Fact Sheet

Terms And Information Pertaining To The Designated Standards Maintenance Organizations, Standards And Operating Rules Under The Health Insurance Portability And Accountability Act Of 1996 (Hipaa) And The Affordable Care Act

DEVELOPED TO PROVIDE BACKGROUND FOR THE NCVHS STANDARDS SUBCOMMITTEE VISIONING MEETING, JULY 10-11, 2019

Definitions

- **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 as adopted for purposes of this part. 162.103 (added July 2011)

- **Standard**: The term "standard," when used with reference to a data element of health information or a transaction referred to in section 1173(a)(1) of the HIPAA legislation[1] means any such data element or transaction that meets each of the standards and implementation specifications adopted or established by the Secretary with respect to the data element or transaction under sections 1172 through 1174.

- **Standard transaction**: A transaction that complies with an applicable standard and associated operating rules adopted under this part. 45 CFR 162.103 and updated in 76 FR 40458 (July 8, 2011).

- **Standard Setting Organization (SSO)**: An organization accredited by the American National Standards Institute (ANSI), including the National Council for Prescription Drug Programs (NCPDP), that develops standards for information transactions, data elements, or any other standard that is necessary to, or will facilitate, the implementation of this part. From Pub. L 104.191. 1996, Section 1171 (8).

Adoption of Standards.

1172 (c) Role of Standard Setting Organizations.

(1) In general - Except as provided in paragraph (2), any standard adopted under this part shall be a standard that has been developed, adopted or modified by a standard setting organization.

(2) Special Rules

[1] Health Insurance Portability and Accountability Act of 1996, or "the Act."

(A) Different Standards. The Secretary may adopt a standard that is different from any standard developed, adopted or modified by a standard setting organization, if

(i) the different standard will substantially reduce administrative costs to health care providers and health plans compared to the alternatives; and

(ii) the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5, United States Code (Administrative Procedures Act or APA).

(3) Consultation Requirement

(A) A standard may not be adopted under this part unless –

(i) in the case of a standard that has been developed, adopted, or modified by a Standard Setting Organization, or SSO, the organization consulted with each of the organizations described in subparagraph (B) in the course of such development, adoption, or modification, and

(ii) in the case of any other standard, the Secretary, in complying with the requirements of subsection (f), consulted with each of the organizations described in subparagraph (B) before adopting the standard.

(B) Organizations Described. The organizations referred to in subparagraph (A) are the following:

(i) National Uniform Billing Committee (NUBC)

(ii) National Uniform Claim Committee (NUCC)

(iii) Workgroup for Electronic Data Interchange (WEDI)

(iv) American Dental Association (ADA)

(f) ASSISTANCE TO THE SECRETARY. The Secretary shall rely on the recommendations of the National Committee on Vital and Health Statistics (NCVHS) and shall consult with appropriate Federal and State agencies and private organizations.

1173 (a) STANDARDS TO ENABLE ELECTRONIC EXCHANGE

(A) the financial and administrative transactions described in paragraph (2); and

(B) other financial and administrative transactions determined appropriate by the Secretary, consistent with the goals of improving the operation of the health care system and reducing administrative costs.

Useful Background Information Related to the DSMO Regulation of 2000

Announcement of Designated Standards Maintenance Organizations HCFA-0149-N (August 17, 2000)

The designated standards maintenance organizations are to **maintain** the standards adopted by the Secretary, and **receive and process requests** for adopting a new standard or modifying an adopted standard.

Final Rule to adopt Standards for Electronic Transactions (August 17, 2000). This final rule included adoption of administrative and financial standards and an explanation of the role of the Designated Standard Maintenance Organizations (DSMO) to maintain the standards, propose modifications to existing standards and responsibility for proposing new standards to NCVHS. These organizations, which could include Data Content Committees (DCC's) and SSOs, could also receive and process requests for the creation of a new standard or the modification of an existing standard. In 162.910, HHS explained that the DSMOs were a subset of DCCs and SSOs. A **Federal Register** notice was published announcing the organization names.

In the rule, HHS wrote: "The Secretary recognized that not every medical specialty or health plan considered itself to have sufficient voting representation or weight within the DMSOs. Therefore, the DSMOs were to operate a process which allowed open public access for requesting changes to the standards, consideration of the request by each organization, coordination and final agreement among the DSMOs on the request, an appeals process for a requester of a proposed modification if the final decision is not satisfactory (65 FR 50344)."

In the August Final Rule, the criteria for the processes to be used for maintenance by the DCCs and SSOs, was established.

§ 162.910 Maintenance of standards and adoption of modifications and new standards.

(a) Designation of DSMOs.

(1) The Secretary may designate as a DSMO an organization that agrees to conduct, to the satisfaction of the Secretary, the following functions:

(i) Maintain standards adopted under this subchapter.

