June 13, 2016

Dear NCVHS Members:

CAQH CORE is the designated operating rule authoring entity for the Affordable Care Act (ACA) operating rules, which includes two sets of mandated operating rules. As the CAQH CORE Board Chair and Vice Chair, our comments below address the draft NCVHS letter to the HHS Secretary "Re: Recommendations for the Proposed Phase IV Operating Rules" which was posted on June 7th to the NCVHS website. NCVHS will be discussing this draft letter on both June 14th and 15th. We ask that NCVHS consider the following points when developing its final version of its letter to the Secretary.

The CAQH CORE multi-stakeholder Board is comprised of executives with responsibility for business functions that create, transmit or receive billions of transactions addressed by operating rules and their underlying standards. For a multi-stakeholder effort such as ours to maintain focus on addressing the industry's evolving data exchange needs, we rely both upon collaboration and taking action that is real-world based, benefit-driven and measurable in its value.

Market Implementation of CAQH CORE Phase I-IV. It is the intent of CAQH CORE to continue to promote industry implementation of all existing CAQH CORE Phases, including Phase IV. In the last few months, hundreds of stakeholders representing an array of organizations have attended public calls hosted by CAQH CORE regarding Phase IV implementation. Per polling on these calls, the majority of these attendees have begun educating staff, and outlining gaps to meet the Phase IV foundational requirements. Many in the industry are demonstrating adoption of mandated Phases I-III via voluntary CORE Certification, which includes digital certificates. As of today, there are nearly 300 Certifications including 18 Medicaid agencies – many of which were awarded certification in the last year. These entities are experiencing improved member satisfaction and streamlined efficiencies. A range of CORE-certified entities, including Medicaid agencies, have publicly shared the benefits to their organizations in implementing the operating rules. Early results of a CORE Certification market share analysis shows that more adoption is needed by all stakeholder types; however, significant progress is being made and adoption is occurring in phases, as expected. Moreover, many CORE-certified entities are now requiring CORE Certification of their trading partners, which includes testing for and use of acknowledgements. We hope to continue to move the industry forward as we believe that the industry is at, or is nearing, a tipping point. We have four requests that focus on two main issues: Momentum and Clarity.

Impact on Momentum.

- Issue 1: We know that you appreciate the efforts of those who actively participated in Phase IV (see March 31st letter in Appendix for participants) and the hundreds who worked on Phase IV indirectly as a result of CAQH CORE outreach efforts to seek input. It is concerning to us, however, that their voices and collaborative actions to drive positive momentum were not referenced in your draft letter. These entities deliberated through a thoughtful process for more than a year, reflecting upon business needs, value, level of manageable change for the industry, and consistency with previous operating rules already adopted, which includes the use of digital certificates. They developed trust that is flexible and can evolve into the future. The final CAQH CORE vote to approve operating rules is required by bylaws to be done exclusively by those entities that directly implement operating rules. Implementers are providers, health plans, clearinghouses, and vendors; associations do not vote in this final step. Approval for Phase IV was 88% at this step, including health plans that alone represent 70% of the commercially insured in the United States plus the publicly insured under Medicare. The ACA requires a "consensus-based" set of rules – not a uniformly supported set of rules. The Phase IV rules are without question consensus-based.

Request 1: NCVHS recommends *voluntary* support by HHS. We ask that you consider what specific actions HHS could take to provide its voluntary support and outline such in your letter. It would be disappointing to lose momentum in improving the efficiency, effectiveness and security of the various transactions that are key to the claims landscape. This is especially true at this point in time given the increase in the insured population and growing reliance on electronic data. Both CAQH CORE and NCVHS should leverage this existing momentum.

Clarity on your recommendations as related to ACA goals and existing statutory requirements.

- Issue 2: Section 1104 of the ACA is specific in its requirement for operating rules. Operating rules were legislated to become part of HIPAA since mandated standards, and voluntary adoption of operating rules, 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.” By statute, operating rules are mandatory for each HIPAA-named transaction. 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”.

  As required by the ACA, Phase IV gave the industry a starting point for driving further use of these standards or filling in key gaps. Your draft letter suggests that the Phase IV operating rules are not valuable in accelerating adoption of the mandated standards that have not been widely implemented. Such foundational requirements as those in Phase IV are critical to transmitting data. They are essential building blocks to an end-to-end transaction view, which includes an emphasis on security. In addition to recognizing operating rules, the ACA established the ‘Review Committee’ to enable the industry to proactively build upon mandated versions without additional legislation. The adoption of Phase IV needs to begin now, so that the industry can lay the foundation and then use new functions like the Review Committee to build upon that foundation.

  Request 2: Clarify if you are asking the Secretary to revisit the intent of the ACA regarding standards and operating rules, including mandated standards that currently have low adoption.

