

December 7, 2011

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

Re: Affordable Care Act (ACA), Administrative Simplification: Recommendation to adopt operating rules to support the Standards for Health Care Electronic Funds Transfers and Health Care Payment and Remittance Advice

Dear Madam Secretary:

The National Committee on Vital and Health Statistics (NCVHS) 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). Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), NCVHS is to advise the Secretary on the adoption of standards and code sets for HIPAA transactions. The Patient Protection and Affordable Care Act (ACA) (Sec. 1104. (g)(3)), enacted on March 23, 2010, calls for NCVHS to assist in the achievement of administrative simplification to “reduce the clerical burden on patients, health care providers, and health plans.” by providing advice and recommendations to the Department of Health and Human Services (HHS) on the development of uniform operating rules for electronic exchange of information not defined by a standard or its implementation specification. Specifically ACA mandates NCVHS to:

- “(A) Advise the Secretary as to whether a nonprofit entity meets the requirements under paragraph (2) of the statute regarding 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.”

This letter is the fifth in a series addressing the ACA charges to the Committee, in concert with our existing responsibility to advise the Secretary on the adoption of standards. Our first four letters addressed: 1) the health plan identifier (HPID); 2) operating rules and their authoring entities for eligibility and claim status transactions, 3) a standard for Electronic Funds Transfer (EFT), and an authoring entity for operating rules to support standards for EFT and Electronic Remittance Advice (ERA); and 4) recommendation on the adoption of standards for the health care acknowledgment transaction. This letter provides an update on our evaluation of the proposed operating rules for EFT and ERA and our recommendations on the adoption of those operating rules.

We have provided support for the concept of operating rules in our earlier letters, and reiterate here that operating rules serve an important role of providing clear guidance on the use of standards, and also to serve as an intermediate, transitional step between consecutive versions of standards.

As stated above, the NCVHS must advise the Secretary on whether requirements are met for an authoring entity to develop operating rules for **each** of the adopted HIPAA standard transactions. We have done so already for the eligibility and claims status standards.

With respect to operating rules for EFT and ERA, after the December 3, 2010 NCVHS hearings and the January 2011 submissions from authoring entity candidates, NCVHS recommended that you name Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) in collaboration with NACHA (The Electronic Payments Association), as the candidate authoring entity for operating rules for all health care EFT and ERA transactions, with the proviso that this entity submit to NCVHS fully vetted operating rules for consideration by the committee, by August 1, 2011.

We stipulated in that recommendation letter that the EFT and ERA operating rules must address the medical and pharmacy communities because pharmacy uses the X12 version of the electronic remittance advice. Further, we stated that the proposed rules would be reviewed by NCVHS and further recommendations would be considered, including that the operating rules submitted may or may not be deemed acceptable for a recommendation for adoption. Finally, we stated that the authoring entity should not be formally recognized as the NCVHS recommended entity, per ACA, until their finished operating rules are reviewed and recommended by our Committee.

Evaluation of the CAQH/CORE Operating Rules for the Health Care EFT and ERA Standard Transactions

On August 1st, CAQH CORE and NACHA sent a letter to NCVHS with information about the five EFT and ERA operating rules that had been developed and balloted. Links to those rules can be found at the end of this letter. The information below is a direct

quote from leadership of both CAQH CORE and NACHA regarding the proposed operating rules. In the document, they stated that:

“...each draft rule has been vetted through multiple stages of development and was deemed a priority among the many suggestions initially considered. Further vetting is underway to finalize the rules per the CAQH CORE process or to identify further dialogue that should occur within the industry. In the four months since the NCVHS recommendation was issued, and in keeping with the direction of NCVHS, the medical, pharmacy and financial services industries have collaborated in the following ways in order to draft these rules:

- 1. Conducted detailed research, e.g., review of over 100 EFT and ERA enrollment forms to identify key gaps in data collection that create a barrier to provider adoption.*
- 2. Identified priorities to ensure a focus on the goal of administrative simplification.*
- 3. Agreed upon evaluation criteria to place emphasis on ensuring that all CAQH CORE operating rules meet the ACA definition of operating rules as opposed to the role of standards.*
- 4. Debated the potential approaches to address high priority areas via operating rules.*
- 5. Held numerous open calls and shared draft documentation with a wide range of constituents.*
- 6. Drafted rule language that addresses requirements specific to pharmacy versus medical.*
- 7. Outlined areas for potential changes to the NACHA operating rules for the CCD+ standard to ensure coordination between the financial services and healthcare industries’ operating rules.*
- 8. Widely vetted the complete draft CAQH CORE operating rules through the weekly call process, open update calls, surveys, straw polls and actively sharing updates on the CAQH CORE and NACHA websites.”*

