

Statement of the Designated Standards Maintenance Organization
National Committee on Vital and Health Statistics'
Subcommittee on Standards
Regarding
Upcoming Regulations on Operating Rules

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RE: DSMO Coordination

On behalf of the Designated Standards Maintenance Organizations (DSMO), I want to thank you for the opportunity to comment. The DSMO was created by regulation (45 CFR § 162.910) for the purpose of maintaining the *Health Insurance Portability and Accountability Act (HIPAA)* standards adopted by the Secretary. With the passage of the *Patient Protection and Affordable Care Act (PPACA)* it included provisions that affect the administrative simplification requirements under HIPAA. One of the provisions calls for the establishment of “operating rules” for all HIPAA transaction standards. These operating rules are to be developed by a non-profit entity/entities through a consensus-based process and then subjected to review by the National Committee on Vital and Health Statistics (NCVHS) and the Department of Health and Human Services (HHS). The DSMO would like to offer our recommendations for the establishment of a process that can foster collaboration and coordination between the DMSO and the new entity/entities charged with the development of operating rules.

Since its inception, the DSMO has 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 Accredited Standards Committee X12 (ASC X12)Version 004010A1 and the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Version 5.1 and Batch 1.2. Once the fast-track review was completed, the DSMO turned its attention to other changes that have been or will be incorporated into future versions of the transaction standards. Each year the DSMO presents a report to the NCVHS on changes adjudicated by the DSMO review process. The DSMO process allows any interested party to submit or view change requests and to view the DSMO recommendations.

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 its interpretation. Additionally, PPACA also 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.

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 entity/entities' membership must represent expertise in the standards and demonstrate balance and consensus in their processes.
3. If multiple entities are selected, they all must apply similar principles of consistency and conformity when approaching the creation and support of operating rules.
 - a. We recommend that the operating rules entity/entities develop and maintain an approved process for updating the operating rules. This can be accomplished by requiring these entity/entities to become accredited by the American National Standards Institute (ANSI).
 - b. We recommend that if multiple entities are selected and there is overlap with the HIPAA-named transaction expertise, that 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 the same HIPAA-named transaction. (For example, we do not recommend multiple operating rules from multiple entities for the same X12 270/271 transaction.)
4. The entity/entities must work closely with the HIPAA Standards Development Organizations (SDO) such as ASC X12 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, when appropriate, be coordinated with updates to the implementation specification version in the regulatory process. The recommendation for operating rules updates must come through the DSMO/NCVHS/HHS process in place today.

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

1. All operating rules must comply with the HIPAA regulatory language.
2. The DSMO is offering assistance with evaluating potential operating rule entity/entities. The DSMO would participate with the operating rules entity/entities on a rotational basis. This is especially true as DSMO representatives are industry participants today.
3. Coordination from the operating rules entity/entities with the DSMO for upcoming rules to existing or new HIPAA mandated standards would require the DSMO review and approval process in existence today be used for the operating rules brought forward for consideration to the NCVHS.
4. A formal regulatory framework for handling the introduction of new operating rules for other transaction standards (existing and future versions) – again 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 known, repeatable process capable of providing a consistent and timely process for updates to the HIPAA mandated transaction standards and the accompanying operating rules.

As the current DSMO Steering Committee Chair, I want to extend our thank you for consideration of our comments and recommendations. Should you have any questions for the DSMO, you may reach us by contacting me at 312/422-3398 or by email at garges@aha.org

Sincerely

George Arges
On behalf of the DSMO