

July 29, 2016

The Honorable Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: National Committee on Vital and Health Statistics
Recommendation Letter to the Secretary
Adoption of CAQH CORE Phase IV Operating Rules

Dear Madam Secretary,

On behalf of CAQH CORE and its nearly 140 multi-stakeholder participating organizations, the CAQH CORE Board of Directors ***supports a federal mandate of the Phase IV Operating Rules per Section 1104 of the Affordable Care Act (ACA). As such, we respectfully submit our disagreement with the July 6, 2016 National Committee on Vital and Health Statistics (NCVHS) letter regarding Phase IV.*** The NCVHS recommendation to support only a voluntary adoption of Phase IV at this time, rather than a mandate, challenges the spirit, scope and purpose of operating rules as outlined in the ACA. Moreover, it challenges the experience with existing mandated operating rules and those who actively participated in the defined process.

As executives from the health care industry and the leadership of CAQH CORE – the HHS-designated operating rule authoring entity – we emphatically urge you to continue to build upon current industry momentum and adopt the Phase IV Operating Rules as required by the ACA. The NCVHS perceived three main issues associated with the Phase IV Operating Rules, and we have outlined our concerns on each.

- NCVHS states the proposed operating rules call for the adoption and use of electronic transaction standards not yet named or defined by the Secretary in federal regulations. Specifically, the operating rules require the use of Acknowledgments, and the ability to support the X.509 digital certificate. *As detailed below, the NCVHS redefinition of allowed scope does not support the ACA vision and contradicts existing mandates.*
- The NCVHS believes the remaining Phase IV Operating Rules (those not related to Acknowledgments and digital certificates) offer limited administrative simplification and efficiency benefits to the industry that do not warrant the cost and resources necessary for their adoption. *As detailed below, entities that implement the transactions, and whose daily business is impacted by the respective transactions, disagree. Phase IV is an essential initial step that establishes much needed foundational requirements and builds consistency with other ACA-mandated operating rules required for all HIPAA transactions.*
- NCVHS states that three of the four HIPAA transactions for which the proposed Phase IV Operating Rules apply have been implemented on a very limited basis across the industry, and, therefore, operating rules are not appropriate at this time. *As detailed below, this view challenges the spirit of why the ACA initiated the creation of mandated operating rules for the HIPAA transactions.*

As background to substantiate our concerns, CAQH CORE has employed a transparent, collaborative and criteria-driven process to fulfill its ACA authoring entity responsibilities since it initiated Phases I, II and III of the operating rules covering eligibility, claim status and electronic funds transfer/remittance advice, all of which have been federally mandated and implemented by the industry. More than 500 entities over the past two and a half years have worked on the Phase IV Operating Rules for the HIPAA transactions for claims, prior authorization, enrollment/disenrollment and premium payments. Taking this wide industry input into consideration, the entities

participating in CAQH CORE came to consensus on a set of Phase IV Operating Rules for these four standards that would address operating rules consistent with those of Phases I, II and III so that electronic, cost-effective data exchange can be achieved.

Ten months since the Phase IV Operating Rules were approved by CAQH CORE, early adopters are already in various phases of implementation, including volunteers that will be beta testing the Phase IV Voluntary CORE Certification test site this summer. This said, the goal of ACA was not just to *hope* early adopters would achieve *voluntary* industry-wide adoption. Rather, the ACA called for *requiring* industry-wide adoption resulting in a consistent, national infrastructure to support administrative data exchange across the HIPAA transactions. This goal was envisioned, but not achieved, by the original HIPAA legislation and, thus, is why Congress amended HIPAA via the ACA. Now is not the time to halt the ACA's directive to make this vision a reality. As industry implementers directly impacted by the HIPAA transactions, we have a firm belief that the Phase IV Operating Rules are a key component to achieving the ACA goal to advance administrative simplification given that the Phase IV Operating Rules:

- A. *Meet the spirit and legislative requirements of the ACA with respect to operating rules;*
- B. *Meet the statutory definition for operating rules;*
- C. *Support the goals of administrative simplification, including efficiency and cost savings;*
- D. *Provide a much needed set of foundational requirements that are already proven good business practices by virtue of their use in existing mandated operating rules; and*
- E. *Received an unprecedented approval by an overwhelming 90% of the CAQH CORE Participating Organizations, which are entities that implement the operating rules.*