To support its application, in its August 1, 2011 letter, CAQH CORE and NACHA provided information about the participants on the work groups, and stated that there were 80 organizations, including large and small health care providers and health plans, as well as Medicare, Medicaid agencies, clearinghouses and vendors. Other accomplishments cited by CORE and NACHA include:

1. CAQH CORE signed an Memorandum of Understanding with National Council for Prescription Drug program (NCPDP).
2. Representatives from NCPDP and Accredited Standards Committee X12 (ASC X12) attended nearly every CORE rule-writing call. Both groups have participated in requests for research reviews and straw polls of the draft rules.
3. Best practices from the State of Minnesota and the State of Washington were reviewed and considered for inclusion in the operating rules.

4. Medicare shared de-identified data on ERAs from FY 2010 that facilitated essential analysis on one of the draft rules.
5. Numerous new entities have participated actively, e.g., US Treasury.
6. NACHA, representing its 11,000 financial institutions participants, has distributed information on the draft operating rules to its healthcare task force members.

NCVHS committee members are aware that while there is evidence that industry engagement in the development of operating rules has increased, there is still room for improvement. We intend to monitor ongoing participation to assess the representation from providers, health plans, clearinghouses, vendors, Medicare and State Medicaid agencies. We recognize that it would be important to evaluate the standards development organizations in the same way, and commit to this effort for 2012.

Though there are some caveats, we believe that the CORE/NACHA partnership generally met the basic operating rule development requirements of ACA as well as NCVHS' specific recommendations to include the pharmacy community and to continue to expand stakeholder and industry participation (as noted above). As with transaction standards and implementation specifications, NCVHS does not evaluate the detailed, technical aspects of the operating rules. Rather, it assesses the applicability of the ACA requirements and verifies that input from a spectrum of stakeholders was considered and that the industry will generally benefit by the purpose and scope of the rules. Based on our review of the rules and additional industry input we've received, NCVHS makes the following comments and recommendations at this time:

Adoption of Operating Rules for EFT and ERA

Recommendation 1.0: The Secretary adopt the set of five operating rules submitted by CAQH CORE and NACHA, conditional on the authoring entities making certain revisions to the proposed operating rules (recommendations 1.1 and 1.2).

At the heart of our recommendations is our shared vision to support the adoption and use of EDI for the benefit of the health care industry, with the expectation that this will reduce costs and administrative burden. In a previous letter we recommended the adoption of a standard for a health care EFT and defined it as the electronic message used by health plans to order, instruct, or authorize a depository financial institution (DFI) to electronically transfer funds through the Automated Clearing House (ACH) network from one account to another. We want to take this opportunity to clarify that this recommendation applies only to the EFT message between the health plan and its financial institution.

Recommendation 1.1: The Secretary ensures that all references to the CORE Certification requirement are removed from any documents that are adopted as mandatory by HHS, and that the CAQH CORE website be similarly updated and amended.

The CORE rules for eligibility and claim status embed a requirement that entities become CORE Certified, and imply that entities using the rules must be CORE Certified. For example, the very first reference to the Operating Rules states that organizations must “sign a binding pledge to adopt, implement and comply with CORE Phase I rules. A CORE authorized testing vendor must certify that their systems are CORE compliant within 180 days of signing the pledge.” Within the Phase III EFT/ERA rule itself, the language appears that states: “A Core-certified health plan or its agent must align its internal codes....” Or that “when receiving a Version 5010 835, a CORE-certified product must...” Finally, the entire front section of the Phase I rule, which governs all subsequent rules, itemizes the requirements for CORE Certification and the means by which this can be attained and the associated fees to attain the “Core Seal.”

In the Interim Final Rule published on July 8, 2011, which adopted the first set of operating rules for eligibility and claims status, HHS explicitly did not adopt certain elements of these operating rules. One of the items specifically excluded in the regulation is the requirement that all entities (providers, health plans and clearinghouses) using the operating rules must be CORE Certified. HHS specifically excluded this portion of the operating rule for several reasons; foremost because there will be a separate CMS compliance certification path for health plans for all standards and operating rules, consistent with the ACA requirements. As you are aware, ACA has an entire provision that mandates health plans to certify their compliance with the transaction standards, implementation specifications and operating rules, beginning December 31, 2013. Furthermore, in today’s environment, certification for compliance with standards and operating rules can be obtained from a variety of certification programs available to covered entities. Thus, the language in the operating rules that requires CORE Certification specifically can be misleading, given the alternatives. It should be noted that the CAQH CORE Certification requirement applies to ALL entities using the rules, while ACA only requires a certification action for health plans. Thus, were the CORE Certification requirement allowed to remain; an added financial burden would be placed on small entities that may not have resources to pay for such an intensive process.

