NCVHS Subcommittee on Standards
Comments Received in Response to Request for Comment
Federal Register Notice 85 FR 37666

Input on the three CAQH CORE proposed Operating Rules

Received as of August 20, 2020

	Organization	Signatory	Notes
1.	ADA	Jean Narcisi Director, Dental Informatics Department ADA Practice Institute	
2.	Aetna	Renee Ghent Chief, Digitalization Officer	
3.	AHA	Terrence Cunningham Director, Administrative Simplification Policy	
4.	AHIMA	Wylecia Wiggs Harris CEO	
5.	AHIP	Kate Berry Senior Vice President	
6.	AMA	Heather McComas Director, Administrative Simplification Initiatives	
7.	Anthem	Christol Green Portfolio Manager, E-Solutions Anthem,	
8.	Athenahealth	Paul Brient Senior VP, Chief Product Officer	
9.	BCBS of Michigan	Amy Turney Business Analyst EDI Business	

	Organization	Signatory	Notes
10.	BCBS of North Carolina	Troy Smith VP, Health Care Strategy & Payment Transformations	
11.	BCBS Association	Gail Kocher Director, Commercial Markets	
12.	Centene	Kim Henrichsen Centene Corporation	
13.	Cooperative Exchange	Crystal Ewing Director of Product, eSolutions	
14.	Defense Health Agency	Danny Sawyer/David Wilderman	
15.	DSMO Committee	Lauri Burckhardt Administrator EDI Regulatory and National Standards	
16.	Edifecs	Gupreet (Sunny) Singh CEO & President	
17.	Epic	Sreevinas Pasumarthi Software Development Lead	
18.	Harvard Pilgrim Health Care	Rhonda E. Starkey Director, eBusiness Services	
19.	LabCorp	Donald Horton, Jr. Sr. VP, Global Government Relations & Public Policy	
20.	Marshfield Clinic Health System	Susan L. Turney, MD Chief Executive Officer	
21.	MGMA	Robert Tennant Director, Health Information Technology Policy	

	Organization	Signatory	Notes
22.	Michigan Medicaid	Diana Fuller Departmental Analyst Medicaid Payments Division	
23.	Montefiore	Noam Nahary MS RHIA Senior Director	
24.	Nacha	Brad Smith Sr. Director, ACH Network Administration & Industry Verticals	
25.	NCPDP	Lee Ann Stember President & CEO	
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27.	NUCC	Nancy Spector Chairperson	
28.	Ohio Health	Margaret Schuler System VP, Revenue Cycle	
29.	Ortho North East	Mona Reimers Director, Administrative Operations	
30.	RadNet	Susan Hollabaugh VP, Regulatory Analysis & Conformance	
31.	United Healthcare	Tim Kaja COO	
32.	Veterans Affairs	Katherine Knapp Program Analyst eBusiness Solutions	
33.	WEDI-PAG	Jay Eisenstock Chairman	
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July 23, 2020

Alexandra (Alix) Goss, Co-chair, Subcommittee on Standards
Richard Landen, Co-chair, Subcommittee on Standards
National Committee on Vital and Health Statistics

Dear Ms. Goss and Mr. Landen,

The American Dental Association (ADA) is the world's oldest and largest professional dental association with over 163,000 members and is named in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as an advisor to the Secretary. As a longstanding member of the standards development community, the ADA appreciates the opportunity to comment on the CAQH Committee on Operating Rules for Information Exchange (CORE) for the adoption of the Prior Authorization (278) Data Content Rule v5.0.0, Prior Authorization (278) Infrastructure Rule v4.1.0, and Connectivity Rule vC3.1.0 under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. In general, we support the adoption of electronic standards and operating rules, with the goal of reducing administrative burdens imposed by disparate requirements by stakeholders throughout the industry.

The ADA itself is a leader in the development, publication, and implementation of interoperability standards in the oral health care setting, and is an American National Standards Institute (ANSI) Accredited Standards Development Organization for dental information technology through its Standards Committee on Dental Informatics (SCDI). The SCDI membership consists of a broad range of stakeholder interests, including technology vendors, dental plans, clearinghouses, national dental specialty organizations, practicing dentists, and academics.

Proposed Operating Rules

The ADA supports CORE's effort to increase the efficiency and standardization of the prior authorization process through these proposed operating rules.

Unfortunately, there is a lack of consensus among industry stakeholders as to whether the requirements of the operating rules will achieve their goal. Yet, providers as a stakeholder group are firmly in favor of the maximum two-day response requirement, as this will only aid providers in serving the needs of their patients in a timely way. In addition, much of the industry across stakeholder groups is in favor of the proposed rule's connectivity requirements. It would be wise for NCVHS to further explore the proposed requirements and the various organizations' expert analyses during its hearing, taking into account where the divisions lie and what might benefit consumers most.

