September 30, 2010

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

Dear Madam Secretary:

Re: Affordable Care Act (ACA), Administrative Simplification: Operating Rules for Eligibility and Claims Status Transactions

The National Committee on Vital and Health Statistics 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). The Patient Protection and Affordable Care Act (ACA) (Sec. 1104. (g)(3)), enacted on March 23, 2010, calls for NCVHS to provide advice and recommendations to the Department of Health and Human Services (HHS) relative to operating rules for electronic exchange of information not defined by a standard or its implementation specification. Specifically, NCVHS was tasked to:

(A) Advise the Secretary whether a nonprofit entity meets the requirements for operating rules development;

(B) Review the operating rules developed and recommended by such nonprofit entity;

(C) Determine whether such operating rules represent a consensus view of the health care stakeholders and are consistent with and do not conflict with other existing standards;

(D) Evaluate whether such operating rules are consistent with electronic standards adopted for health information technology; and

(E) Submit to the Secretary a recommendation as to whether the Secretary should adopt such operating rules.

There have been a number of implementation challenges over the past six years for the HIPAA financial and administrative transaction standards. Specifically, health plans have imposed unique requirements on providers to accommodate

state laws and their own system complexities, proprietary software and business operations. These requirements resulted in the creation of hundreds of "companion guides" that require providers to adhere to different transaction implementation rules for different health plans. Companion guides are more commonly used for non pharmacy transactions, but the pharmacy community is not immune to having such guidance provided them by health plans – typically in the form of "payer sheets."

The use of companion guides and payer sheets by health plans has created inconsistency in the use of the standard transactions – this has been confusing and costly to providers. In order to control the variance and inconsistency, some large and small scale industry efforts have been undertaken to reach consensus on standard operating rules for specific standard transactions. These efforts included an attempt to agree on a common structure and content for companion guides. With respect to operating rules to "standardize the standards," for example, there is at least one national private sector initiative that has developed operating rules with an emphasis on the eligibility and claims status transactions. This is the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE). CORE has also created a companion guide template. There is at least one regional initiative, LINXUS, focusing on the greater New York and surrounding states, that has developed operating rules or "implementation specifications" for eligibility, claims status, and remittance transactions. AHIP and BCBSA have implemented a pilot project where health plans in Ohio and New Jersey offer a single website for providers to connect with most of the health insurers for certain administrative functions. There are several states that have addressed the need for consistency by requiring adoption of a single statewide companion guide with common operating rules, or voluntary adoption of best practices. Minnesota and Washington are two states that provided testimony to NCVHS about their experiences in this area. The Workgroup on Electronic Data Interchange (WEDI) has also developed a recommended format for companion guides. The National Council for Prescription Drug Programs (NCPDP), an ANSI-accredited standards development organization has created a payer sheet template for the pharmacy transactions since the advent of HIPAA, and this template is used by the pharmacy industry.

To understand the issues associated with operating rules and potential authoring entities, NCVHS contracted for an environmental scan to be conducted (see Appendix A, the Environmental Scan which is also available at www.ncvhs.hhs.gov ) and held hearings on July 20-21, 2010. A wide range of stakeholders provided in-person or written testimony, including health plans, providers and provider organizations, health care clearinghouses, pharmacy industry representatives, standards developers, professional associations, representatives of Federal and State health plans, WEDI, the banking industry. Two entities came forward to propose that they serve as authoring entities (CAQH CORE and the National Council for Prescription Drug Programs (NCPDP)) for the operating rules (see Appendix B for list of testifiers and written testimony).

At the hearings, many testifiers reiterated the need for greater consistency and standardization in the use of the HIPAA transactions. Their issues were consistent with the provisions in the Affordable Care Act, which call for an increase administrative simplification. The administrative simplification provisions highlight the need to improve the use of standards, increase industry adherence to the implementation specifications of the standards, encourage greater adoption of automated transactions, and enable more timely updates and adoption of the HIPAA standards. All of these activities could all help reduce the clerical burden of both paper and the non-standard use of the existing transactions.

