Statement of the Designated Standards Maintenance Organizations
to the
National Committee on Vital and Health Statistics
Subcommittee on Standards

November 2011

The members of the Designated Standards Maintenance Organizations (DSMO) thank the National Committee on Vital and Health Statistics' (NCVHS) Subcommittee on Standards for inviting input on the review of current industry processes for requesting, processing and communicating change requests and ideas for process improvements.

Since the formation of the DSMO, the individual DSMOs and the DSMO Steering Committee have worked closely with NCVHS and its Subcommittees. While most of the membership of this Subcommittee is aware of the DSMO's history and process, we would like to use this opportunity to provide a brief outline to establish a base understanding for those here today and for others in the health care industry.

Background

Formation of the DSMO

The DSMO was formed through the Final Rule and Notice, titled Health Insurance Reform: Standards for Electronic Transactions; Announcement of Designated Standard Maintenance Organizations, published on August 17, 2000. A separate announcement published the same day named the six organizations that make up the DSMO, which are:

- Accredited Standards Committee X12 (ASC X12),
- Dental Content Committee of the American Dental Association (DeCC),
- Health Level Seven (HL7),
- National Council for Prescription Drug Programs (NCPDP),
- National Uniform Billing Committee (NUBC), and
- National Uniform Claim Committee (NUCC)

ASC X12, HL7, and NCPDP are standards development organizations (SDOs) and DeCC, NUBC, and NUCC are data content committees (DCCs).

The regulatory language in the Final Rule establishes the framework for the DSMO and the maintenance processes as follows:

- The Secretary may designate as a DSMO an organization that agrees to conduct the following functions:
    - Maintain standards adopted under HIPAA, and
    - Receive and process requests for adopting a new standard or modifying an adopted standard.
- Maintenance of standards by the appropriate DSMO constitutes maintenance of the standard.
- The Secretary will consider a recommendation for a proposed modification to an existing standard or a new standard only if the recommendation is developed through a process that provides for:
    - An open public access,
    - Coordination with the individual DSMOs,
    - An appeals process,
    - Expedited process to address content needs identified, and
    - Submission of the recommendation to NCVHS.

The six DSMOs entered into a Memorandum of Understanding (MOU) and following this announcement, established the DSMO Steering Committee and a Protocol for operations. Officially, the Steering

Committee is made up of one voting representative and one alternate from each of the respective DSMOs. Each organization has one vote. A representative from the Department of Health and Human Services (HHS) serves in a non-voting liaison role.

Current DSMO Process

The DSMO operates under a process that includes the following guiding principles.

- Allow open public access
- Provide for timely review
- Cooperate and communicate
- Consider all viewpoints
- Evaluate the impact of each change request
- Maintain a national perspective
- Conform to law

The DSMO established a website, www.hipaa-dsmo.org, to manage the change request system and established a process for:

- submission of requests,
- review by the DSMO,
- notification to the requester, and
- appeal, if necessary.

The DSMO also established yearly reporting to the NCVHS on maintenance completed in the previous year and recommendations of next regulatory actions from the industry.

Assessment of the Current Process

Since its inception, the DSMO established a proven framework for the review and maintenance of HIPAA mandated standards. Initially the focus was to incorporate modifications to the original HIPAA mandated transaction standards, beginning with a fast-track effort resulting in the ASC X12 Version 004010A1 and the NCPDP Telecommunication Standard Version 5.1 and Batch Standard Version 1.2. Once the fast-track review was completed, the DSMO was able to turn its attention to other changes that have been or will be incorporated into future versions of the transaction standards.

Hundreds of change requests have been processed through the DSMO process since the completion of the fast-track review. While the industry is familiar with the process, we do believe that modifications to the current process timeline, as well as updates to both the DSMO website and potentially individual organizational websites, could benefit the industry as we move into the future. The DSMO believes that these proposed modifications will align with the Patient Protection and Affordable Care Act (ACA) recommendations to establish an expedited process for introducing new HIPAA mandated standards.

The monthly average of change requests, both received and completed, had decreased significantly in more recent years, which could be attributed to the versions being in place for several years and any immediate changes had already been addressed.