Attachments and Data Content

In general, providers often must submit additional documentation to health and dental plans to support prior authorization requests and still, sadly, must rely on manual processes to do so. While outside the scope of these CORE operating rules, the entire health care industry, including dentistry, is in dire need of an attachments standard to bring much needed efficiency, decreased cost, and standardization to the electronic exchange of additional documentation, whether for purposes of prior authorization or claims adjudication. The prior authorization standard transaction and operating rules, if adopted by HHS, will not have the hoped for impact in the absence of a HIPAA Attachments Rule. Also, the industry has been waiting for more than 20 years for an Attachments Rule, which is still not yet published. The ADA urges HHS to publish a final Attachments Rule without delay, and to make plans to revise that regulation when adopting the next set of X12 transactions as HIPAA standards.

Connectivity and Security

The ADA is in favor of enhancing connectivity performance for the sake of timelier transaction processing that enables timely, effective care. Taking incremental steps to improve connectivity to support enhanced transaction performance, especially in advance of major HHS rulemaking on attachments, is most desirable. How that is to be achieved needs to take into effect the needs and resources of the implementers, but these considerations should not be cause to indefinitely delay needed improvements.

The ADA appreciates the opportunity to comment on CAQH CORE's request to have these operating rules adopted under HIPAA. If you have any questions, please contact me at (312) 440-2750 or narcisij@ada.org.

Sincerely

Jean Narcisi, Director, Department of Dental Informatics
ADA Practice Institute
Center for Informatics and Standards

cc: David M. Preble, DDS, JD, CAE, Senior Vice President, ADA Practice Institute

July 24, 2020

William W. Stead, MD
Chair
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: CAQH CORE Operating Rules Proposed to NCVHS – 2020

Dear Dr. Stead,

Thank you for the opportunity to provide feedback on the CAQH Committee on Operating Rules for Information Exchange (CORE) Operating Rules proposed to the National Committee on Vital and Health Statistics (NCVHS). Aetna fully supports the proposal and recommends the three CAQH CORE Operating Rules to NCVHS and the Department of Health and Human Services (HHS) for federal adoption under HIPAA.

Aetna, a CVS Health business, serves an estimated 34 million people with information and resources to help them make better informed decisions about their health care.

Over 125 organizations, including Aetna, participated in the development of the proposed operating rules through a collaborative, consensus-based process. The operating rule package proposed by CAQH CORE is designed to drive greater automation, increase efficiencies, and enhance health plan and provider data exchange.

Aetna just completed its fourth CORE Certification this month which includes the CAQH CORE Connectivity Rule vC3.1.0. This version of the CAQH CORE Connectivity Rule enhances security and promotes uniform interoperability requirements across administrative transactions. A single, updated safe harbor connectivity method for the industry will simplify data exchange and eliminate the need to support the older, outdated versions of CAQH CORE Connectivity that are currently mandated.

Further, we believe the proposed CAQH CORE Operating Rules set the stage for future innovation to further enable the critical convergence of administrative and clinical data and support the use of new technologies with existing standards.

Aetna applauds NCVHS's efforts to improve healthcare data exchange and care delivery. We encourage NCVHS to promote industry progress by supporting and advancing industry-driven efforts like the CAQH CORE Operating Rules.

Thank you for the opportunity to provide comment. Please do not hesitate to reach out with questions.

Sincerely,
Renee Ghent
Chief Digitalization Officer, Aetna

American Hospital Association™
Advancing Health in America

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National Committee on Vital and Health Statistics
Subcommittee on Standards
Hearing on Proposed Operating Rules
Aug. 24-25, 2020

Testimony from the American Hospital Association

Submitted by:
Terrence Cunningham, Director, Administrative Simplification Policy

Dear Subcommittee Members:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including 750 hospital-based skilled-nursing facilities, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment before the National Council on Vital and Health Statistics on the proposed prior authorization infrastructure and data content operating rules.

The Affordable Care Act defined operating rules as "the necessary business rules and guidelines for the electronic exchange" for HIPAA electronic transactions. The AHA recommends adoption of the proposed rules, which establish crucial improvements to the prior authorization process.

Prior authorization is a process whereby a provider, on behalf of a patient, requests a health plan's approval before delivering a treatment or service in order to qualify for coverage and payment. Although health plans contend that prior authorization programs are enacted "to help ensure patients receive optimal care based on well-established evidence of efficacy and safety, while providing benefit to the individual patient,"[1] many health plan prior authorization processes are inefficient, widely varied and can result in dangerous delays in the delivery of patients' medically necessary care.

