

March 23, 2011

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: Recommendation for entity to submit proposed operating rules to support the Standards for Health Care Electronic Funds Transfers and Health Care Payment and Remittance Advice

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.”

Based on the ACA mandate, this letter is the fourth 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 three letters addressed: 1) the health plan identifier (HPID); 2) operating rules and their authoring entities for eligibility and claim status transactions, and 3) a standard for Electronic Funds Transfer (EFT). This letter addresses the requirements for authoring entities for operating rules to support electronic funds transfers (EFT) specific to health care use and the health care payment and remittance advice, commonly referred to as electronic remittance advice (ERA).

One of the most important roles operating rules can have is to serve as an intermediate, transitional step between consecutive versions of standards. Operating rules can fill gaps or correct deficits in a current version of a standard while the next version is being developed. As a standard is being updated in preparation for adoption, some rules may become part of that new version. At the same time, new operating rules could be developed to help industry with implementation as new issues are identified. There will always be a need for some operating rules for specific transactions, related to infrastructure, technology, testing, best business practices and processes, communication, and relationships. Operating rules can also enhance the clarity of a given field or data element, and can be proposed for incorporation into new versions of a standard, voted on, and absorbed into the updated standard. In this way, the standard will be improved, and the operating rule will have served its purpose. Most importantly, the operating rule process will enable industry to achieve greater administrative efficiency in real time.

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, recommending two organizations for the task – the Council for Affordable Quality Healthcare Committee on Operating Rules for Information Exchange (CAQH CORE) and the National Council for Prescription Drug Programs (NCPDP).

To identify potential operating rule authoring entities for EFT and ERA, NCVHS held hearings on December 3, 2010 during which a wide range of stakeholders testified, including health plans, provider organizations, health care clearinghouses, retail pharmacy, standards developers, operating rule authors, professional associations, representatives of Federal and State health plans, and the banking industry. After the hearings, three organizations expressed interest in being considered as authoring entities: Accredited Standards Committee (ASC) X12, the National Council for Prescription Drug Programs (NCPDP), and

the Council for Affordable Quality Healthcare Committee on Operating Rules for Information Exchange (CAQH CORE) in collaboration with the National Automated Clearing House Association (NACHA). In January 2011, each organization received an application requesting certain documentation describing how they met the statutory requirements, the status of current operating rules they could put forward, or how they would propose to develop operating rules in the time frame available to meet regulatory deadlines. The applications were received by the January 31, 2011 deadline.

Based on the hearing, followed by a review of the applications, NCVHS is submitting this letter which includes: 1) a list of overarching themes concerning the selection of operating rule authoring entities, 2) evaluation of the candidate authoring entities, and 3) recommendations for authoring entities for operating rules for the health care EFT and ERA.

Overarching Observations about the testimony and applications

Following consideration of the testimony and review of the applications, several points can be made:

- *No organization has operating rules for EFT and ERA vetted and ready for use by the industry*
- *Greater, more visible collaboration among SDOs, operating rule entities and stakeholders is imperative*
- *Stakeholders require clear guidance on HHS policies with respect to the roles of standards and operating rules and the expected relationship between the two.*
- *Entities interested in serving as an authoring entity for operating rules need to fully understand the process for preparing and submitting applications and the operating rules themselves. NCVHS and CMS will work to provide very clear directions to interested parties on expectations for content and quality.*
- *Entities interested in serving as an authoring entity for operating rules need to fully understand that these rules must be separate and distinct business rules from those found in the standard and implementation guides, consistent with the Affordable Care Act provisions (ACA Sec 1104, (b) (1)).*
- *Submission of any document to be considered operating rules for specific transactions should be self-contained and easily referenced.*

- *Applicant authoring entities should demonstrate an understanding that operating rules must be directional, specific, unambiguous and clear about what the stakeholders that are required to comply with them must do, consistent with the Affordable Care Act provisions (ACA Sec 1104, (b) (2) (B))*

Evaluation of the Candidates for Operating Rules for the Health Care EFT and ERA Standard Transactions

In January 2011, three organizations applied to be authoring entities of operating rules: ASC X12 (for non-pharmacy ERA transactions), NCPDP (for pharmacy ERA transactions) and CAQH CORE (for all EFT and ERA transactions). Each application was evaluated based on the statutory requirements such as: 1) focus on administrative simplification, 2) having a multi-stakeholder and consensus-based process for development of operating rules, and 3) building on the transaction standards issued under HIPAA, and 4) their plans to develop operating rules that meet the functional requirements defined in the statute. These requirements are: 1) allowing for automated reconciliation, 2) addressing acknowledgements, 3) reducing manual effort, and 4) describing data elements in unambiguous terms.

