NCVHS
National Committee on Vital and Health Statistics

November 23, 2020

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

Re: **Recommendations for Proposed Operating Rules for Prior Authorization and Connectivity for HIPAA Transactions**

Dear Secretary Azar:

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 advises the Secretary on the adoption of standards, implementation specifications, code sets and identifiers for the HIPAA-named transactions.

In February 2020, NCVHS received a proposal from the Council for Affordable and Quality Health Care (CAQH) Committee on Operating Rules (CORE) for three new operating rules.[1] Two operating rules address data content and infrastructure and apply to the HIPAA prior authorization transaction. The third addresses connectivity and applies to the prior authorization and certain other adopted transactions. In August 2020, NCVHS held a hearing to obtain industry input on the three proposed operating rules, receiving testimony from 37 organizations and individuals.[2] The Committee also solicited written input from stakeholders.[3]

This letter conveys the following four recommendations to HHS:

> **Recommendation 1:** Adopt an attachment standard.

> **Recommendation 2:** Support and encourage voluntary use of the two proposed operating rules for prior authorization prior to an action for adoption.

> **Recommendation 3:** Do not adopt the proposed operating rule for connectivity and encourage CAQH CORE to complete its new version.

> **Recommendation 4:** Increase visibility of enforcement information related to operating rules.

BACKGROUND AND SUPPORTING DETAILS

CAQH CORE has proposed three operating rules for adoption:

1. CAQH CORE Prior Authorization & Referrals (X12 278) Data Content Rule Version PA.1.0
2. CAQH CORE Prior Authorization & Referrals (X12 278) Infrastructure Rule Version PA.2.0
3. CAQH CORE Connectivity Rule Version C3.1.0.

The prior authorization transaction (X12 278), has the lowest implementation rate of all the mandated HIPAA transactions - currently at 13% - according to the CAQH 2019 Index.[4] In keeping with HHS and administration priorities, several efforts are underway to understand the challenges of the prior authorization process, and identify opportunities to increase electronic prior authorization, thereby reducing burden on providers, payers and patients. The proposed operating rules are one effort aimed at mitigating some of the barriers in the workflow for prior authorization.

In general, both oral and written testimony supported the proposed operating rules for prior authorization. The key values of the CAQH CORE rules are that they could shorten payer prior authorization response times for review and reduce administrative burden by improving the consistency of information across payers. Most commenters agreed that these rules were a step forward on the path to automating prior authorization requests, but that they did not encompass a full solution for digital prior authorization workflows.

Importantly, those testifying were emphatic that without an adopted standard for attachments to convey related clinical information, use of the adopted HIPAA standard for prior authorization would not substantially increase, even with the proposed operating rules.

With respect to the proposed operating rule for connectivity, many organizations stated that while the update provided consistency, there were concerns about the implementation costs for small provider practices, current alignment with industry security best practices, potential conflict with National Institute of Standards and Technology (NIST) recommended security standards, and the burden of making certain system changes that might not be necessary but would only be required because of these operating rules. Further, the operating rule language is crafted such that it would apply to prior authorization and already-adopted operating rules for HIPAA transactions. The applicability of the connectivity rule to HIPAA transactions should be clarified in future proposed operating rules.

NCVHS analyzed the testimony and deliberated the proposed operating rules in light of current use of the prior authorization standard transaction, the rapid evolution of interoperability innovation and burden reduction, and the principles of HIPAA. The recommendations in this letter reflect our analysis of industry input, in concert with recognition of other federal policy initiatives[5] underway to evaluate opportunities to improve electronic prior authorizations.

RECOMMENDATIONS

Recommendation 1: Adopt an attachment standard.

NCVHS understands that adoption of a standard for attachments is a prerequisite to adoption of operating rules for the prior authorization transaction. Without an attachment standard, providers and payers indicated during the August 2020 hearing and in written submissions that an increase in implementation or use of a prior authorization standard transaction would be unlikely. For further details on the value of an attachment standard, see previous NCVHS recommendations.[6]

Recommendation 2: **Support and encourage voluntary use of the two proposed operating rules for prior authorization prior to an action for adoption.**

NCVHS recommends the Secretary encourage voluntary use of the proposed operating rules for data content and infrastructure for the HIPAA prior authorization standard transaction in light of the strong support from industry. During the voluntary use phase, HHS could identify meaningful measures to evaluate stakeholder use of the operating rules, and consider an objective evaluation process, data capture and final report. Based on the data and results of the voluntary adoption phase, HHS could consider adopting the operating rules through the notice and rulemaking process. The Subcommittee received some conflicting testimony on certain elements of the operating rules, e.g., the turnaround time, use of X.509 digital certificates, and the potential for unintended consequences (for example the potential for more prior authorization transactions being "pended" for a longer period of time). In order to ascertain which is more correct, the voluntary uptake period will enable HHS to measure the results of actual use on a broader scale.