Unlike other HIPAA Administrative Simplification electronic standards, prior authorization involves clinical information and has a direct impact on patient care. A prior authorization request is often the final barrier between a patient and the

[1] https://www.ahip.org/wp-content/uploads/Prior-Authorization-FAQs.pdf

implementation of their provider's recommended treatment. As a result, prior authorization requests' timely, efficient processing are extremely important.

Unfortunately, there currently are no requirements mandating that health plans respond to prior authorization requests in a timely fashion, the results of which are delays in patient care and negative patient health outcomes.[2] Additionally, prior authorization requirements can vary widely between health plans, creating administrative burdens and, for providers, uncertainty.

Infrastructure Rule
The CAQH CORE Prior Authorization & Referrals Infrastructure Rule would help reduce potential delays in care by establishing timeframes within which plans must respond to providers' prior authorization requests. Specifically, the rule requires plans to indicate, within two business days, cases in which additional documentation is needed for prior authorization adjudication, while also requiring plans to make final determinations within two business days of receipt of all necessary documentation and information.

The establishment of reliable time restrictions will allow providers and their patients the ability to accurately craft care plans and help reduce patients' uncertainty regarding their health.

Data Content
The CAQH CORE Prior Authorization & Referrals Data Content Rule improves for providers the transparency and efficiency of the prior authorization process by creating a standard format for plans to request specific clinical information necessary for adjudication.

The rule establishes standard codes (LOINC or PWK) for requesting information. This represents a significant step for the industry, as the current unregulated methodology varies widely between plans and often leaves providers unclear as to their requests' statuses and whether any additional information is needed.

Additional Improvements to Prior Authorization Regulation
Prior authorization has long been a significant source of procedural angst for providers and patients, and the creation of operating rules is a significant step in the right direction towards improving the process.

The operating rules do not, however, address all provider concerns with prior authorization. We encourage NCVHS to consider the following additional measures to simplify the process for providers and help protect patient care:

- Attachment standard: In order to approve a prior authorization request, health plans frequently require the exchange of clinical information. There is

[2] https://www.ama-assn.org/system/files/2020-06/prior-authorization-survey-2019.pdf

currently no standard method for providers to send clinical information to health plans. In the absence of a standard, health plans vary significantly in how they require the submission of information, often utilizing inefficient methods such as phone or fax. In order for prior authorization to be successfully streamlined, the industry needs a consistent, standard method of delivering clinical information.

- Removal of the "Business Day" concept: Hospitals care for patients 24 hours a day, 365 days per year. If a health plan chooses to insert prior authorization as a step into the clinical workflow, they should be required to process at any time. In order to prevent patients from waiting unnecessarily for care, health plans should be required to process prior authorization requests 24 hours a day.
- Stricter compliance requirement: The proposed operating rules require health plans to comply with their requirements at least 90% of the time per month. While 90% compliance is appropriate for other standard electronic transactions, it is insufficient for prior authorizations. One of the benefits of the proposed rules are that they could enable physicians to provide patients with clear timeframes within which their request will be processed (48 hours from when the plan receives all necessary documentation). A system that permits 10% noncompliance, however, hinders this ability, as one out of every ten patients could have their care delayed in excess of the timeframe without the plan being held accountable.

Thank you for the opportunity to comment on this important topic. If you have any questions, please feel free to contact me at tcunningham@aha.org or (312) 422-3346.

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July 24, 2020

Alexandra (Alix) Goss
Richard W. Landen
Co-Chairs, National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards
3311 Toledo Road Hyattsville, MD 20782-2002

Re: Request for Public Comment on Three CAQH CORE Proposed Operating Rules

Submitted electronically to: NCVHSmail@cdc.gov

Dear Ms. Goss and Mr. Landen:

Thank you for the opportunity to provide input to the National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards consideration of CAQH CORE Proposed Operating Rules in the areas of the Prior Authorization (278) Data Content, the Prior Authorization (278) Infrastructure, and Connectivity.

AHIMA is a global nonprofit association of health information (HI) professionals. AHIMA represents professionals who work with health data for more than one billion patient visits each year. AHIMA's mission of empowering people to impact health drives our members and credentialed HI professionals to ensure that health information is accurate, complete, and available to patients and clinicians. Our leaders work at the intersection of healthcare, technology, and business, and are found in data integrity and information privacy job functions worldwide.