(ii) Receive and process requests for adopting a new standard or modifying an adopted standard.

(2) The Secretary designates a DSMO by notice in the FEDERAL REGISTER.

(b) Maintenance of standards. Maintenance of a standard by the appropriate DSMO constitutes maintenance of the standard for purposes of this part, if done in accordance with the processes the Secretary may require.

(c) Process for modification of existing standards and adoption of new standards. The Secretary considers a recommendation for a proposed modification to an existing standard, or a proposed new standard, only if the recommendation is developed through a process that provides for the following:

(1) Open public access.

(2) Coordination with other DSMOs.

(3) An appeals process for each of the following, if dissatisfied with the decision on the request:

(i) The requestor of the proposed modification.

(ii) A DSMO that participated in the review and analysis of the request for the proposed modification, or the proposed new standard.

(4) Expedited process to address content needs identified within the industry, if appropriate.

(5) Submission of the recommendation to the National Committee on Vital and Health Statistics (NCVHS).

Following publication of the Federal Register Notice, the six DSMOs[2] executed a Memorandum of Understanding.

The MOU includes a process or Standard Operating Procedure (SOP) for handling change requests, managing the web site, and submitting reports to NCVHS.

Changes to this MOU, including additional signatories, must be approved by three-fourths majority of the Steering Committee, and by HHS. Modifications can be made to the MOU to keep the HIPAA Standard Change Request management system aligned with industry and regulatory needs. The MOU includes a statement that says, "as appropriate, the Committee will address urgent issues."

Operating Rules

Operating rules were introduced as part of the administrative simplification provisions of the Patient Protection and Affordable Care Act of 2010 (ACA)

ACA required that operating rules be adopted for each individual adopted HIPAA transaction, and that NCVHS advise HHS on the appropriate operating rule authoring entities. In 2011, NCVHS recommended that CAQH CORE be the designated authoring entity for operating rules for the administrative, non-pharmacy transactions. NCPDP is the operating rule authoring entity for pharmacy transactions; these rules are often incorporated into the standard or payer sheets.

Operating rules are submitted by the authoring entity to NCVHS for consideration to be recommended to the Secretary for adoption.

Operating Rule Authoring Entities must meet certain requirements:

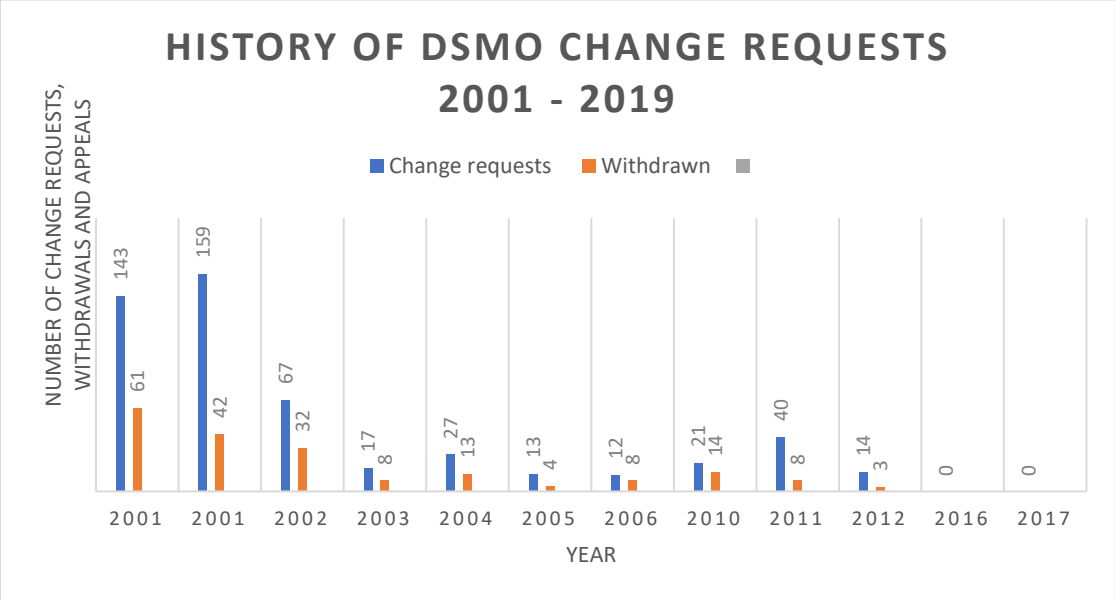
1. Mission be focused on administrative simplification
2. Demonstrate multi-stakeholder and consensus based process for development of operating rules
3. Have a public set of guiding principles that ensure the operating rules and processes are open and transparent
4. Build on the transaction standards issued under HIPAA
5. Be an entity that allows for public review and updates of the operating rules
6. Create operating rules that do not conflict with other existing standards and are consistent with electronic standards adopted for health IT

[2] The six (6) DSMOs: NUCC, NUBC, ADA, X12, HL7, NCPDP

DSMO Status

The DSMO reported to NCVHS on a regular basis between 2001 and 2017. Reports are available on the DSMO website at www.hipaa-dsmo.org

DSMO change requests have declined over the years, in large part due to change in stakeholder strategy of sending change requests directly to the SDOs where the work group activities take place for each transaction and standard.