A. Phase IV meets the spirit and legislative requirements of the ACA with respect to operating rules. Section 1104 of the ACA specifically calls for operating rules to become part of HIPAA since mandated standards alone were not able to provide the national framework or impetus needed for electronic data exchange. Section 1104 states: “The Secretary shall adopt a single set of operating rules for each transaction referred to under subsection (a)(1) with the goal of creating as much uniformity in the implementation of the electronic standards as possible. Such operating rules shall be consensus-based and reflect the necessary business rules affecting health plans and health care providers and the manner in which they operate pursuant to standards issued under the Health Insurance Portability and Accountability Act of 1996” (Social Security Act §1173(g)). Under Section 1104 (and codified in 42 U.S.C. §1320d–2), the NCVHS’ role is to “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.” The Phase IV Operating Rules meet these statutory requirements by applying uniform infrastructure requirements across the HIPAA standards and because, as the NCVHS has recognized, “CORE uses an open, consensus-based process to develop the operating rules.”

Furthermore, the ACA states that operating rules be adopted for all named HIPAA transactions, without mention of consideration of current utilization. In fact, we believe that the intent of the ACA was to further the use of all HIPAA transactions – especially those with low adoption rates – through mandated operating rules. The Phase IV Operating Rules are essential building blocks to creating an end-to-end transaction view, which includes an emphasis on security. The ACA also established a Review Committee to ensure that mandated versions of transaction standards and operating rules would be kept current and could be proactively updated without additional legislation. Mandated Phase IV Operating Rules and new adoption approaches, such as those under the purview of the Review Committee, can foster further industry utilization of these HIPAA transactions.

B. Phase IV meets the statutory definition for operating rules. The ACA defines operating rules as “the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications” (Social Security Act §1171(9), added by ACA §1104(b)(1)). Per this definition, the Phase IV Operating Rules establish basic infrastructure expectations for national data exchange, many of which

are already required by federal mandate for the eligibility, claim status and electronic remittance advice (ERA) transactions. Consistent with requirements in the mandated operating rules, the Phase IV infrastructure requirements include:

- Offering at least one common method of connectivity with expected security (i.e., a “safe harbor”) among entities transmitting data electronically.
- A minimum amount of time that systems must be available to receive and send data, and the ability to track and report system downtimes.
- A common format that entities must use when providing information about their proprietary data exchange systems via “companion guides”.
- A common acknowledgement to ensure the transaction has been received, has not been lost between entities and will be addressed.
- Required response times for acknowledgement and processing for both real-time and large record “batch” submissions.

As in previously mandated operating rules, the Phase IV Operating Rules include non-HIPAA, industry neutral standards such as SOAP, WSDL and X.509 digital certificate for submitter authentication. Inclusion of such standards in the existing federally mandated Phases I, II and III Operating Rules did not prevent or delay federal adoption of the operating rules for use with the eligibility, claim status and ERA transactions and, as such, should not prevent adoption of the Phase IV Operating Rules. Moreover, these industry neutral standards are also in other federal regulations such as Meaningful Use Stage 2: ONC Health IT Certification Criteria (which references Federal Information Processing Standard Publication 140-2 and relates to Directed Exchange), and Electronic Prescriptions for Controlled Substances.

With regard to the inclusion of Acknowledgements, CAQH CORE Phase I, II and III Operating Rules included the requirement for use of Acknowledgements. Although the federal mandates for these operating rules excluded the requirement for use of Acknowledgements, their inclusion did not preclude the mandate to adopt the remaining components of these operating rules. CAQH CORE continues to press for use of Acknowledgements, and is the only large scale national effort outlining, testing and tracking their use. NCVHS and many others have called for mandating Acknowledgements many times and have noted that they are an essential supporting infrastructure to HIPAA transactions for administrative simplification. On a data exchange, business and technical basis, Acknowledgements are not conducted as stand-alone transactions like the HIPAA transactions. Therefore, CAQH CORE continues to support the use of standard Acknowledgements whenever a HIPAA transaction is used, and as part of operating rules. Nearly 20 CORE-certified Medicaid agencies are now using the CAQH CORE Phase I-III Operating Rules for Acknowledgments. We hope that HHS recognizes that CAQH CORE Operating Rules requiring Acknowledgements means that “black holes” do not exist for senders and receivers of the HIPAA transactions. The ACA envisioned operating rules would address this issue given there are billions of these transactions.

C. Phase IV supports the goals of administrative simplification, including efficiency and cost savings. Industry analysis and the CAQH CORE Participants determined Phase IV is a significant step in meeting industry needs to drive well-documented cost reduction, while being technically and resourcefully achievable, with a common infrastructure. The Phase IV Operating Rules will require trading partners to improve the efficiency and effectiveness of these transactions and, thus, increase adoption. Since the federal mandate of the first two sets of operating rules, public case studies, as well as the annual, national CAQH Index Report have documented a notable increase in the number of these administrative transactions that are conducted electronically. This translates into billions of dollars in administrative savings in the delivery of health care in this country. See example ([2015 CAQH Index Report](#)).