AHIMA applauds the Subcommittee and CAQH CORE for seeking to address challenges with prior authorization, including operating rules to support the existing HIPAA transaction standards. As noted in the CAQH CORE materials, the current prior authorization process is "time-consuming and costly process" that involves a considerable amount of manual work and use of multiple portals, phone calls, and fax.

AHIMA members experience the challenges of negotiating prior authorization, as well as other exchanges of health information between providers and payers, on a routine basis. The Association recently convened a group of members to help paint the picture of what is happening on the ground when providers share clinical data with payers. Our scope went beyond prior authorization to also include concurrent review and post-discharge processes. The attached presentation to the ICAD task force on June 23 summarizes the group's findings (see attached). Our members' experience confirms that exchanges of all sorts, including prior authorizations, suffer from variability and lack of clarity about the documentation that is need, changes in rules over time and without notice, and the need for multiple formats for sharing information, even for a single patient stay or encounter.

To support improvement in provider-payer exchanges of information, including prior authorization, it is important to acknowledge that automation, while important, is only one part of solving the issues. Factors beyond automation – such as continued variation in the information required, lack of

standardization for business processes, ensuring patient privacy, and promoting trust and representation – must also be addressed. We encourage the Subcommittee to keep these larger issues in mind, even as you evaluate the details contained in the proposed operating rules under consideration.

We appreciate the opportunity to submit information relevant to the work of the Subcommittee. Should you or your staff have any additional questions or comments, please contact Lauren Riplinger, Vice President of Policy & Government Affairs, at lauren.riplinger@ahima.org and (202) 839-1218.

Sincerely,

Wylecia Wiggs Harris, PhD, CAE
Chief Executive Officer
AHIMA

America's Health Insurance Plans
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July 31, 2020

William Stead, MD
Chair, National Committee on Vital and Health Statistics
c/o Rebecca Hines
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782

Submitted electronically via NCVHSmail@cdc.gov

RE: AHIP Comments for the Record on Proposed CAQH CORE Operating Rules

Dear Dr. Stead:

On behalf of America's Health Insurance Plans (AHIP)[1] members, we appreciate the opportunity to submit written comments for the record in advance of the National Committee on Vital and Health Statistics (NCVHS) virtual hearing on August 25-26, 2020 regarding operating rules proposed by the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE). Specifically, in February 2020, CAQH CORE submitted three operating rules to be considered for adoption under the Health Insurance Portability and Accountability Act (HIPAA) and the Patient Protection and Affordable Care Act (ACA):

- **CAQH CORE Prior Authorization (278) Data Content Rule v5.0.0**
- **CAQH CORE Prior Authorization (278) Infrastructure Rule v4.1.0**
- **CAQH CORE Connectivity Rule v4.0.0**

We appreciate NCVHS' efforts to engage stakeholders and solicit input on the CAQH CORE operating rules. Our comments are informed by the experiences of AHIP's member health plans in implementing HIPAA transaction standards and Administrative Simplification requirements under the ACA.

AHIP believes these operating rules represent positive progress toward increasing automation, streamlining processes, standardizing data elements, and decreasing manual work. However, we acknowledge that implementation of these rules may be costly and burdensome and does not provide a seamless solution to prior authorization. Some of the proposed requirements would require major technology system changes and upgrades that will be resource-intensive in terms of both personnel time and technology investments, so plans and providers should be granted reasonable time to gradually implement them. It is especially important to allow sufficient time – at least 24 months - for implementation, in light of the COVID-19 pandemic, competing Department of Health and Human Services (HHS) priorities, such as implementation of the Interoperability Rule, and the resulting capacity of health plans, providers, and technology intermediaries or trading partners to dedicate sufficient attention to the complexity of implementing the three operating rules being considered for adoption. In addition, we are concerned that some of the accelerated turnaround timeframes included in the prior authorization rules and safe harbors allowing providers to continue to use older methodologies in the connectivity rule pose potentially significant additional challenges.

We provide detailed responses to the Committee's questions below:

1. **Participation in development of the rules: If your organization participated in identification and development of the proposed operating rules for prior authorization and/or connectivity, describe the skill set of the individuals involved (business or technical) and in what way they participated in the process.**

AHIP did not participate in development of the proposed operating rules. Our comments are informed by member health plans who participated in the development and review of all three proposed operating rules, including the CAQH CORE Prior Authorization Subgroup, the CAQH CORE Rules Work Group, and the CAQH CORE Connectivity Subgroup.

