# Evaluation of Operating Rules and Authoring Organizations
## Appendix C

**Executive Summary**: The ACA legislation charges NCVHS with selecting and informing HHS on the entity/entities that meet the requirements to serve as authoring organizations for operating rules. The committee is also to select and inform HHS on which operating rules should be adopted for the HIPAA transaction standards. The first two operating rules to be adopted are for eligibility and claims status transactions.

**Process**: In July and August 2010, NCVHS engaged in a comprehensive review process for operating rules and their authors. The first effort consisted of a full day of testimony on July 20, 2010, with over 20 stakeholders representing a cross section of industry. Two candidates asked to be considered – CAQH CORE and NCPDP[1]. A third author of EXISTING operating rules in a region of the country also asked to participate in the hearings, and testified about their organization, and also provided input as to changes that were needed in the over arching structure of standards development and operating rules. The July hearings were followed by a request to each candidate to respond to a detailed questionnaire about the statutory requirements. The questionnaire solicited specific documentation to validate the testimony. These included minutes, voting records and copies of bylaws. Both CAQH CORE and NCPDP responded to the request. A synopsis of the responses is provided here.

**Outcome**: Both organizations meet the statutory requirements for an authoring entity because both: a) focus their missions on administrative simplification, b) use and demonstrate a multi-stakeholder and consensus based process for development of their operating rules, c) have a public set of guiding principles that ensure the operating rules and process are open and transparent, d) support nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory practices, e) build on the transaction standards issued under HIPAA, and f) allow for public review and updates of their rules. However, given the transition that will take place as the rules become mandatory rather than voluntary, there are still a number of adjustments to process and procedure that may be required for both organizations, such as more formalized relations with each other and with other SDOs, inclusion of a more diverse cadre of stakeholders, and a more formal public review process. Both organizations acknowledged these issues in their submissions. Nonetheless, the intent of the first part of the legislation is met for the authoring entity requirements.

With respect to the requirements for the operating rules themselves, both organizations do not meet all of the requirements for both sets of standards. There are weaknesses and limitations for each organization, and they differ between them. The legislation requires the adoption of operating rules for the eligibility and claims status standard transactions, and this requirement applies to both X12 and NCPDP standards, since both have standards for eligibility. Based on review of the submissions, neither organization can unilaterally provide operating rules to support both sets of standards. NCPDP naturally focuses on the NCPDP pharmacy standards, while CAQH CORE has focused on the medical, X12 administrative transactions. While both entities have similar policies related to securing a consensus view of health care stakeholders and ensuring that rules are consistent with (and do not conflict with) other existing standards, neither organization has actual rules in place for both sets of standards. NCPDP clearly meets the requirements for the pharmacy transactions but does not have any existing rules to accommodate the X12 standards. CAQH CORE has phases of operating rules that accommodate the X12 standards and some pieces of pharmacy transactions, but no operating rules specific to the NCPDP transactions.

Based on the evidence provided, the committee is recommending the adoption of NCPDP for pharmacy transaction operating rules, and CAQH CORE for non-pharmacy transaction operating rules. There is a caveat on the recommendation for the CAQH CORE non-pharmacy transaction operating rules. While CAQH CORE Phases I and II have some traction within industry, there are clearly industry issues and state stakeholder needs that have not been addressed. Furthermore, some of the issues are significant enough to impact the effective implementation of these rules for Version 5010. The committee feels strongly that if there is to be success with the operating rules, that the industry and CAQH CORE should take advantage of the brief window of time to make them truly relevant and useful. The same requirement is not the case for NCPDP, as these operating rules have been in use by the industry for many years, and have not been subject to change requests. The table on the following page provides a summary of the committee's review of each organization's submissions.

[1] These organizations are described in the Environmental Scan available at www.ncvhs.hhs.gov

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| Requirements for authoring entities and operating rules | NCPDP | CAQH |
|---|---|---|
| **THE ENTITY** | | |
| focuses its mission on administrative simplification | ✓ | ✓ |
| demonstrates a multi-stakeholder and consensus-based process for development of operating rules | ✓ | ✓ |
| has a public set of guiding principles that ensure the operating rules and process are open and transparent, | ✓ | ✓ |
| builds on the transaction standards issued under HIPAA | ✓ | ✓ |
| allows for public review and updates of the operating rules | ✓ | ✓ |
| **OPERATING RULE FOR ELIGIBIILITY** | | |
| to the extent feasible and appropriate, enable determination of an individual's eligibility and financial responsibility | ✓ Pharmacy only | ✓ Non-pharmacy only |
| be comprehensive, requiring minimal augmentation by paper or other communications | ✓ Pharmacy only | ✓ Non-pharmacy only Addresses variety of needs, not necessarily all |
| provide for timely acknowledgment, response, and status reporting | ✓ Pharmacy only | ✓ Non-pharmacy only |
| describe all data elements (including reason and remark codes) in unambiguous terms, require that such data elements be required or conditioned upon set values in other fields | ✓ Pharmacy only | ✓ Non-pharmacy only. Addresses variety of data elements; not all |
| **OPERATING RULE FOR CLAIMS STATUS** | | |
| to the extent feasible and appropriate, enable determination of an individual's eligibility and financial responsibility | NA for claims status | NA for claims status |
| be comprehensive, requiring minimal augmentation by paper or other communications | NA pharmacy transactions do not use claims status | ✓ Non-pharmacy only. Addresses variety of needs, not necessarily all |
| provide for timely acknowledgment, response, and status reporting | NA pharmacy transactions do not use claims status | ✓ Non-pharmacy only |
| describe all data elements (inc. reason and remark codes) in unambiguous terms, require such data elements be required or conditioned upon values in other fields | NA pharmacy transactions do not use claims status | Under development (Phase III) applies to non-pharmacy only. |