A second potential cause of the decrease in DSMO change requests is the shift in requests being submitted directly to the SDOs as more of the industry has become involved directly with the individual SDOs. The SDOs track changes made based on DSMO change requests. They also produce a summary of all changes made to respective implementation guides, which is included in their final work product. As newer versions of HIPAA adopted implementation guides are brought forward, the DSMO continues to pay specific attention to those changes in the guides that did not come through the DSMO approval process.

The DSMO would like to note that there has been an increase in change requests over the last three months, most likely due to the announcement by ASC X12 that any changes for the next version of the ASC X12 TR3s needed to be submitted by February 4, 2011. Those requests are currently under review according to the schedule based on when they were submitted. It is anticipated that change requests will return to the lower volume highlighted above until the next SDO development cycle.

Recommendations on Process Improvement

The DSMO would like to offer recommendations for the establishment of a process that can foster collaboration and coordination between the DSMO and the new entity/entities charged with the development of operating rules.

It is vitally important that the entity/entities responsible for developing operating rules coordinate with the DSMO to ensure that the industry recommendations for modifications and implementation timelines are consistent with HIPAA mandated transaction standards. Coordination is also needed to help identify changes to future HIPAA mandated guides and to ensure that any operating rules criteria being developed are supported by the applicable standard and are consistent in interpretation. Additionally, ACA seeks to establish an expedited process for introducing new HIPAA mandated standards; this too will require coordination with the DSMO, as new standards and underlying operating rules are being contemplated for those standards requiring operating rules.

The DSMO recommends a framework for coordination and collaboration as follows:

1. The entity/entities responsible for the creation of operating rules for each of the transactions must adhere to the consistency and conformity in each of the standards.
2. The Operating Rules entity/entities' membership must represent expertise in the standards; demonstrate balance of representation, openness and consensus with all industry parties in their processes.
3. The Operating Rules entity/entities develop and maintain an approved process for updating the operating rules. This can be accomplished by requiring the entity/entities to become accredited by the American National Standards Institute (ANSI).If multiple entities are selected and there is overlap with the HIPAA-named transaction expertise, collaboration must take place within the entities for a single set of operating rules for that specific HIPAA-mandated transaction. The industry cannot effectively support multiple operating rules for a single HIPAA-named transaction providing the same industry function.
4. The Operating Rules entity/entities must work closely with the HIPAA SDOs including ASC X12, HL7, and NCPDP as new standards or versions of standards are being developed.
    a. As industry requirements are brought forward, updates need to be evaluated as to their appropriateness in the implementation specification or in the operating rules guidance (for example data content rules would be brought forward to the appropriate SDO for consideration of inclusion in the implementation specification).
    b. The updates for the operating rules must be in coordination with the implementation specifications referenced.
    c. The schedule for operating rules updates must be coordinated with updates to the implementation specification version in the regulatory process, when appropriate. The recommendation for operating rules updates must come through the DSMO/NCVHS/HHS process.

The DSMO also recognizes that the deadlines in ACA require adoption of operating rules to the standards already adopted. As such, the DSMO is suggesting these recommendations as a starting framework.

1. All operating rules must comply with the HIPAA regulatory language.
2. The DSMO is reviewing processes to see where streamlining can occur.
3. Coordination by the Operating Rules entity/entities with the DSMO must be completed for adoption of rules to existing or new HIPAA mandated standards utilizing the DSMO review and approval process.
4. A formal regulatory framework for handling the introduction of new operating rules for other transaction standards (existing and future versions) must include coordination and collaboration with the DSMO prior to the rules being brought forward to the NCVHS.

Coordination between the DSMO, the SDOs, and the operating rules entity/entities is vital to provide the industry with a consistent and timely process for updates to the HIPAA mandated transaction standards and the accompanying operating rules.

Items Taken Into Consideration by the DSMO Relative to Its Recommendations:

1. Organizations pull from the same pool of volunteers in given industry expertise and this expertise must be used in an efficient manner.
2. Implementation specifications adopted are already subject to modification adoption via the Interim Final Rule (IFR) comment process.
    a. Approved change requests will appear in the implementation specification during the next cycle. Requirements, guidance, etc belong in the implementation specifications.
    b. Operating rules must address issues outside the scope of the implementation specification.
        i. If they do not "fit", the topic may be appropriate for an operating rule.