2. **Workflow (prior authorization rules): In what way(s) will the proposed operating rules for prior authorization improve workflow for your organization's industry sector? Discuss the prior authorization data content and infrastructure rules and describe how the proposed requirements from each will impact your workflow, reduce burden (if relevant) and better support patient care.**

The proposed operating rules clarify expectations for prior authorization submission and responses between payers and providers. Some AHIP members report that adoption of these operating rules and use of the 278 transaction by providers will support implementation of an automated response process for prior authorization requests that are currently reliant on more manual methods (e.g., phone, fax). The requirements would support an automated workflow for pending a request due to the need for additional documentation as well as returning a response regarding why an initial 278 request could not be successfully processed.

At the same time, our members raise three important concerns related to the prior authorization rules. First, the ability of the health care ecosystem, including health plans, to realize benefits of adopting the prior authorization operating rules depends on whether providers and trading partners increase their use of the mandated 278 transaction. It is not clear whether adoption of these operating rules will result in increased use of the transaction across the entire ecosystem – health plans, intermediaries/trading partners, electronic health records (EHRs), doctors and other providers. Unless that happens, the promise of the potential progress will not be realized despite the significant investment required by health plans. Given the momentum of many health care organizations working on Fast Healthcare Interoperability Resources (FHIR) and application programming interfaces (API) to accelerate electronic information exchange and interoperability, including for prior authorization, it is difficult to know the potential impact of these rules.

Second, there is concern that lack of an attachment standard will limit the success of the 278 transaction and proposed operating rules. While we should continue to make progress toward more automated prior authorization, an attachment standard is needed for broader adoption and use of the 278 transaction.

Third, we are aware there are significant concerns with some of the accelerated response timeframes included in the proposed prior authorization infrastructure operating rule. The proposed operating rule requires a 20 second response time. Payers with existing automated processes for the 278 report response times closer to 60 seconds, and would need to revert to old processes or significantly rework their processes to move closer to a 20 second response time. The difference between a 20 second response time and a 60 second response time is unlikely to have material impact on providers or patients and may not be an appropriate requirement. We note there is some concern that applying the same initial response time

that is applied to the less complex 270/271 transaction could have the unintended consequence of stalling progress on end to end automation. In addition, we are concerned that the required two-day time frame in the infrastructure rule for health plans to review a prior authorization request and either request the additional documentation needed to support the request or make a final determination, does little to speed the process when parallel timeframes are not applied to providers to supply the required documentation.

3. Transaction exchange (connectivity rule): In what way(s) will the proposed operating rule for connectivity improve the processing of transactions, message payload, connectivity, security, etc. if adopted by HHS? What are the anticipated benefits that this operating rule offers vs. the current state?

The proposed operating rules for connectivity have the potential to provide two key benefits. First, it would create a minimum floor for exchanging health care data. Creating an industry-wide method for transaction exchange could reduce the complexity some payers face in supporting transaction exchange. Second, it would promote more secure transmission of data and could enable newer interoperability technologies that support greater privacy and security protocols. However, safe harbor provisions allow providers to continue to use older and different connectivity methodologies, forcing plans to maintain and support multiple methods or use contractual provisions to ensure consistency in connectivity methods among their providers. This is likely to add cost and limit the benefits of implementation.

4. Improving use of transactions and/or adoption of standards (all proposed operating rules): Describe how adopting the proposed operating rules will or could increase in the use of any of the adopted HIPAA transaction standards.

Currently, inconsistent expectations and variable processes hinder adoption and use of transactions, especially as it relates to the 278 transaction. Adopting the proposed operating rules could enhance electronic exchange of administrative health care data by promoting more uniformity in connectivity and data content. Standardizing baseline requirements for the 278 transaction should promote uniformity in prior authorization products, which would enable payers and providers to move away from payer-specific processes or requirements and engage in more standardized exchange of prior authorization requests. Consistency in standards and processes should encourage greater adoption and use of those standards. However, this promise relies on entities not currently using the 278 transaction to adopt and use the transaction and new operating rules. And given that prior authorization is a more complex and interactive transaction, adoption of these operating rules remains an imperfect solution, particularly given the efforts underway to use newer business interoperability technologies like FHIR to exchange information.

6. Implementation time frame for each proposed rule:

a. What is the anticipated lead time needed by your organization to develop, test and implement the proposed operating rules? What are the dependencies that impact the timeline, e.g., vendors, trading partners and business associates? If possible, please provide an estimate of the amount of time your vendors would require to develop their component of the solution?

To promote successful adoption and implementation of the prior authorization and connectivity operating rules, we recommend at least 24 months for implementation. Some of the requirements will entail major system changes and upgrades and therefore significant investments. Plans and providers should have reasonable time to gradually implement, especially in light of the COVID-19 pandemic. Trading partners should be strongly encouraged to conduct testing prior to the compliance date.