We suggest that CAQH CORE certification be explicitly and separately noted as a voluntary option for HIPAA covered entities, and that references to CORE certification be eliminated from operating rules that apply to the Acknowledgment transaction standards and any future operating rules that NCVHS may be asked to consider for recommendation to the Secretary.

Recommendation 1.2: The Secretary work with CAQH CORE to develop a naming convention that consistently and easily identifies the transaction to which the rule applies.

CORE currently names its operating rules using the term “Phase” in each one: *CORE Phase I Eligibility and Benefits Operating Rules*; *CORE Phase II Policies and Operating*

Rules; CORE Phase III (which includes a host of information about claim status, acknowledgments, and the EFT/ERA proposed rules).

We wish to underscore the robust content of the operating rules by highlighting that the current set contains both *business* rules and *technical* rules. Business rules are those which tell the user “what” is to be done – e.g., provide certain information in each transaction. The technical rules tell the user “how” it is supposed to be done – e.g. provide the data in one hour. In the CORE rules, the technical rules could be applicable to all transactions (claims status, eligibility, EFT, ERA), so these could be more appropriately maintained in a separate set of “base infrastructure” operating rules (such as those that pertain to system availability, access, internet access etc.), which would clear the way for a clearer naming convention – one name per rule per transaction – to be implemented. Industry users would apply the technical rules across all transactions, and use the documents for EACH transaction to implement the business rules for that specific transaction.

Recommendation 2.0: HHS fund studies that will effectively obtain data on implementation costs and benefit of both standards AND operating rules.

The new operating rules (for EFT and ERA) are truly new – meaning they have never been implemented before. Industry has not had the benefit of early adopter use and testing. This is because of the time frame between their development and required timing for adoption (based on the dates mandated under ACA). There are no available data on cost, usefulness, usability, impact on efficiency or cost savings. NCVHS will monitor adoption of operating rules and work with the industry to identify issues as the first round of operating rules move into production. With financial support and objective testing, private and public sectors will be better served with standards and operating rules that can be reliably and efficiently adopted.

Maintenance and Change Requests for Operating Rules. Each of the named standards development organizations (SDOs) has documented and publicly identified procedures in place to solicit, receive and reconcile requests for changes on a rolling basis. At present, CORE does not have a similar process for accepting requests for changes to the rules. Rules are created and vetted through subgroups and work groups initially, and then approval takes place through a Steering Committee followed by a final vote by the CORE voting organizations (a subset of organizations from the sub groups and work groups). During our November 18th hearing, we addressed the change request and maintenance process for both standards and operating rules. At this time, we wish to apprise you of our intent to carefully evaluate how change requests are made, received, evaluated and disposed of; ballot procedures for updated versions, solicitation of industry involvement and the like – for SDOs and operating rule entities. We understand that CMS is already receiving inquiries about how to change individual rules within the set of operating rules for eligibility and claims status. This is likely happening because those operating rules were initially drafted and voted upon with less industry involvement – in large part because they were voluntary. This is no longer the case and we are aware of industry concerns. The November hearing provided insights

that will be useful to us in making recommendations to you to ensure an effective and appropriate change request process.

NCVHS remains available to answer any questions and will continue to support the Secretary's initiatives towards administrative simplification in every way possible.

Sincerely,

/s/

Justine M. Carr, M.D.
Chairperson,
National Committee on Vital and Health Statistics

Cc: Data Council Co-Chairs

The rules are:

- Draft Phase III CORE ERA Infrastructure (835) Rule - http://www.caqh.org/pdf/RWG_Ballot_PIII_835InfrastructureRule.pdf
- Draft Phase III CORE EFT Enrollment Data Rule – http://www.caqh.org/Host/CORE/EFT-ERA/ERA_Enrollment_Data_Rule.pdf
- Draft Phase III CORE EFT & ERA Re-association (CCD+/835) Rule - http://www.caqh.org/Host/CORE/EFT-ERA/DRAFT_EFTERAREassociationRule.pdf
- Draft Phase III CORE Uniform Use of CARCs and RARCs (835) Rule – http://www.caqh.org/Host/CORE/EFT-ERA/DRAFT_CARCRARC835.pdf
- Draft Phase III CORE - Required Code Combinations for CORE-defined Business Scenarios - http://www.caqh.org/Host/CORE/EFT-ERA/DRAFT_CORE-requiredCodeCombos.pdf