D. Phase IV provides a much needed set of foundational requirements that are good business practices. The CAQH CORE Board, the CAQH CORE Participating Entities and the industry at large view the Phase IV Operating Rules as a critical initial step, but far from the last step, to increase adoption of the HIPAA transactions. During rule development, some organizations pushed for more requirements, including data content, while others supported fewer requirements. Phase IV represents multi-stakeholder compromise and consensus on a foundational set of requirements, exactly as the ACA intended. This approach is especially important for prior authorization, a complex transaction that calls for an iterative process and successive milestones. Without basics like response times and time stamping, more advanced goals will be even more difficult to define and implement, and cost savings will continue to elude the industry. The CAQH CORE Board is committed to developing additional operating rules that will promote standardization of the complex prior authorization process and accelerate industry adoption of this HIPAA transaction. The Phase IV Operating Rules are the initial foundation of this commitment.

E. Phase IV was approved by an overwhelming percent of the CAQH CORE Participating Entities. Finally, as previously outlined in this letter and to the NCVHS, it cannot be ignored that there was tremendous industry and unanimous CAQH CORE Board support for Phase IV throughout all stages of the consensus-based voting process. By their affirmative Phase IV Operating Rules vote, over 100 entities representing more than 70% of the commercially insured and Medicare and Medicaid insured, disagree with the NCVHS recommendation as they voted to support Phase IV, with the expectation that a federal mandate would follow. The market share these implementer entities directly represent and impact greatly outnumbers the entities that provided testimony at the half-day NCVHS hearings on this topic, the majority of which do not implement the standards and operating rules directly themselves and, thus, do not represent industry impact with first-hand experience.

In closing, we would like to reiterate that this is not the time to halt the industry-wide momentum gained via the ACA administrative simplification provisions. Health care industry experience shows that after a regulation's adoption date it can take two years to fully move toward compliance. Basic foundational needs, such as those established by the Phase IV Operating Rules, must be in place throughout the United States now so that the industry can move forward to tackle more complex challenges. In accordance with CAQH CORE's mission to accelerate adoption, we will continue to work with the industry to improve the return on investment for all existing and future operating rules, such as those addressing prior authorization. We look to HHS to help us in this effort.

Time is of the essence if the nation is to bring all of the HIPAA transactions into alignment and continue the drive toward low cost, high quality and efficient health care data exchange.

Sincerely,

The CAQH CORE Board of Directors

A handwritten signature in black ink, appearing to read "George S. Conklin".

George S. Conklin, CIO and SVP for Information Management
CHRISTUS Health
Immediate Past Chair, CAQH CORE Board

A handwritten signature in black ink, appearing to read "Lou Ursini".

Lou Ursini, Head IT Program Delivery & Testing
Aetna
Chair, CAQH CORE Board



Susan L. Turney, MD, MS, FACP, FACPME, CEO
Marshfield Clinic Health System
Vice Chair, CAQH CORE Board



Joel Perlman, Executive Vice President
Montefiore Medical Center



Barbara L. McAneny, MD, CEO
New Mexico Cancer Center
Immediate Past Chair, American Medical Association Board of Trustees



Tom Miller, SVP/CIO
Anthem



Raza Fayyaz, Director of Information Systems
AultCare



John Fong, MD, MBA, Executive Medical Director
Blue Cross Blue Shield of North Carolina



Tim Kaja, SVP, Optum Cloud/Link
UnitedHealth Group



Mitchell Icenhower, VP of Solutions Management
Allscripts



Matthew Levesque, Vice President, Product Management
athenahealth

cc:

Robin Thomashauer, CAQH Executive Director

Gwendolyn Lohse, CAQH CORE Managing Director, CAQH Deputy Director

Shana Olshan, Director, National Standards Group, Office of Enterprise Information, CMS

Dave Nelson, Director and CMS Chief Information Officer, Office of Enterprise Information, CMS

Members, National Committee on Vital and Health Statistics

Appendix I: CAQH Committee on Operating Rules for Information Exchange (CORE) Participants

In August 2015, 90% of CAQH CORE Participating Entities that can implement operating rules participated in the Final CAQH CORE Vote on the Phase IV Operating Rules; 88% voted to approve the complete Phase IV CAQH CORE Operating Rule Set, including health plans representing almost 70% of commercially insured lives, plus Medicare and Medicaid beneficiaries. Non-implementers do not vote at the Final CAQH CORE Vote, however, they voiced support in earlier stages of voting along with the implementers, thus allowing the rules to move forward to the final vote.