11. General: For each rule, please provide the rationale for your support or opposition to its adoption to inform the Committee's deliberations.

Overall, we are supportive of adoption of the three proposed operating rules for their potential to enhance adoption and use of mandated electronic transaction standards, lower administrative costs, improve interoperability, and streamline payer-provider communication if implementation is not required for at least 24 months. However, the success of these operating rules is contingent upon resolution of the aforementioned concerns and adoption not just by health plans but by the entire ecosystem - trading partners, EHRs, and providers.

Thank you for the opportunity to provide comments on the three proposed CAQH CORE operating rules. If the Committee has any questions regarding our comments, please feel free to contact us.

Sincerely,

Kate Berry
Senior Vice President

National Committee on Vital and Health Statistics
Subcommittee on Standards

Hearing on CAQH CORE Proposed Operating Rules
August 25-26, 2020

Written Testimony from the American Medical Association
Submitted by Heather McComas
Director, Administrative Simplification Initiatives

On behalf of the physician and medical student members of the American Medical Association (AMA), we appreciate the opportunity to provide testimony on operating rules proposed for a federal mandate by the Council for Affordable Quality Healthcare (CAQH), Committee on Operating Rules for Information Exchange (CORE). Our comments to the National Committee on Vital and Health Statistics (NCVHS) reflect the AMA's overall goal of reducing administrative burdens so that physicians can focus their time and attention on patient care.

Participation in Operating Rule Development

To ensure that operating rules for electronic transactions meet the needs of physicians, the AMA participated in all discussions and straw polls involved in the development of the CAQH CORE rules under consideration. Our feedback during the rule development process aligns with AMA policy and reflects our efforts to maximize the efficiency of physician practice workflows and business processes. In addition, an AMA physician leader served on the CAQH CORE Board throughout the development of these operating rules, bringing the critical perspective of a practicing clinician to the final phase of operating rule approval.

Of note, the AMA urged CAQH CORE to refine the original Prior Authorization Infrastructure Rule to address the response time for final determinations. The first iteration of the rule only established a timeframe for health plans' initial response to PA requests. Because health plans initially pend most medical service PAs due to the need for supporting clinical documentation, CAQH CORE's updated rule—which adds processing time requirements for final PA decisions— is a critically important step to move the industry forward in improving the onerous PA process.

Background on AMA PA Research and Reform Advocacy

The results from an AMA survey of 1000 practicing physicians conducted in December 2019 reveal the significant negative impact of PA on patient care. An overwhelming majority (91%) of physicians say that PA leads to delays in necessary care, while nearly three-quarters (74%) indicate that PA can lead to treatment abandonment. Even more alarming is the impact of PA on patients' health: 90% of physicians report that PA has a negative impact on clinical outcomes, and nearly one-quarter (24%) say that PA has led to a serious adverse event for a patient in their care, including 16% who state that PA has led to a patient's hospitalization. The AMA's grassroots advocacy website FixPriorAuth.org captures the stories of patient harm behind these troubling statistics.

The AMA's physician survey also reflects the major burden placed on physician practices by PA requirements, with 86% of physicians describing PA burdens as high or extremely high. Moreover, PA-related hassles are growing, with 86% of physicians saying that PA burdens have increased over the past 5 years. Practices report completing an average of 33 PAs per physician, per week, with this weekly PA workload consuming nearly two business days of physician and staff time. Practices invest considerable

resources in addressing PA, with almost one-third (30%) of physicians reporting that their practice has staff who work exclusively on PA.

These data clearly show that the PA process must be improved, both so that patients can receive the treatment they need in a timely fashion and to avoid substantial administrative waste in our health care system. For nearly four years, the AMA has been engaged in a multi-pronged campaign to reform health plans' PA programs. In January 2017, the AMA, in partnership with 16 organizations representing physicians, hospitals, medical groups, pharmacists, and patients, released a set of 21 Prior Authorization and Utilization Management Reform Principles. These principles outline key changes needed to meaningfully improve the PA process and spurred conversations between the health care professional and health plan communities. An important outcome of those discussions was the Consensus Statement on Improving the Prior Authorization Process, which was issued in January 2018 by the AMA, other national health care professional associations, and trade organizations representing health plans. In this statement, health care professionals and health plans agreed on key PA reforms, including reducing the overall volume of PA requirements, improving transparency, ensuring patient continuity of care, and increasing process automation.