- Issue 3: The initial set of operating rule regulations published July 8, 2011 in the Federal Register defined operating rules and clarified the difference between standards and operating rules. (See Table 2 in July 8, 2011 regulation: Could an Operating Rule Conflict with a Standard.) CAQH CORE was given the responsibility to draft the Phase IV operating rules and did so, adhering both to this definition and the goals established in the ACA.

  Request 3: The draft letter appears to challenge the above noted definition. We ask NCVHS to state if it is asking for HHS to redefine the scope of operating rules in anyway, and thus also modify existing mandated operating rules which encompass infrastructure (including connectivity and security) and data content (that does not conflict with standards but supports their use; standards could be health care specific or industry neutral as seen with existing regulations).

- Issue 4: Your draft letter states that more testing of the Phase IV rules should occur. As previously shared by CAQH CORE, the testing of the Phase IV requirements has occurred both through the use of the requirements with Phases I-III and by some as existing best practices. There is testing for new standards, such as needed with Attachments, but it appears that you could be referring to other forms of testing. Given the requirements are best practices, the Phase IV rules were approved with a Test Suite for which a testing site has been built so that new adopters can test their conformance. Finally, some of the Phase IV requirements are basic operational expectations that should already be uniformly in place across the industry, e.g., the ability to track and report response time, and transparency on how coordination of benefits (COB) is handled with an electronic claim; but, unfortunately, they are not. Enforcement of basic expectations versus testing of such are two separate actions.

Request 4: We ask that NCVHS specify the type of testing that would be consistent for foundational expectations of existing standards such as those in Phase IV, versus testing for new data content standards; please address whether real world use or testing of that use by an external body would be considered sufficient. Moreover, we ask NCVHS to define the other non-statutory criteria of which authors should be aware.

CAQH CORE Future Operating Rule Development. This March, the CAQH CORE Board issued the aforementioned letter to NCVHS regarding the Phase IV hearings. We have reattached both that letter and a statement the CAQH CORE Board made in June 2015 committing to content, infrastructure and maintenance. CAQH CORE views Phase IV as an important step but only a starting point. This view of ongoing progress is key for the standards addressed in Phase IV that have low adoption, such as Prior Authorization. It was our commitment to move forward, building on these first steps, to address more complex issues while simultaneously driving market implementation of the Phase IV foundational requirements. As we determine future priorities with our participants and other industry partners, we will build in consideration of your recommendations for what CAQH CORE should focus on for future operating rules.

We look forward to continuing our partnership with you.

Regards,

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

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

cc: CAQH CORE Board and Advisors
CAQH CORE Participants

Attachments:
CAQH CORE Board letter to NCVHS dated March 31, 2016
June 2015 CAQH CORE Board Commitment to Content, Infrastructure and Maintenance

ATTACHMENT 1

March 31, 2016

Walter G. Suarez, MD, MPH
Chair, National Committee on Vital and Health Statistics
Executive Director, Health IT Strategy & Policy, Kaiser Permanente
2221 Broadbirch Drive
Silver Spring, MD 20904-1984

Dear Dr. Suarez:

As the HHS-designated operating rules authoring entity and per the Affordable Care Act (ACA) mandate, CAQH CORE has submitted to NCVHS the Phase IV Operating Rules for the claims, prior authorization, enrollment/disenrollment, and premium payment transactions. The multi-stakeholder industry, which CAQH CORE represents, spent over two and a half years using transparent, collaborative, criteria-driven and established steps to determine the focus, and then the detail, of the Phase IV Operating Rules. In doing this, the industry came to agreement on the first set of operating rules for these four standards so that the vision of electronic, cost-effective data exchange can be achieved.

At all stages of the Phase IV process, required quorums and approval rates were greatly exceeded. Every entity in Appendix I had an opportunity to vote. The CAQH CORE Participating Entities that approve the operating rules in the final step of the multi-layered voting – ***those participants who must implement – overwhelmingly supported the Phase IV Operating Rules with 90% participation in the vote and 88% voting in favor. Please see Appendix I for a list of the CAQH CORE Participants. These entities are driving market change. As noted in the Appendix, they represent a very significant sector of the marketplace, including over 70% of the commercially insured***. The Phase IV Operating Rules were also unanimously approved by the executive-level CAQH CORE Board, which includes representation from payer and provider organizations. Throughout the process, the industry placed significant value on ensuring that the Phase IV infrastructure was consistent with previous phases of mandated operating rules, and building up capability to improve security. As it is now six months from the date that the Phase IV Operating Rules were approved, the industry is already starting to implement Phase IV, including volunteers that will be beta testing the Phase IV Voluntary CORE Certification test site.