DSMO Report Highlights

2017: most recent report confirms that no change requests have been submitted to the DSMO between 2016 the present.

2012: DSMO Activities

- Discussed improvements to the current review process and recommendation to NCVHS that they pursue recommendation to HHS again for adoption of acknowledgements.
- Developed educational presentation re: change request process in response to industry confusion about roles and responsibilities. Available on the HIPAA-DSMO website.
- Began discussions for implementation of recommendations to streamline the change request process and said they plan to continue that work in CY2012.

2010: Report covers a 20 month period and addresses the decline in requests since 2002. Potential reasons cited were the amount of time since implementation of 4010, and the shift in

requests being submitted directly to the SDOs. None of the DSMO reports indicate how many change requests each of the SDOs were receiving individually in any of the years e.g. for X12 vs. NCPDP. Note, we adopted version 5010/D.0 in 2009 with mandatory compliance date in 2012.

In this report, the DSMO wrote that it would continue to coordinate with WEDI on the cost/benefit impact analyses for each transaction being put forward for adoption (5010/D.0 at the time). Once the change requests and cost/benefit analyses have been completed, the DSMO and WEDI would forward the recommendations and information to NCVHS for its consideration. The DSMO would be prepared to present testimony on its recommendations.

2009 Report. Developed proposal for the modification of the HIPAA standards adoption process. This proposal was initial effort to improve the process of adopting standards to meet the needs of the health care industry. The first predictability roadmap was proposed in 2006, and finalized in 2009. At that time, all SDOs agreed to a process with WEDI and OESS (former name for NSG) in which the proposed and final rules would be completed within 2 years. Proposal included a "call for standards." If the industry is ready to move, then an updated standard is placed into the known queue. If the industry is not ready, the standard waits until the next call cycle. New versions might not be named each year, but the process would be in place so that it is predictable and timely. After the call for standards, the regulatory process fits within a predictable timeline so industry can plan adequately from cycle to cycle. The standards would reflect current business requirements and not force stakeholders to code work arounds while the standard go through the process. The 8 problems identified in this 2009 paper, were also identified in 2002:

a. Constraints from the regulatory and APA processes
b. Lengthy of time from industry approval to implementation of new versions
c. Modifications being made to approved implementation specifications
d. Lack of predictability in the process
e. Pilot testing as a possible requirement step
f. Lack of industry understanding of the cyclical process at the SDO
g. Not enough industry input at the time of SDO development (it's too late once an NPRM is published), and
h. Lack of agreement on how often the industry wants to move to a new version vs. market need for making that change.

2008 Report. Discusses upgrade to 5010, D.0, and recommendation to NCVHS. Report indicated that a cost benefit impact had been provided by WEDI for the X12 and NCPDP transactions. The DSMO indicated that it would review the NPRM when released. The DSMO was also anticipating release of a rule from HHS on modifications and emergency processes for the HIPAA adoption processes. The DSMO had provided input to CMS on the topic in 2004 and 2005 (Page 3). http://www.hipaa-dsmo.org/reports/2006%20Annual%20Report.pdf

For details on these and all other previous reports back to 2001, please visit the DSMO website at www.hipaa-dsmo.

Under the Affordable Care Act, there were a number of provisions related to Administrative Simplification that have remained unaddressed under both 1104 and 10179. One of them is this:

Review and recommendations for amendment of standards and operating rules by a review committee (which may be NCVHS[3], and which must be coordinated with standards recommended by the HIT Standards Committee[4] that supports certified electronic health record [EHR] technology approved by Office of the National Coordinator [ONC]), must:

- be promulgated as an IFR 90 days after receipt of report
- include public comment received within 60 days of IFR publication
- become effective within 25 months of the close of the public comment period

[3] The law does not require NCVHS to serve in this role; another committee with appropriate technical skills and sufficient time could serve this function.

[4] The HIT Standards Committee was disbanded through the 21st Century Cures Act, and replaced by a new Federal advisory committee for the Office of the National Coordinator – the Health IT Advisory Committee, or HITAC. HITAC unifies the roles of, and replaces both the Health IT Policy and Standards Committees. HITAC will recommend to the National Coordinator policies, standards, implementation specifications and certification criteria relating to the implementation of a national and local health information technology infrastructure that advances the electronic access, exchange and use of health information.