Unfortunately, progress on the changes agreed to over 2.5 years ago remains sluggish, as shown by additional results from the AMA's 2019 PA physician survey. As we will discuss in more detail below, CAQH CORE's PA operating rules have the potential to advance the goals of improved PA transparency and process automation outlined in the consensus document. However, the rules will not address the steady rise in the number of medical services and prescription drugs requiring PA reported in the AMA's survey data. **The AMA maintains that health plans must reduce the overall volume of PA requirements for the industry to achieve real progress on this issue; automation alone is not a full solution to the PA problem.** Even the most streamlined, widely deployed electronic PA process cannot protect patients from clinical harm or physicians from administrative burdens if health plans do not apply utilization management requirements more judiciously and rationally.

Prior Authorization (278) Infrastructure Rule v4.1.0

Support for Rule Adoption

The AMA supports federal adoption of the PA Infrastructure Rule, as it represents an important and necessary initial step in reducing patient care delays associated with utilization management programs. The AMA's physician survey data and stories collected via the FixPriorAuth campaign illustrate the serious consequences of PA-related delays on patient safety and well-being. Existing industry accreditation requirements allow for liberal PA processing times (14–15 days)—clearly insufficient to protect patients from PA-related harms. The CAQH CORE PA Infrastructure Rule requires health plans to respond with a final PA determination within two business days of receiving all necessary information. **Given the current status quo, we believe that the Infrastructure Rule's significantly shorter processing time requirement for final decisions will move the industry forward in improving the PA process.**

Other specifications of the Infrastructure Rule further increase its value. Health plans must respond to real-time X12 278 PA requests within 20 seconds and indicate any additional information needed to make a determination when documentation requirements are referenced in published policy. This provision will increase the transparency of health plans' PA programs and minimize the time physicians and their staff spend searching for documentation requirements, which vary considerably across payers. The AMA also strongly supports the element of the rule that requires health plans to send a second, unsolicited X12 278 response with the final determination when an initial PA request is pended. We believe that this will push the industry to build an end-to-end automated PA process, as most pended PAs currently drop to manual workflows when practices are instructed to complete the process via phone, fax, or web portal. This

situation is reflected in the AMA's physician survey results, which show that phone and fax are still the most common methods for completing PAs. The PA Infrastructure Rule would improve practice efficiency and reduce administrative burdens by keeping the PA process in an automated workflow. **Because we expect that widespread implementation of the PA Infrastructure Rule will both improve patient care and reduce practice administrative burdens, the AMA urges NCVHS to recommend its federal adoption.**

Additional Considerations and Recommendations

While we believe the response time requirements in the PA Infrastructure Rule represent a necessary and long-overdue step toward reducing patient care delays, we ask NCVHS to recommend that these specifications be viewed as a "floor" for the industry, and that future operating rules more fully reflect the needs of patients. As stated in the Prior Authorization and Utilization Management Reform Principles, the AMA, our 16 original partner organizations, and the over 100 other organizations that have signed on as supporters of the document, believe that health plans should provide a final determination for nonurgent PAs within 48 hours of obtaining all necessary supporting documentation, with a shorter deadline of 24 hours for urgent PAs. We note that there is a very real difference between the 48 hours called for in our PA principles and the Infrastructure Rule's two business day requirement; it is easy to imagine "two business days" translating into nearly a calendar week for a PA submitted during a long holiday weekend. Health care is a 24/7 industry, and health plans should sufficiently staff and resource their PA programs to meet our 48-hour processing time policy. **We strongly urge health plans and their vendors to abide by the processing times outlined in our principles to avoid the dangerous care delays detailed in our physician survey results and described in the FixPriorAuth story gallery.**

We also remain extremely concerned that the Infrastructure Rule does not dictate a processing time requirement for urgent PAs. This is particularly troubling because the rule's response time specification for nonurgent PAs is measured in business days vs. hours; again, **health care is not a business that closes on weekends or holidays.** To prevent patient harm when a faster response is needed, any federal rulemaking should include a provision for urgent PAs. **The AMA urges NCVHS to recommend that a 24-hour response time requirement for urgent PAs be included in any federal rulemaking addressing X12 278 infrastructure requirements.**

Prior Authorization (278) Data Content Rule v5.0.0

Support for Rule Adoption

The AMA supports federal adoption of the PA Data Content rule due to the anticipated enhancements in PA-related transparency and communication. Physicians cite the opacity of PA requirements as one of the most frustrating and time-consuming aspects of this onerous process. In the AMA's survey, almost seven in 10 (67%) physicians report that it is difficult to determine whether a prescription drug or medical service requires PA, and this lack of transparency extends to the clinical documentation needed to make a determination.

