



NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS

May 5, 2012

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

Re: Recommendations to Designate an Authoring Entity and Ensure Industry Collaboration for the Development of Operating Rules for Health Care Administrative Transactions

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). Specifically, under the Patient Protection and Affordable Care Act (ACA) (Sec. 1104. (g)(3)), enacted on March 23, 2010, NCVHS is 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 HHS on the development of uniform operating rules for electronic exchange of information not defined by a standard or its implementation specification.

NCVHS has already recommended authoring entities as outlined in ACA including: Council for Affordable Quality Healthcare Committee on Operating Rules for Information Exchange (CAQH CORE) for non-retail pharmacy-related eligibility and claim status; National Council for Prescription Drug Programs (NCPDP) for retail pharmacy-related eligibility and claim status; and National Automated Clearing House Association (NACHA) and CAQH CORE for Electronic Funds Transfer (EFT) and Electronic Remittance Advice (ERA). To complete the ACA assignment there is a need to name an authoring entity for the remaining standard administrative transactions under ACA provisions, namely: health care claims, member enrollment/ disenrollment, premium payment, prior authorization and claim attachments. The Committee is pleased to present to you a new set of recommendations (Attachment 1) regarding the next stage in the development of operating rules that enhances efficiency as well as collaboration and transparency. These recommendations are as follows:

- Designate the Committee on Operating Rules for Information Exchange (CORE) as the **authoring entity of operating rules** for the remaining transactions.
- Ask CORE to explicitly collaborate with WEDI, as the organization named in the HIPAA statute to provide industry advice to NCVHS and to the Secretary.
- Ask SDOs and DCCs to actively engage with the process of identifying and developing operating rules for each remaining transaction, through active participation in the entire CORE process and active participation in the WEDI workgroups supporting the CORE process.

We have had extensive discussions over the past two months about this approach with major key industry stakeholders involved, including CAQH CORE, the Workgroup for Electronic Data Interchange (WEDI), and representatives of the standards development organizations (X12, HL7 and NCPDP), and carefully considered and incorporated their feedback as we deemed feasible. The resulting recommendations are consistent with recommendations made by this Committee over the past 18 months on this subject.

We acknowledge the following comments received regarding this final recommended approach that we are submitting to you:

- A letter cosigned by the Council for Affordable Quality Healthcare (CAQH), the America's Health Insurance Plans (AHIP) and the American Hospital Association recommending to move ahead with the designation of CAQH CORE, but also requesting a one-month timeframe to vet separate recommendations detailing how to ensure all parties, including WEDI, continue to provide advice and counsel on the development and support of operating rules.
- A report from the most recently held WEDI Board of Directors meeting at which the Board recommended to approve the proposed recommended approach with one modification to help clarify WEDI's role and relationship to CAQH CORE.

The recommendations that we are submitting take into consideration and incorporate both the designation of CAQH CORE as authoring entity as well as the changes suggested by WEDI to clarify its role in this process. Outlining the details of how to ensure all parties interact was deemed by the Committee to be best addressed as part of rulemaking.

We believe these recommendations leverage the strengths of both CAQH CORE and WEDI and address the issues brought to the Committee over the past 18 months regarding missed opportunities for increased collaboration and transparency. This will also serve as a starting point for the longer-term strategy the Committee is working on to respond to the ever-growing needs for greater collaboration, coordination and active participation across the industry to determine the need for, conduct research on, develop, ballot, adopt and implement standards, implementation specifications and operating rules in health care.

ACA provides a unique opportunity to improve the efficiency and cost-effectiveness of our health care industry by requiring the adoption of operating rules that complement existing standards and implementation specifications for health care administrative transactions. Your adoption of these recommendations will help move the industry forward working together to maximize the value of both standards and operating rules. We stand ready to assist you with any further advice or guidance on this matter, at your request.