We believe the proposed operating rules provide opportunities for improvements in the prior authorization process such as consistency in response times across payers. However, the lengthy rulemaking process, if initiated, would not provide immediate results. Therefore, voluntary adoption of the proposed operating rules would serve two purposes: 1) near-term improvements in the prior authorization process; and 2) capture of critical and necessary data to support the rulemaking impact analysis.

The Committee is aware of the Secretary's prioritization of other initiatives, including interoperability, application programming interface (API) implementation with Fast Healthcare Interoperability Resources (FHIR), clinical decision support (which can be foundational for automating prior authorization), and improved public health reporting based on lessons learned in the COVID pandemic. Supporting voluntary adoption of the proposed operating rules does not conflict with these other HHS priorities. Furthermore, HHS support for, and industry's subsequent action on operating rules, could mitigate certain workflow barriers related to the prior authorization process. For example, use of the operating rules in concert with the adopted HIPAA standard transaction for prior authorization could reduce delays in approvals, once the provider has submitted necessary documentation.

The Committee has observed that there is significant innovation occurring around prior authorization among multiple industry sectors and groups, including recently released recommendations from HITAC[7] and the collaborative work between NCVHS and HITAC on the

convergence of administrative and clinical data. NCVHS understands that HHS must evaluate several promising initiatives and determine how to incorporate any recommendations into a larger strategic plan. Apropos of operating rules, NCVHS believes that a voluntary use phase would provide time to garner value while bringing clarity to the mid to longer term priorities for national interoperability. As such, we suggest a period of at least 12 months for this voluntary use phase.

Recommendation 3: Do not adopt the proposed operating rule for connectivity and encourage CAQH CORE to complete its new version of this proposed operating rule.

NCVHS does not recommend that HHS adopt the proposed operating rule for connectivity. The Committee has decided not to recommend the proposed connectivity rule because it both adopts a security standard that has known vulnerabilities and it allows continued use of other obsolete security practices. The Committee suggests that CAQH CORE move toward the newer Transport Layer Security (TLS) standards as put forward in recommendations by NIST. Based on industry input, CAQH CORE may wish to consider removing the safe harbor provision that would enable continued use of certain security practices that may be outdated. The Committee heard some testimony indicating that the change in authentication from Username and Password to X.509 digital certificates will be too burdensome and costly, without demonstrable value for many smaller entities and will not enjoy widespread adoption. One testifier representing a large stakeholder group indicated that because this was the only option for authentication, it limited stakeholders' ability to meet differing business needs and could impede EDI adoption. The cost of X.509 digital certificates could be passed on to providers, which could be a shift in the transaction cost, increasing burden. One organization indicated that the proposed operating rule could limit the inclusion of new and emerging technologies such as RESTful APIs, OAuth, and SAML[8] authorization and identity services.

The Committee heard additional testimony from a variety of perspectives, including some positive testimony in favor of immediate adoption. Some testifiers indicated that the articulation of this rule was complex and difficult to understand. We also heard from HHS that the change in the CAQH CORE new operating rule structure might require re-promulgation and adoption of already-implemented operating rules.[9]

The Committee understands that CAQH CORE is working on revisions to the connectivity operating rule.[10] We encourage publication of a new version that takes the above considerations into account and that is written in clear language for a broader audience.

Recommendation 4: Increase visibility of enforcement information related to operating rules.

Consistent with previous testimony, stakeholders requested that HHS act upon and publicize its efforts on compliance and enforcement for already-adopted operating rules. The Committee made recommendations in previous letters about publicizing enforcement data on an appropriate website, and we commend recent efforts by HHS to do so.[11] Data on compliance and enforcement activity specific to operating rules, as well as de-identified case summaries on operating rule issues, could be educational for stakeholders. Furthermore, in alignment with compliance reviews underway for standard transactions, the Committee suggests HHS consider

implementing compliance reviews for the adopted operating rules to determine the level of compliance with those that have been mandated to date.