At present, the update and adoption process for standards is slower than industry would like. Some testifiers noted that few recommendations for changes are brought to the Designated Standard Maintenance Organizations (DSMO) or through the ASC X12 change process. The DSMO is the national body responsible for reviewing requests for changes to the standards. While the DSMO process is very thorough, industry has experienced frustration with the length of time between when new versions of standards are balloted by the SDOs and readied for adoption, as well as the lengthy rule making process for adoption of new standards or updated versions of existing standards. The Affordable Care Act seeks to resolve this dilemma.

Operating rules can play an important role in filling "gaps" created by the flexibility or lack of definition in the standards. Testifiers placed an emphasis on the need to clearly define the respective purpose of standards, implementation specifications, and operating rules to avoid conflicting roles among the three tools. Several testifiers suggested that new industry requirements that could be addressed by operating rules, implementation specifications and/or standards, be brought to the DSMO Committee and adjudicated there as to whether the need was operational or content-oriented.

Finally, testifiers expressed the desire for a future implementation strategy that coordinates adoption of new versions of standards, implementation specifications and operating rules. Testifiers urged that sufficient time be provided for adoption of operating rules such that industry testing is enabled. Testifiers also noted that any subsequent adoption of new versions of operating rules should be appropriately staged with the timing of the adoption of new versions of standards and implementation specifications.

Based on the testimony and its analysis of the qualifications of the candidate authoring entities (see Appendix C, Evaluation of authoring candidates and operating rules), NCVHS has developed six observations and a set of recommendations for each observation. These observations and recommendations serve as input to the Secretary with respect to operating rules authoring entities and operating rules for eligibility and claim status transactions. Observations and recommendations are provided on (1) naming operating rules authoring entities, (2) adopting operating rules for eligibility and claim status transactions, (3) content of operating rules, (4) uses of companion guides, (5) coordination between operating rules authoring entities and standards development organizations, and (6) certification of compliance with operating rules.

1. **Observations relating to authoring entities for operating rules**: There are two organizations that expressed interest in being authoring entities: CAQH CORE and NCPDP. CAQH CORE has produced operating rules for the eligibility (ASC X12 v5010 270/271) and claim status (ASC X12 v5010 276/277) transactions. NCPDP has incorporated operating rules for the pharmacy transactions (Version D.0) within its implementation specifications and does not believe that additional, separate, operating rules are needed for these transactions. There are, however, "payer sheets" that are used as companion guides for business operations purposes. Although NCPDP does not currently have operating rules for X12 standards beyond the pharmacy industry use of the X12 standards, NCPDP testified that it has the processes in place to produce such operating rules as well.

**NCVHS advises the Secretary that:**

1.1 CAQH CORE meets the requirements as the authoring entity for operating rules for non-retail pharmacy-related eligibility (ASC X12 v5010 270/271) and claim status (ASC X12 v5010 276/277) transactions, with additional qualifying requirements addressed in recommendations below.

1.2 NCPDP meets the requirements as the authoring entity for operating rules for retail pharmacy-related operating rules for eligibility transactions (Telecommunications Standard Implementation Guide vD.0), with additional qualifying requirements addressed in recommendations below. For pharmacy transactions, the operating rules are embedded in the standard itself. The pharmacy industry does not currently use the claim status transaction, and operating rules are not relevant to their business operations for claims status. .

**Recommendations – HHS should:**

1.3 require authoring entities to maintain minutes, attendance, voting records, and other appropriate documentation that will help NCVHS conduct verification that the authoring entities have utilized an open, consensus-driven process with broad stakeholder participation and provided an opportunity for public comment in authoring any new operating rules or new versions of existing operating rules, consistent with such processes followed by ANSI-accredited standards development organizations.

1.4 continue to use NCVHS and its open process to evaluate, select, and recommend any new qualifying operating rules authoring entities when it comes time to adopt operating rules for other transactions, or for newer versions of the operating rules for the transactions for which CAQH CORE and NCPDP are being recommended to be named authoring entities at this time.

1.5 not require use of additional, separate, operating rules in NCPDP transactions beyond those that NCPDP has already adopted and might develop in the future as part of its implementation specifications during normal versioning cycles.