Government (Includes health plan and provider implementers)

Arizona Health Care Cost Containment System
 California Department of Health Care Services
 Federal Reserve Bank of Atlanta
 Florida Agency for Healthcare Administration
 Kansas Department of Health & Environment
 Louisiana Medicaid – Unisys
 Michigan Department of Community Health
 Michigan Public Health Institute
 Minnesota Department of Health
 Minnesota Department of Human Services
 Missouri HealthNet Division
 National Medicaid EDI Healthcare Work Group (NMEH)
 North Dakota Medicaid
 Oklahoma Employees Group Insurance Division
 Oregon Department of Human Services
 Pennsylvania Department of Public Welfare
 TRICARE
 US Centers for Medicare and Medicaid Services (CMS)
 US Department of Treasury Financial Management Services
 US Department of Veterans Affairs
 Washington State Office of the Insurance Commissioner

Health Plans

Aetna Inc.
 Ameritas
 Anthem, Inc.
 AultCare
 Blue Cross Blue Shield of Louisiana
 Blue Cross Blue Shield of Michigan
 Blue Cross and Blue Shield of North Carolina
 BlueCross BlueShield of Tennessee
 CareFirst BlueCross BlueShield
 Cigna
 Community Health Plan of Washington
 Coventry Health Care
 EmblemHealth
 Excellus Blue Cross Blue Shield
 GEHA
 Group Health Cooperative
 Harvard Pilgrim Health Care
 Health Care Service Corporation
 Health Net, Inc.
 Highmark, Inc.
 Horizon Blue Cross Blue Shield of New Jersey
 Humana Inc.
 Kaiser Permanente
 Medical Mutual of Ohio
 Palmetto GBA
 Premera Blue Cross
 Providence Health Plan
 Tufts Health Plan
 UnitedHealth Group

Providers

Adventist HealthCare, Inc.
 Adventist Health System
 American Academy of Family Physicians (AAFP)
 American Hospital Association
 American Medical Association (AMA)
 Cedars-Sinai Health System
 CHRISTUS Health
 Community Health Systems
 Confluence Health
 Emory Healthcare
 Greater New York Hospital Association (GNYHA)
 Healthcare Partners Medical Group
 Lab Corporation of America
 Mayo Clinic
 Medical Group Management Association (MGMA)
 Mobility Medical, Inc.
 Montefiore Medical Center of New York
 NYU Langone Medical Center
 Ortho NorthEast (ONE)
 Sound Family Medicine
 Tampa General Hospital
 University of Maryland Faculty Physicians, Inc.
 UNMC Physicians
 Virginia Mason Medical Center

Vendors / Clearinghouses

Allscripts
 athenahealth, Inc.
 Automated HealthCare Solutions
 Availity LLC
 Cerner
 ClaimRemedi
 Computer Sciences Corporation
 DST Health Solutions
 Edifecs
 Change Healthcare
 EMS Management & Consultants
 Epic
 Fifth Third Bank
 GE Healthcare
 HEALTHeNET
 HMS
 HP Enterprise Services, LLC
 inMediata
 InstaMed
 Medical Electronic Attachment
 MedTranDirect, Inc.
 NaviNet
 NextGen Healthcare Information Systems, Inc.
 OptumInsight
 Passport Health Communications
 PaySpan, Inc.
 PNC Bank
 Post-N-Track
 RealMed, an Availity Company
 Recondo Technology, Inc.

RelayHealth
 The Clearing House
 The SSI Group, Inc.
 TriZetto Corporation, a Cognizant Company
 TriZetto Provider Solutions
 Ventanex
 VISA, Inc.
 Wipro Infocrossing
 Xerox
 ZirMed, Inc.

Other

Accenture
 Cognizant
 Cognosante
 CSG Government Solutions
 MEDIX Consulting LLC
 NASW Risk Retention Group
 OptumHealth Financial Services
 TIBCO Software, Inc.

Associations / Regional / Standard Setting Organizations

America's Health Insurance Plans (AHIP)
 ASC X12
 Blue Cross and Blue Shield Association
 Delta Dental Plans Association
 Health Level 7 (HL7)
 Healthcare Billing and Management Association
 Healthcare Financial Management Association
 NACHA – The Electronic Payments Association
 National Committee for Quality Assurance
 National Council for Prescription Drug Programs
 NJ Shore (WEDI/SNIP NY Affiliate)
 OneHealthPort
 Private Sector Technology Group
 Utah Health Information Network
 Utilization Review Accreditation Commission
 Work Group for Electronic Data Interchange (WEDI)