

March 2, 2012

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

Re: Additional analysis of the update and maintenance process for standards and operating rules

Dear Madam Secretary,

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 for HIPAA transactions. The Patient Protection and Affordable Care Act (ACA) (Sec. 1104. (g)(3)), enacted on March 23, 2010, calls for NCVHS to assist in the achievement of administrative simplification to “reduce the clerical burden on patients, health care providers, and health plans.”

On November 18, 2011, the NCVHS Subcommittee on Standards held a hearing to revisit the status of the development, maintenance and update process for standards and operating rules related to health care administrative transactions. As you are aware, we have had several hearings over the past 18 months dedicated to the issue of standards maintenance. We also receive an annual report from the Designated Standards Maintenance Organization (DSMO), which represents the standards development organizations (SDOs) and the data/code content committees (DCCs). And we hold hearings at least once a year to monitor the status of implementation of HIPAA standards (and now operating rules too).

For this most recent hearing, we sent out several questions in advance to solicit input on the value of the current maintenance and update process for standards and operating rules, as well as on opportunities for change in the current era. A representative from DSMO presented, along with individuals from the Council for Affordable Quality Health’s Committee on Operating Rules for Information Exchange (CAQH CORE), the National Council for Prescription Drug Programs (NCPDP), and the Workgroup for Electronic Data Interchange (WEDI).

Maintenance and update of ASC X12 standards and implementation specifications

Development and maintenance of the health care administrative transaction standards adopted under HIPAA and recently expanded under ACA rests primarily on the standards development body that owns the adopted standard. The DSMO was created in 2000 under the final rule adopting the initial set of HIPAA-regulated transaction standards. Its purpose is to bring together SDOs and DCCs and establish a vehicle to receive, collect, document, process and dispose requests for changes to the existing standards. The DSMO also brings recommendations periodically to NCVHS for the adoption of new standards.

As we have described in the past, one of the intended benefits of the current DSMO process is its mission of openness to allow any interested organization or individual to participate in the development and maintenance of standards. There are processes in place to receive and address requests for changes to an existing standard. However, over the past few years, the number of change requests submitted to DSMO has decreased significantly, and many requests are submitted directly to the respective standards development organization (e.g., NCPDP and ASC X12).

Findings and Observations from the Hearing

One of the most important findings and consistently reported observations from the hearing was that the complexity of the development and maintenance process for standards and operating rules has significantly increased.

It was also observed that there are ongoing inter-organizational issues and limited cross-collaboration between standards development bodies and operating rules authoring entities (ORAEs), primarily due to fears and concerns on the part of SDOs that ORAEs are establishing a parallel process for making modifications to the standards, outside of the process established by the SDO.

In addition to this, and in spite of the original intent and plan for the DSMO, we heard concerns that the number and type of volunteer participants needed to support the work done by each of the standards and operating rule bodies are limited by time and resources. Many stakeholders are not in fact “at the table” to provide input to the update of a standard, and the number of ‘tables’ to be at has grown. WEDI also noted that the public comment periods offered by these bodies are typically short and that communication is limited to those who are already participating – leaving out those who would have a stake in the issue, but are not sufficiently engaged to provide feedback.

Another issue of concern was the timing of review and input of a new version of a standard being vetted by an SDO. In many cases, the SDO requests input for a new version of a standard even before the previous version is fully implemented. This results in lack of input from the industry, and risk of missing important gaps that won't be identified until after the previous version has been fully implemented and used for at least a few months.

Another key issue addressed by testifiers, as well as others through letters, was the lack of full testing of new or updated versions of the standards. This results in the inability to identify gaps and other unintended problems until after the version has been adopted in regulation and often not until after implementation.

Maintenance and updates of operating rules

One of the requirements of the Affordable Care Act is for the Secretary to adopt operating rules to support the adopted standards under HIPAA. The first of these operating rules was adopted in an Interim Final Rule on July 8, 2011, with covered entities to be compliant on January 1, 2013. While operating rules had been implemented on a voluntary basis to date, they will now be required. Therefore, the maintenance and update process for these rules is as important as the update process for standards. CAQH CORE is the authoring entity of the first two operating rules for eligibility and claim status. There is naturally renewed interest in the process for keeping the operating rules up to date and representative of industry needs.

Findings and Observations from the Hearing

During the November 18th hearing, CAQH CORE (CORE) presented its process for maintenance and change requests. CORE uses an open, consensus-based process to develop the operating rules, and has experienced significant participation growth in the work groups in the past year through use of virtual meetings. The representative reported that in 2012, it will ensure there is even greater visibility to the process and will seek input from CMS on how CORE can best support industry compliance. Additionally, CORE will ensure that Town Hall calls and education sessions highlight an on-line process for requesting modifications and viewing aggregated disposition. They specifically discussed the work they will do with NACHA (the National Automated Clearinghouse Association) to ensure that there is stakeholder input from the health care industry on any adjustments to the NACHA Operating Rules governing EFT.