2. **Observations for operating rules for eligibility and claim status:** NCPDP has incorporated operating rules into the Telecommunications Standard Implementation Guide vD.0, following an open, consensus-based process as an ANSI-accredited standards development organization.

   CAQH CORE Phase I rules were adopted in 2006 and over 50 organizations are certified by CAQH CORE to use the Phase I rules. However Phase I rules did not cover claims status. CAQH CORE Phase II rules were adopted in 2008 and added some operating rules for claims status. Phase II also accommodates changes made to ASC X12 v5010. However, Phase II rules do not fully address all stakeholder needs, as evidenced by states and other entities developing their own operating rules or best practices. Phase II does not include all of the desired functionality for claims status transactions, as these are being addressed in Phase III. There are 19 organizations certified to use Phase II, which while not a large number of plans, does represent significant enrollment. During and after the hearings, other organizations stated their commitment to becoming certified and/or using the operating rules. CAQH CORE testified that it has support from organizations such as Aetna, Blue Cross and Blue Shield Association, AAFP, ACP, AMA, Enclarity, HIMSS, Microsoft, and others for its operating rules. CAQH CORE has also testified that Colorado, Ohio, Texas, and Virginia have expressed interest in adopting the CAQH CORE rules for state initiatives. For the record, CAQH CORE is still in the process of developing Phase III operating rules in collaboration with stakeholder partners.

   **Recommendations – HHS should:**

   2.1 adopt CAQH CORE Phase I and Phase II operating rules for non-retail pharmacy eligibility (ASC X12 v5010 270/271) and claim status (ASC X12 v5010 276/277) transactions.

   2.2 strongly encourage CAQH CORE to collaborate with current and new stakeholders such as Medicaid agencies and states to identify priority elements and best practices (those items with best ROI opportunities) to enhance Phase II. The enhanced Phase II should be submitted to NCVHS in time for its December 1, 2010 meeting. If changes to Phase II cannot be made by December, HHS should adopt Phase I and Phase II as they stand.

   2.3 adopt NCPDP for retail pharmacy-related eligibility transactions the operating rules incorporated by NCPDP in the Telecommunication Standard Implementation Guide vD.0.

2.4 require that the specific versions of CAQH CORE Phase I and Phase II and NCPDP operating rules adopted by regulation not be altered until a new version is adopted.

3. **Observations relating to content of operating rules:** operating rules can play an important role in filling "gaps" created by the flexibility or lack of definition in the standards. These gaps include:

- Performance and system availability requirements
- Connectivity and transport requirements
- Security and authentication requirements
- Business scenarios and expected responses
- Data content refinements (to situational data elements and codes used within specific data elements)

Some testifiers added to this that operating rules fill gaps between the time changes are requested and can be incorporated into a new version of the standard, implying that the need for operating rules might either be short term or temporary. Testifiers also observed that operating rules must not add, modify, or remove requirements defined in the standard implementation specifications.

In the past, companion guides were used to establish business practices, such as response time, system availability, communication protocols, and hours of operation, amount of claim history available for inquiries and real-time adjustments, security practices, and others.

**Recommendations – HHS should:**

3.1 ensure that any changes to the content of a standard's implementation guide included or being considered for inclusion in future versions of operating rules, be evaluated by the DSMO. This evaluation would ensure that the operating rule is not attempting to add, change, or remove requirements defined by the implementation guide.

3.2 request, consistent with Recommendations in Section 2 above, that CAQH CORE establish and widely publicize an open process to receive, evaluate, and incorporate into the Phase I and Phase II operating rules to be adopted, additional items received from states and other entities that have adopted standard operating rules, companion guides, implementation specifications, or best practices.

3.3 recognize that the content that NCPDP has incorporated into Telecommunications Standard Implementation Guide vD.0 meets the requirements for the operating rules for retail pharmacy eligibility transactions.

3.4 direct CAQH CORE and NCPDP to enable operating rules to be sufficiently generic that they can be accommodated within any type of covered entity's business operations.