The three candidates have some common strengths in core areas and unique strengths in specific areas. Every candidate was very clear in its focus on administrative simplification and its use of a multi-stakeholder, consensus-driven process. The differences among the applications were clearer in: 1) how each entity understood the purpose and intent of operating rules, 2) how they addressed the substance of the operating rules applicable to EFT and ERA. 3) their progress in formulating a strategy for developing the rules, and 4) their suggestions for what could be included in operating rules. In the applications, each candidate gave different levels of descriptions of some of the issues with the current standards, and discussed elements that should be addressed in operating rules for EFT and ERA standard transactions in the future.

The application from CAQH CORE in collaboration with NACHA to develop EFT and ERA operating rules was the most robust, with strong research behind its substantive, detailed recommendations. While X12 and NCPDP both proposed a few operating rule ideas such as modifications to the use of claims adjustment and reason codes, their emphasis was on the work they would do in the future to obtain new ideas, through new work groups that are just forming. At the time of the application submission, neither organization had formally started work groups or undertaken research to address specific opportunities. In the CAQH CORE application, substantial detail was provided about the research its organization had already done to identify and vet a number of issues. It provided fairly detailed suggestions for operating rules, including: standardizing the content of an enrollment form for ERA, creating health care operating rules that are

complementary to those in the NACHA operating rules (specific to EFT), specifying maximum time span between provider receipt of the ERA and EFT, requiring use of essential codes within the CARC and RARC code sets (including not permitting the use of discontinued codes); and requiring correct use of adjustments, requiring all participants to maintain the integrity of the payer-supplied re-association trace number for each ERA and EFT transaction throughout the process to enable providers to match the two transactions at their end.

All three applications clearly stated that the potential of multiple authoring entities making demands on the same subject matter experts would represent a challenge, and would impact the overall quality of anyone's product. The candidates agree that in order for the standards and operating rules to be built and enhanced effectively, resources must be coordinated, and equally important, the message about this critical item must be set by each organization's leadership.

In spite of the difficulty of this deliberation, and the valuable strengths of all candidates, NCVHS believes it is essential to make the following recommendations at this time:

NCVHS recommends that the Secretary:

1. Name CAQH CORE in collaboration with NACHA 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.
 - a. These rules must address the medical and pharmacy community, because pharmacy uses the X12 version of the electronic remittance advice; this will require collaboration with NCPDP and pharmacy stakeholders;
 - b. The proposed rules will be reviewed by NCVHS after they are received, and further recommendations will be considered. In other words, the operating rules submitted may or may not be deemed acceptable for a recommendation for adoption;
 - c. The authoring entity will not be formally recognized as the NCVHS recommended entity, per ACA, until their finished operating rules are reviewed and recommended by NCVHS.
2. Require CAQH/CORE to establish mechanisms for greater direct engagement of X12, NCPDP, HL7 and other SDOs at a leadership level as well as at the membership level of CORE workgroups, to ensure operating rules are developed through a more open, collaborative and multi-stakeholder consensus-driven process. It is only through larger and

focused participation that a) resources will be conserved and b) the best rules possible will be created.

3. Call on X12, NCPDP, HL7 and other SDOs to actively engage with CAQH/CORE and to provide timely input and feedback to the operating rules to be developed for EFT and ERA.
4. Further clarify the scope, focus, and limitations between operating rules and standards, and define a framework for how operating rules will relate to standards in the future.
5. Require CORE/CAQH to identify more effective means to engage greater and broader provider participation and input, particularly with practice management and software vendors who provide technical solutions for providers.

NCVHS is planning to conduct hearings later this spring with operating rule authoring entities, SDOs, and representatives from various stakeholders to discuss additional opportunities to improve cross-industry collaboration and coordination in the development of operating rules and to improve the relationship between rules, standards and implementation specifications.

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: HHS Data Council Co-Chairs