SUMMARY

NCVHS finds that CAQH CORE has achieved constructive industry debate and consensus building in alignment with the NCVHS Predictability Roadmap findings and recommendations. CAQH CORE and members of its work group understand the scope of industry challenges that have been expressed regarding the prior authorization process and have proposed operating rules for the HIPAA transaction standard to attempt to address the challenges. The Committee commends CAQH CORE and its members for their commitment. To this end, the Committee strongly encourages CAQH CORE members to proceed with voluntary implementation of the proposed prior authorization data content and infrastructure operating rules as part of a structured learning process.

First and foremost, the Committee encourages HHS to move forward to adopt a standard for attachments (i.e., publish a proposed rule per the Unified Agenda), without which, the second part of these operating rule recommendations may not have the intended impact of increasing the rate of electronic prior authorization. Secondly, we suggest the Secretary support voluntary use or piloting of the proposed prior authorization operating rules to enable industry to determine if there are in fact substantive improvements in the use of the adopted HIPAA prior authorization transaction. HHS may be able to use the data from the voluntary uptake of these proposed operating rules as a basis for the regulatory impact analysis needed in proposed rulemaking, including reliable observational data about costs, benefits and possibly unanticipated consequences from implementation efforts. Based on the principles of its Predictability Roadmap recommendations, the Committee believes that experiential data will be useful to support the value proposition for a proposal on adoption before HHS rule promulgation.

As always, NCVHS remains available to answer any questions and will continue to support HHS efforts in the promotion of administrative simplification and nationwide interoperability.

Sincerely,

 /s/

Nick Coussoule, Chair
National Committee on Vital and Health Statistics

Cc: Mary Greene, MD, MPH, Director, Office of Burden Reduction and Interoperability, CMS
         Chris Gerhardt, Director, National Standards Group, CMS

Endnotes

[1] Request letters to NCVHS from CAQH CORE available at: https://ncvhs.hhs.gov/wp-content/uploads/2020/04/CAQH-CORE-NCVHS-Review-Request-2.24.20_FINAL-508.pdf and https://ncvhs.hhs.gov/wp-content/uploads/2020/07/CAQH-CORE-NCVHS-Update-Letter-6.26.20-508.pdf

[2] August 25-26, 2020 NCVHS Standards Subcommittee Hearing agenda and presentations available at: https://ncvhs.hhs.gov/meetings/standards-subcommittee-meeting-2/

[3] Compiled Public Comments for August 25-26, 2020 NCVHS Standards Subcommittee Hearing available at: https://ncvhs.hhs.gov/wp-content/uploads/2020/08/Public-Comments-CAQH-CORE-Proposed-Operating-Rules-for-Federal-Adoption-508.pdf

[4] CAQH Report: https://www.caqh.org/sites/default/files/explorations/index/report/2019-caqh-index.pdf

[5] Link to HITAC Intersection of Clinical and Administrative Data (ICAD) Task Force webpage: https://www.healthit.gov/hitac/committees/intersection-clinical-and-administrative-data-task-force

[6] NCVHS Letter to HHS Secretary, "Recommendations for the Electronic Health Care Attachment Standard." (July 5, 2016): https://ncvhs.hhs.gov/wp-content/uploads/2018/03/2016-Ltr-Attachments-July-1-Final-Chair-CLEAN-for-Submission-Publication.pdf

[7] Recommendations to the National Coordinator for Health IT, Intersection of Clinical and Administrative Data (ICAD) Task Force Report (November 17, 2020):   https://www.healthit.gov/topic/federal-advisory-committees/recommendations-national-coordinator-health-it

[8] RESTful APIs, OAuth, and SAML refer to security protocols to authenticate user identity (https://www.nist.gov)

[9] New structure for CAQH CORE Operating Rules: https://www.caqh.org/core/new-operating-rule-structure

[10] Proposed CAQH CORE Connectivity Rule: https://www.caqh.org/sites/default/files/core/Connectivity-Rule-vC310.pdf?token=k33dpzhD

[11] NCVHS Letter to the HHS Secretary, "NCVHS Recommendations on New Approaches to Improve the Adoption of National Standards for the Health Care Industry," including improving the visibility of the enforcement program. (February 19, 2019):   https://ncvhs.hhs.gov/wp-content/uploads/2019/02/Recommendation-Letter-Predictability-Roadmap.pdf