Sincerely,

/s/

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

cc: HHS Data Council Co-Chairs



Attachment 1

Recommendations to Designate an Authoring Entity and Ensure Industry Collaboration for the Development of Operating Rules for Health Care Administrative Transactions

Background:

ACA has ushered significant efforts to transform healthcare, including recognition and support for operating rules. Based on a recommendation from the NCVHS, the Office of eHealth Standards and Services (OESS) within the Centers for Medicare & Medicaid Services (CMS) accommodated a listening session with standards development organizations (SDOs), code set content committees, WEDI and operating rule authoring entities (ORAEs) to discuss options for the future development and maintenance of operating rules. The participants in the listening session proposed an approach that they believe would ensure transparency, objectivity, expediency, efficiency and equitable industry representation and deliver quality tools for industry's use in conducting Electronic Data Interchange (EDI) with administrative health care transactions. The group agreed on the following premise for a proposal, that:

NCVHS will advise the Secretary to name a single entity that will serve as the responsible body to develop and maintain operating rules in coordination with other entities. Operating rules would be created for the remaining transactions as needed, and will be developed through the coordination and active engagement of individuals or organizations with appropriate expertise.

After consideration of the discussion during the listening session, the NCVHS Standards Subcommittee co-chairs created a draft proposal for consideration by the full Committee. This proposal focuses on the need to identify, develop and deliver operating rules for the remaining transactions under the Affordable Care Act (ACA) provisions (claims, enrollment, premium payment, prior authorization and claim attachments) to meet the timeframe established by ACA (for the adoption of these operating rules). The proposal is founded on the following principles: 1) enhance openness in the process; 2) ensure direct engagement and collaboration among stakeholders; 3) ensure transparency throughout; and 4) leverage existing resources and expertise in an effective and efficient manner. The proposal was vetted with SDOs, ORAEs and WEDI during individual phone calls. These calls resulted in helpful feedback to further refine the proposed approach for naming an operating rule authoring entity and a process to achieve collaboration and engagement.

Across all HIPAA related activities, there is clear consensus of the need to ensure ongoing improvement in industry engagement, coordination and education. All of the entities mentioned above are committed to continued and enhanced progress, considering this growing momentum. NCVHS has, over the past 18 months, documented the issues with the current process of identifying, reviewing and recommending the adoption of standards, operating rules, and identifiers and is currently developing a long-term approach to address the varied and complex issues. These recommendations focus on the immediate need of identifying, developing and delivering operating rules for the remaining ACA mandated transactions to NCVHS by early 2013. To help NCVHS and industry meet this requirement, we recommend the following:

- Designate the Committee on Operating Rules for Information Exchange (CORE) as the **authoring entity of operating rules** for the remaining transactions.
 - As the authoring entity, CORE would be accountable for developing and delivering the Operating Rules through active collaboration, and in coordination, with subject-matter experts (SMEs) through a process that ensures balanced representation from industry stakeholders (including representatives from health plans, providers, clearinghouses, federal/state government programs, vendors), and inclusion of representatives from X12, NCPDP, HL7, NACHA and other SDOs, data content committees (DCCs - such as the National Uniform Billing Committee, National Uniform Claim Committee, American Medical

Association Committee on Common Procedure Terminology, American Dental Association Committee on Dental Coding, CMS for HCPCS and CMS and NCHS/CDC for ICD-9-CM and ICD-10 code sets) and other industry experts and relevant stakeholders.

- CORE would apply the CORE process, e.g., scoping, prioritization, conducting research, drafting, vetting/balloting, to deliver to NCVHS the recommended operating rules. It would be expected that CORE would update NCVHS periodically on the status of the process in a manner that will be determined by NCVHS.
 - CORE will be required to meet all current requirements on ORAEs, per ACA provisions, including documentation of the openness and transparency of the process and participation from stakeholders.
- Ask CORE to explicitly collaborate with WEDI, as the organization named in the HIPAA statute to provide industry advice to NCVHS and to the Secretary¹. The collaboration would be designed and executed to achieve the following goals, with the understanding that CORE is the accountable organization:
- Enhance the network of SMEs and industry stakeholders involved in the process of identifying and developing operating rules. This includes opportunities to engage members of WEDI workgroups in the CORE process.
 - Conduct targeted outreach during various phases of the development of operating rules to specific groups of stakeholders, as needed.
 - Ensure that WEDI communications regarding operating rules are aligned with CORE's in order to avoid market confusion, and that the organizations will work together on messaging.
 - Identify any opportunities to expand education and outreach efforts, including other collaborations to inform industry at large regarding all aspects of operating rules.
 - Members of WEDI can hold a voting position within CORE, if they are CORE participating organizations.
- Ask SDOs and DCCs to actively engage with the process of identifying and developing operating rules for each remaining transaction, through active participation in the entire CORE process and active participation in the WEDI workgroups supporting the CORE process.
- The success of any collaboration is dependent on the relationship evolving over time to address changing needs, especially when there is significant market transformation. Therefore, this collaborative and participatory relationship will be revisited periodically to identify any adjustments needed to assure accomplishment of ACA intended goals.