> **CAQH CORE, on behalf of its Board, participants and many others who contributed to Phase IV, urges NCVHS to recommend to the Secretary of HHS adoption of the Phase IV Operating Rules. 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 data exchange.**

CAQH CORE heard the concerns raised by those invited to the NCVHS Hearing on February 16, 2016, many of whom are not implementers themselves. We would ask NCVHS to consider not only the above industry process and support, but also note:

- ***Achievable and a Foundational Start.*** As communicated at the hearing, the Board, the CAQH CORE Participants and the industry at large view the Phase IV Operating Rules as a critical initial step, but far from the last step, for the transactions. Viewing Phase IV as the initial step is especially important for prior authorization; the layered complexity of this transaction in both its content and exchange calls for an iterative process by which successive milestones are achieved. The Phase IV Operating Rules lay this essential foundation by setting basic data exchange expectations that currently do not exist. Without basics like response times and time stamping, more advanced goals will be twice as hard to define and implement, and cost savings will elude the industry. Therefore, while trading partners implement this first step in the journey, CAQH CORE, as committed by its Board, can simultaneously collaborate on agreeing to further improvements. This ongoing journey to evolve was what the ACA envisioned, and the strong support for Phase IV ensures a solid step in initiating the path forward to transparent and low cost data exchange.

- ***Compatible Safe Harbor***. The concerns expressed regarding the Connectivity Rule Safe Harbor, many of which were focused on cost or flexibility, demonstrated that there are some with a significant misunderstanding concerning the meaning of Safe Harbor in the CAQH CORE Operating Rules. Safe Harbor is explicitly defined in the Phase IV Operating Rules on page 48 (and copied in Appendix II to this letter). The same concept is included in the previously mandated Phases I – III Operating Rules, and has proven valuable to those exchanging transactions due to its flexibility. As applied in Phase IV, while the X.509 digital certificate must be *offered* and used if requested by a trading partner, the Operating Rules clearly state there is no requirement to use a CAQH CORE-compliant method if trading partners agree to use different security requirements, such as a virtual private network (VPN) or secure file transfer protocol (SFTP).

- ***Flexible by Being Payload Agnostic.*** Low adoption of the prior authorization, enrollment/disenrollment, and premium payment transactions was cited by some at the hearing as a reason for not adopting Phase IV at this time – with a myriad of reasons, all pointing to waiting; waiting for more data content, new versions of the ASC X12 standards, mandates on attachment standards or other reasons. At the same time, the arguments for waiting did not address the fact that the Phase IV Rules can be applied to any standard or version (i.e., Phase IV is payload agnostic). As stated by one member of NCVHS at the meeting of the Full Committee, "mandating the operating rules would start the process, where if they were not mandated, there may never be a start." As a country, we need to establish basic infrastructure expectations.

- ***Best Practice.*** While there is virtually full agreement by those in the data exchange arena, including previous calls to action by NCVHS, that Acknowledgements are needed, some testimony again included a recommendation to wait. Some suggested waiting for Federal regulatory action adopting an Acknowledgements standard prior to the adoption of Acknowledgements in the operating rules. However, delaying adoption for this reason continues to do harm to the industry. Acknowledgements are not conducted independently, but are used only with a transaction. Therefore, they are a key part of infrastructure operating rules. CAQH CORE previously supplied a legal opinion that Acknowledgements can legally be mandated by HHS through operating rules, and would urge that NCVHS explicitly call out support for this in its recommendation to the Secretary of HHS. Every entity that is voluntarily CORE-certified on existing CAQH CORE Operating Rules must use Acknowledgements as every phase of CAQH CORE Operating Rules requires Acknowledgements. This inclusion is driving value to providers and health plans, and, thus, overall transaction adoption.

- ***Enforcement.*** NCVHS asked if Phase IV can be enforced, and CAQH CORE was clear that it can. CAQH CORE continues to evolve its proactive, non-profit, interactive Certification Testing Program given our commitment to driving and tracking adoption by both HIPAA and non-HIPAA covered entities. To this end, Voluntary CORE Certification for Phase IV will be available to the industry starting this summer. Enforcement activities focused on adoption of operating rules and their underlying standards is an essential component of data exchange. Without enforcement, adoption rates and compliance will continue to be challenges for the industry. CAQH CORE urges NCVHS to request that HHS recognize and act upon the critical role of enforcement for all entities.

CAQH CORE remains committed to supporting education and technical assistance for implementation of its operating rules and to their continued maintenance. Please contact Gwendolyn Lohse, who testified to NCVHS on behalf of CAQH CORE, at glohse@caqh.org if we can be of any further assistance.

As the Federal Advisory Committee to HHS on HIPAA, we urge you to encourage industry progress.