3.5 direct CAQH CORE and NCPDP to enable operating rules to be sufficiently generic that they can accommodate needs of various types of providers (i.e., hospitals, clinics, nursing homes, etc.) and various forms of health plans (i.e., indemnity, HMOs, PPOs, etc.) as applicable to the scope of the rules.

3.6 direct CAQH CORE and NCPDP to openly collaborate with health plans and providers to include requirements for use of the Health Plan Identifier (HPID) in each applicable field in the standard transaction in existing operating rules,

**4. Observations for use of companion guides**: NCVHS heard testimony concerning the continued use of companion guides when operating rules are adopted. NCVHS does not wish to encourage the perpetual use of companion guides which subvert the adoption of standards. However, testifiers did indicate that companion guides may be necessary for transmission instructions and other limited business purposes.

**Recommendations – HHS should:**

4.1 require that any companion guides deemed necessary by health plans do not conflict with the standards, implementation specification and operating rules adopted by regulation and follow a standard format and content agreed upon by industry consensus across all sectors. Companion guides should be limited to providing basic trading partner facts, such as contact information, websites, service phone numbers, etc.

5. **Observations for coordination among operating rules authoring entities and standards development organizations:** NCVHS observes that the industry has been frustrated with the lengthy period of time between the creation and balloting of new versions of the HIPAA standards and the lengthy rule making process to adopt them. ACA seeks to rectify this issue by calling for a more regular cycle of updating, review and adoption of new versions. NCVHS also heard that the standards development organizations are very open to recommendations for changes in order to keep their standards up-to-date. Standards development organizations also expressed frustration that recommendations for changes are not being made to the Designated Standard Maintenance Organizations (DSMO) Committee convened for this purpose.

**Recommendations – HHS should:**

5.1 designate any operating rules authoring entity as a DSMO and require its participation in the DSMO.

5.2 incorporate into rulemaking that, as recommended in 3.1, all future changes to operating rules and standards be made through the DSMO, to enable changes to be made to the applicable artifact (standard, implementation guide, or operating rule).

5.3 require operating rules authoring entities to adopt a standard versioning methodology and phraseology for operating rules similar to standards development organizations.

5.4 Designate CMS as a non-voting participant in the DSMO Committee.

6. **Observations relating to compliance certification for health plans specific to operating rules**: There are no certification requirements for compliance with standards under the current HIPAA transactions and code sets regulations. ACA requires compliance certification of health plan use of standards and operating rules starting in December 2013. This does not apply to providers or healthcare clearinghouses. CAQH CORE administers a voluntary certification process for a fee. The fee is based on organization size for any entity (including health plans, providers, and health care clearinghouses) that chooses to be CORE-certified. Such fees may be onerous on small entities. Other organizations offer certification testing for compliance with standards, implementation specifications and CORE operating rules, including the Claredi certification testing solution from Ingenix (www.ingenix.com) and Edifecs, Inc. (www.edifecs.com), which may be free or included in service agreements.

**Recommendations – HHS should:**

6.1 require CMS to develop a certification process for all standards, implementation specifications and operating rules in accordance with the ACA legislation. CMS may designate one or more independent outside entities to provide health plan compliance certification. Until the certification process is developed and such entities are formally designated, any current certification process should be considered voluntary and not required.

6.2 enable CMS to work with the industry to identify free or low cost options recognized by CMS for validating compliance with standards, implementation specifications and operating rules.

NCVHS believes there is an opportunity created by the Affordable Care Act to improve the effectiveness of the health care system through improved adoption of standards. NCVHS embraces opportunities for such improvements, while believing that there are some serious and significant challenges that must be addressed and monitored. Though the time frames are extremely tight for carrying out the recommendations in this letter, they will allow the industry to capitalize on the opportunities presented by the operating rules to support the goals of administrative simplification. NCVHS continues to stand ready to provide additional guidance or assistance to the Secretary as requested.

Sincerely,

/s/
Chairperson, National Committee
on Vital and Health Statistics

Enclosures:
Appendix A: Environmental Scan
Appendix B: List of Testifiers and Submitters of Written Testimony
Appendix C: Evaluation of Operating Rules and Authoring Entities

Cc: HHS Data Council Co-Chairs