Maintenance and updates of pharmacy standards

NCPDP is the Standards Development Organization responsible for maintaining and updating the standard transactions used for pharmacy claims, eligibility inquiries, and authorizations and referrals.

Findings and Observations from the Hearing

During the November 18th hearing, NCPDP described its standards maintenance process. NCPDP reviews requests four times a year. In 2010, NCPDP reviewed over 60 requests for enhancements. NCPDP processes ballots four times a year and, in 2010, processed over 12 ballots. The changes are applied as brought forward, but it is important to note that industry may not wish to implement approved changes more than once every few years. NCPDP submitted 9 DSMO Change Requests over the years, either concerning HIPAA Policy or requesting a standard or new standard version to be named.

Conclusion

In sum, we continue to hear that the issues affecting the current process include barriers to participation, lack of stakeholder representation, increased complexity of the standards and operating rule maintenance process, timing of vetting of new versions of standards, and limited and inconsistent communication. There are also ongoing inter-organizational issues between SDOs, DCCs, and ORAEs that need to be resolved to ensure a smooth and coordinated cross-collaboration.

We also heard, apropos of the inclusion of operating rules as a mandatory tool for EDI, that there are other improvements that need to be made. Industry continues to request a clear definition of the difference between a standard and an operating rule to avoid duplication of effort or potentially conflicting information, and to provide clear direction of where requests for changes or clarification should be directed. We applaud CMS for providing, as a starting point, a detailed definition and examples of these differences in the Interim Final Rule published in July 2011. We do, however, believe additional clarification and guidance is needed.

In line with the recent implementation of ASCX12 Version 5010, we have heard that there are a number of issues with the standard's implementation specifications that have only now been identified during final testing, with many issues surfacing only three months before the compliance date. However, there is no process, either within the SDO or at the government, to accommodate emergency changes. Thus, despite the checks and balances in

the current processes, there may still be need for corrections or adjustments that were not identified prior to implementation. We agree with industry that it is not efficient or appropriate to wait for several years for such issues to be corrected so that industry has to implement multiple unique “work arounds” until the issues are resolved.

We wish to emphasize to the Secretary, the obvious need for all standard setting and operating rule entities to work more closely together to avoid conflicts, ensure consistency, and facilitate successful implementations. The range of standards used in health care to support administrative health data exchange has grown beyond the original HIPAA-adopted standards, and beyond the realm in which DSMO provided support in the early years of EDI adoption.

Recommendation 1: Based on the repeated question regarding the continued need for the Designated Standards Maintenance Organization process (DSMO) vs. enhancing the procedures and engagement within the individual standards development organizations, we recommend that the Secretary encourage the industry to immediately convene an intensive working group involving SDOs, operating rule authoring entity, DSMO, and key stakeholders to fully evaluate the strengths and weaknesses of the process, with an expressed goal of submitting specific recommendations back to NCVHS and HHS within six months.

Recommendation 2: HHS should work with SDOs and ORAEs to establish an expedited modification and adoption process for ‘emergency’ changes to the standards and operating rules. As mentioned above, it seems that there will always be a need for expeditiously modifying standard requirements during implementation, to accommodate unforeseen issues and oversights, unintended consequences, or new industry needs. This will require an expedited change process as well as expedited acceptance and adoption process, separate from the customary development and adoption process in place today. Recommendations from SDOs and ORAEs on the expedited process should be provided to NCVHS and HHS within six months.

Recommendation 3: HHS should require that before a new standard or operating rule is to be adopted, or a new version of an existing standard or operating rule is to be implemented, testing is completed and findings included in the submission of recommendations to NCVHS for consideration to adopt. In other words, before an entity brings a new version or edition of a standard or operating rule to NCVHS for review and recommendation, there should be a mandatory testing requirement so that the authoring entities can bring that information forward in support of the version of the standard or rule being recommended for adoption. NCVHS will work with HHS to refine existing criteria and develop additional criteria to consistently evaluate the readiness

and adoptability of new standards and operating rules, or new versions of existing standards and operating rules. HHS should also consider working with the industry to establish simulation and testing laboratory environments where new or revised versions of transactions, operating rules, and code sets can be appropriately tested prior to adoption.

Thank you for consideration of these recommendations. We will continue to support your efforts in the promotion and expansion of the adoption process for standards and operating rules.

Sincerely,

/s/

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

Cc: HHS Data Council Co-Chairs