Sincerely,

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

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

Susan L. Turney, MD, MS, FACP, FACPME, CEO
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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 North Carolina

Tim Kaja, SVP, Optum Cloud/Link
United Health 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 75% 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)

Appendix II: CAQH CORE Safe Harbor

5 CAQH CORE SAFE HARBOR

This rule specifies a "Safe Harbor" that any stakeholder can be assured will be supported by any HIPAA-covered entity or its agent. This rule further specifies the connectivity method that all HIPAA-covered entities or their agents and all voluntarily CORE-certified organizations must implement and with which conformance must be demonstrated.

As such, this rule:

- **DOES NOT** require trading partners (e.g., a provider or a health plan) to discontinue using existing connections that do not match the rule.
- **DOES NOT** require trading partners to use a CAQH CORE-compliant method for all new connections.
- **DOES NOT** require all trading partners to use only one method for any connections.
- **DOES NOT** require any entity to do business with any trading partner or other entity.

CAQH CORE expects that in some circumstances, trading partners may agree to use different communication method(s) and/or security requirements than those described in this rule to achieve the technical goals of the specific connection. Examples of potential different communication methods that could be implemented under this CAQH CORE Safe Harbor provision include a VPN (virtual private network) or SFTP (secure file transfer protocol.) Such connectivity gateways are not considered compliant with this Phase IV CAQH CORE 470 Connectivity Rule v4.0.0. When a HIPAA-covered entity or its agent implement a different communication method(s) as permitted by this CAQH CORE Safe Harbor all payload processing modes specified for the transactions addressed by this rule must be supported in each connectivity gateway implemented which does not comply with this Phase IV CAQH CORE 470 Connectivity Rule v4.0.0 requirements. (See §4.4.3.1)

This Phase IV CAQH CORE 470 Connectivity Rule v4.0.0 is the CAQH CORE Safe Harbor connectivity method that a HIPAA-covered entity or its agent MUST use if requested by a trading partner. If the HIPAA-covered entity or its agent do not believe that this CAQH CORE Safe Harbor is the best connectivity method for that particular trading partner, it may work with its trading partner to implement a different, mutually agreeable connectivity method. However, if the trading partner insists on using this CAQH CORE Safe Harbor, the HIPAA-covered entity or its agent must accommodate that request. This clarification is not intended in any way to modify entities' obligations to exchange electronic transactions as specified by HIPAA or other federal and state regulations.

ATTACHMENT 2

CAQH CORE Board Statement:
Commitment to Content, Infrastructure and Maintenance

June 2015

CAQH CORE Operating Rules set national responsibilities and requirements for timely, accurate electronic transactions within the healthcare claims cycle. These operating rules address both the necessary infrastructure (such as response times, acknowledgements) and basic content (such as patient financial responsibility) needed to conduct the daily business of healthcare. The operating rules support further use of existing standards wherever possible. Significant work is still needed for all HIPAA transactions to improve both infrastructure and content, and thus achieve true interoperability between all parties in this work flow.

CAQH CORE began as a voluntary effort. As such, before any CAQH CORE operating rules were mandated, CAQH CORE drove voluntary adoption and maintenance of operating rules. The mandated CAQH CORE operating rules now include a feature for CAQH CORE to conduct ongoing maintenance based on use, need and lessons learned. This model has proved successful, and compliments more substantive maintenance updates. CAQH CORE believes that a cycle of maintenance for mandated operating rules and standards will help drive the vision of an ever-evolving, improving system of electronic transactions. Regular updates driven by market needs can help transform our current claims process.

As part of its commitment to address both infrastructure and content - and its commitment to maintenance overall - the CAQH CORE Board embraces the Review Committee (RC) formed by the Affordable Care Act (ACA). It is anticipated that the RC will support the industry in its efforts to have regularly scheduled updates of both operating rules and standards, rather than waiting for approval of new legislation to make needed updates, which have previously focused on major overhauls. CAQH CORE also hopes the RC will recognize the value of ongoing maintenance, when such an option is appropriate.

Gaining uniform agreement on basic infrastructure was prioritized by both CAQH CORE and non-CORE participants as the first step in the Phase IV Operating Rules development. Reasons include: the range of current market capabilities for the transactions addressed, the array of trading partners that send and receive these transactions, and that two of the transactions are between the health plan and a non-HIPAA covered entity - the employer. In 2016, CAQH CORE will drive the adoption of the Phase IV infrastructure, including acknowledgements, and conduct its ongoing maintenance of earlier CORE phases. Additionally, it will work with the industry to identify priority draft content needs for Phase IV Operating Rules and any new needs for existing phases. CAQH CORE will update the RC on this work.