Benefits of Recommended Process:

- ACA calls for a new approach to administrative simplification.
 - NCVHS and OESS are committed to the implementation and success of new models, given operating rules and standards are separate but complementary efforts.
 - Direct involvement, support, active engagement/participation and coordination of and among WEDI, CORE, X12, NCPDP and HL7 are required for the success of this proposal.
 - There will be an iterative process between the standards and operating rules. Where appropriate, SDOs will be encouraged to incorporate lessons learned from operating rule adoption, as well as incorporate appropriate components of relevant, published operating rules in future standards.
 - Maintenance of the standards and operating rules is the responsibility of the SDOs and ORAEs, as applicable

¹ It is the intent that this collaboration would not require a formal legal, contractual process to be established between the two organizations, but it will be left to them to work together on an appropriate arrangement, in a way that does not delay the start of the entire process.

- The objective of these recommendations is to enhance openness of the entire process, achieve greater transparency, increase direct engagement of SMEs in the operating rule process, improve assessment of real-world impact and outcomes, and ensure greater collaboration, coordination, and cross-participation between the various SDOs and authoring entities to develop operating rules in support of standards. Specifically, it is expected that this process will:
 - Highlight the essential goal of having HHS advisors, operating rules authors and standard setting bodies collaborate on driving industry engagement and participation.
 - Mitigate perception of competition and conflict between standards and operating rules.
 - Leverage the capabilities and domain expertise of existing entities in the industry to provide solutions.
 - Ensure appropriate representation from industry stakeholders.
 - Harmonize ideas across the domain experts/entities through a collaborative, open and objective venue.
 - Leverage lessons learned from this approach to assist in future efforts to revise or update standards.

Roles and Strengths:

- CORE
 - CORE employs a consensus-based integrated model.
 - CORE has strong multi-stakeholder engagement that has improved over the past year in breadth and diversity.
 - CORE has a solid track record of pulling in quantifiable and verifiable data to support the rules.
 - The CORE record on research, rule development, vetting/balloting and work products is excellent.
 - Both NCVHS and HHS have determined that the existing CORE structure and processes meet the statutory requirements for an operating rules authoring entity under the ACA.
 - CORE has cultivated and developed executive level involvement, which has been essential to driving change and obtaining support for the resources needed by the industry.
- WEDI
 - WEDI is the industry organization named in the 1996 HIPAA Law as advisor to NCVHS and HHS.
 - WEDI is seen across the industry as a neutral facilitator that involves representation from providers, plans, clearinghouses, vendors, government, SDOs, ORAEs, DCCs and others.
 - WEDI's work groups have the depth in SME participation to discuss policy, business and implementation issues of each transaction based on regulations, standards and operating rules (e.g. the PAGs).
 - WEDI's stakeholders include providers, health plans, clearinghouses, vendors, state Medicaid agencies, representatives from property and casualty, SDOs, and a variety of other entities and individuals.
- SDOs, DCCs, Others
 - SDOs, DCCs and other industry groups and stakeholders would bring SME into the entire process.
 - These organizations would be expected to solicit the support and active engagement and participation in the process to identify operating rules needed and the CORE-led effort to develop the operating rules.

Proposed Timeline (acknowledging that the start and end dates will likely change)

- Implementation of recommendations (NCVHS sends formal letter to HHS): May, 2012
- Identification, development and Vetting of Operating Rules: May, 2012 – January, 2013
- Operating Rules development updates to NCVHS: September 2012, November, 2012
- Delivery of Operating Rules to NCVHS: February, 2013
- NCVHS Review and Approval: February-March, 2013
- NCVHS Delivers Letter to HHS: March, 2013
- HHS Rule-writing: April, 2013 – January, 2014

■ Regulations published by January 2014

Diagram of Collaborating Roles Among CORE, WEDI, SDOS/DCCs and Others