Recommendations/Topics of Importance to Note:

1. The DSMO recommends a clear statement be issued to the industry that operating rules are not "interim" implementation specification rules. For example, they are not intended to "fix" the implementation specification, add additional requirements to a transaction, or provide a stop gap until the next version of the implementation specification is published.
2. The DSMO recommends that it be clear that operating rules are subject to modification adoption via the IFR process.
3. It is expected the public will not always know whether a request may need to be in an implementation specification or an operating rule document.
    a. The public may submit a request to the incorrect entity. In that event, the DSMO recommends that the entities will forward these requests to the correct reviewing entity and inform the submitter of this action.
    b. The DSMO recommends that the requests should be sent to the DSMO or the SDO first unless it is clear to the submitter that the request can go directly to the operating rules entity.
4. The DSMO is analyzing its current website and processes for efficiencies and opportunities for improving public and industry education regarding the process.
5. The DSMO recommends that the operating rule entities will have a mechanism to receive public requests for modifications.
6. The DSMO recommends any operating rules authoring entity to coordinate their recommendations for operating rule version upgrades with the DSMO by submitting Change Requests. This recommendation will contribute to transparent review of operating rules that should be incorporated into future HIPAA implementation standards.
7. Recommendations for version upgrades to operating rules should following the existing processes. The DSMO submits an annual report of change requests to NCVHS and then NCVHS makes recommendations to HHS for subsequent rulemaking.

Recommendation for Future Change Request Process

Change Requests for a standard or operating rule will originate either from the public:

1. Requests can go into the DSMO Change Request System or directly to the Operating Rule entity (this gives the public another entry point).
    a. If the DSMO receives a change request that, after initial review, is determined to be "only an operating rule request", it will be sent to the appropriate Operating Rule entity and given the newly created DSMO category status of "Sent to operating rule entity".
        i. This allows the DSMO to be able to verify that when a new version of the operating rule document comes forward through the DSMO, it did address requests received by the DSMO. (The DSMO verifies today that a new version of

an implementation specification brought forward did address requests received by the DSMO.)

Or, change requests will originate from the SDO and be sent to the appropriate operating rule entity:

1. There may be requests that come into the SDO process that may be considered for operating rules. The SDO can submit a DSMO change request or send the request to the appropriate operating rule entity directly.

Or, change requests will originate from the operating rule entity and be sent to the appropriate SDO:

1. There may be requests that come into the operating rule process that must be considered for implementation specification modifications. The Operating Rule entity can submit this request into the DSMO process or directly to the appropriate SDO.

Once the operating rules are developed, the existing process to request naming of updated versions or new operating rule documents must be followed. This process occurs in a new cyclical timeline based on the requirements outlined in ACA and the use of an IFR.

The process will be as follows:

1. Operating rule document is requested to be named via DSMO change request.
2. DSMO deliberates as usual, which includes verifying that all change requests received and approved have been addressed in the operating rule document.
3. DSMO reports recommendation to NCVHS.
4. NCVHS hears testimony.
5. NCVHS notifies HHS of recommendation.
6. HHS chooses whether to adopt recommendation.
7. If chosen, HHS proceeds with rule making.

Other Consideration

The DSMO previously submitted a recommendation for a process to streamline the adoption of standards through the regulatory process. ACA has addressed concerns about the use of the Notice of Proposed Rulemaking (NPRM) process. The DSMO requests that you review this proposal to see if there are additional improvements that could be made to the standards and operating rules development processes to make them more efficient for the industry.

Summary

The DSMO appreciates the opportunity to participate in these hearings and present our recommendations on the current change request process and ways to improve its efficiency and effectiveness. The introduction of operating rules into the administrative requirements will be a significant change for the industry. We are pleased to see NCVHS playing a central role in the development of processes to coordinate the development of standards and operating rules. I will be happy to answer your questions now and the DSMO looks forward to continuing to be a part of this conversation in the future.