (NCPDP, X12 and HL7) and the code content committees (NUBC, NUCC and ADA)

operating rule and the standard and implementation specification it (the operating rule) supports. We understand that the first Interim Final Rule adopting operating rules for claims status and eligibility has provided clarification. We will use that information in our follow up correspondence with recommendations. However, based on testimony, it is clear that communication and collaboration between the operating rule entities and the SDOs will be critical as enhancements and cross-coordination needs between these three data exchange tools are identified.

Observations Related to the Standards Maintenance Process

Based on the testimony received (both written and oral) NCVHS has developed several observations regarding the maintenance and update process for standards, implementation specifications and operating rules.

Establishing a dependable, orderly, coordinated, predictable and time-defined process for adopting new versions of standards and operating rules is necessary. One of the biggest concerns expressed by testifiers was the lack of an established timeline for adopting subsequent versions of existing standards, and soon to be adopted operating rules. Appropriate strategies need to be developed by HHS, NCVHS and the authors of the standards and operating rules to enable compliance with a defined timeline for maintenance and adoption that is consistent, predictable and aligned between the two. Such timeline should be no sooner than every two years, and no later than every three years.

Standards, implementation specifications and operating rules need to be tested before adoption: Testifiers agreed that standards and operating rules must be tested before they are recommended for adoption – before they are brought to NCVHS, and before NCVHS recommends them to the Secretary. Provider, vendor and payer participation in the testing process will help uncover functionality issues that may have been missed during the development and balloting of the standard. Funding for such efforts is not currently available, and options for such support needs to be explored.

There is a need to formalize the emergency errata process: Each time standards are being implemented and tested, technical flaws may be identified. In many cases, these can be accommodated by “work arounds” that do not violate the specifications. However, in other cases, the flaws are considered “fatal” and the standard and its implementation specification must be changed in order to allow that version of the standard to be used. The current process allows the change to be formally accommodated in a document called an “errata,” which can then be submitted and adopted by HHS. There are apparently other proprietary ways of dealing with these flaws or errors, which lead to inconsistent implementation. This situation demonstrates the need to develop a clearly defined mechanism for making and adopting expedited fixes. Testifiers expressed concern that there are limited avenues to accommodate and allow for “quick but important” fixes identified during testing and long before compliance is required. There needs to be a way to address these issues without

having to wait years until a new version of a standard or operating rule is officially adopted, or building expensive and unique "fixes."

A new structure and process are needed to coordinate maintenance activities, including change requests, for standards, implementation specifications and operating rules: Given that standards and operating rules are in an iterative cycle of enhancement, and are inextricably linked, there is a strong need to ensure changes being requested through one organization, are also reviewed and considered by the other organization(s). The organizations responsible for developing and maintaining standards and operating rules must collaborate in this process to assure consistency and "interoperability" across their products, to develop tools that are useful to the industry and mitigate inefficiencies. NCVHS is in an excellent position to evaluate the change request processes and identify opportunities for improvement. It is clear from stakeholder testimony, however, that these efforts must be coordinated and that every effort should be made to avoid redundancy and any participation burdens.

These are our observations concerning the Standards and Operating Rules Development and Maintenance Process under HIPAA and ACA. NCVHS is fully committed to helping address these important issues. We will follow up with the industry by conducting additional hearings to develop consensus recommendations. We hope to have these recommendations completed by December 2011.

NCVHS believes there is an opportunity created by the Affordable Care Act to improve the effectiveness of the health care system through improved adoption of standards. NCVHS embraces opportunities for such improvements, while believing that there are some serious and significant challenges that must be addressed and monitored. NCVHS continues to stand ready to provide additional guidance or assistance to the Secretary as requested.

Sincerely,

/s/
Justine M. Carr, M.D.
Chairperson,
National Committee on Vital and Health Statistics

Enclosure
Cc: Data Council Co-Chairs

Definitions
(alphabetic order)

Implementation Specification or Implementation Guide (IG): The document(s) explaining the proper use of a *standard* for a specific business purpose. The ASC X12N HIPAA guides are the primary reference documents used to implement the associated transactions, and are incorporated into the HIPAA. The guides or specifications are the specific instructions for implementing a *standard*.

Operating Rules: The necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications. These rules cannot conflict with the standard, or cause an entity to violate any of the requirements in the standard.

Standards: Prescribe the formats, character sets, and data elements used in the exchange of business documents and forms. The EDI standard says which pieces of information are mandatory for a particular document, which pieces are optional and give the rules for the structure of the document.