The AMA believes that several elements of the PA Data Content Rule will improve transparency of health plan requirements and reduce practice burdens. First, the rule requires health plans to include either a PWK01 Code and/or a Logical Identifiers Names and Codes in an X12 278 pended response to indicate the clinical information needed to support a PA determination. While ideally this specification would apply across all medical service types and not just those detailed in the Data Content Rule, this provision will improve the transparency of PA documentation requirements and save physicians and staff the hassle of referring to insurer manuals, websites, or bulletins for this information. We also believe that other elements of the rule will improve communication regarding the PA process between health plans and practices. The rule requires health plans to include one or more Health Care Service Decision Reason

Code in the X12 278 response and that the code offer "the most comprehensive information back to the provider." In addition, the rule provides for consistent and uniform use of AAA error and action codes, which should minimize variability in messaging between payers and reduce confusion.

Additional Considerations and Recommendations
Although outside of the scope of the PA Data Content Rule for the X12 278, we must highlight another significant barrier to PA automation: the lack of standards for electronic clinical attachments. From numerous previous hearings on this topic, NCVHS surely understands that the lack of electronic standards for the exchange of supporting clinical data remains a rate-limiting step to widespread adoption of an electronic PA process. Although we see value in the PA Data Content Rule, we remain concerned that the lack of standards for attachments will limit the rule's ability to increase adoption of the X12 278. **The AMA urges NCVHS to reiterate its previous recommendations on the need for adoption of standards for electronic clinical data exchange between physician practices and health plans.**

Connectivity Rule 3.1.0

Support for Rule Adoption
The AMA supports federal adoption of the Connectivity Rule, as we believe it will enhance the interoperability, efficiency, and security of electronic health care transactions. We also acknowledge and reiterate that to have the desired impact, the rule must replace the current connectivity requirements in the federally mandated Eligibility, Claim Status, and Electronic Remittance Advice Infrastructure Operating Rules.

We support CAQH CORE's creation of a single set of connectivity requirements across transactions, as this reduces complexity and creates a single safe harbor for revenue cycle transmissions. In contrast, CAQH CORE's current connectivity requirements permit different safe harbors depending on transaction type, which is cumbersome and burdensome for the industry. By nature, connectivity methods underlie and facilitate the transmission of all transactions, regardless of the transaction content (i.e., they are "payload agnostic"). As such, efficiency is best served by a single set of connectivity requirements applicable across all electronic transactions.

Crucially, we also note that Connectivity Rule v3.1.0 makes necessary updates to the baseline security protocol established within the connectivity requirements of currently mandated operating rules. The vulnerable username + password option has been removed, and all trading partners must support the more secure X.509 Client Certificate-based authentication. These updates promote best practices in information technology security and protect industry systems from exposure associated with outdated authorization methods.

The AMA also sees value in adopting Connectivity Rule 3.1.0 as an intermediary "stepping stone" to a new, more comprehensive set of connectivity requirements currently under development by CAQH CORE. We are concerned that without a federally mandated "glide path" to the more advanced connectivity specifications expected for the future, vendors will not have sufficient motivation to voluntarily update their technologies. The end result will be a much larger—and undoubtedly costly—implementation lift for meeting the requirements of future iterations of the CAQH CORE Connectivity Rule. **The AMA requests that NCVHS recommend federal adoption of CAQH CORE's Connectivity Rule 3.1.0, as it is a necessary and logical step in preparing the industry for more sophisticated future requirements.**

Additional Considerations and Recommendations
While we support adoption of Connectivity Rule 3.1.0, we believe that future CAQH CORE connectivity rule development should also address system availability requirements, and that not doing so in this

iteration represents a serious omission. Like the other connectivity concepts outlined in the rule, system availability requirements should be consistent across electronic transactions and be grouped under a single connectivity umbrella, consistent with CAQH CORE's new approach to operating rule organization. Like the other topics addressed in the Connectivity Rule, system availability is "payload agnostic," having nothing to do with transaction content. Currently, system availability is addressed in CAQH CORE infrastructure rules for individual transactions, which obviously allows for potentially disparate requirements and serves as a barrier to improving system availability to better meet industry needs.

In addition, we note that current system availability requirements are inadequate. During the update of the PA Infrastructure Rule, the AMA strongly advocated that the X12 278 system availability requirement be increased from 86% to 95% to prevent patient care delays related to downtime/outages. Participants across stakeholder groups seemed generally supportive of this change but were unwilling to raise system availability requirements for a single transaction. We maintain that the current system availability requirement of 86%—**which allows for nearly 24 hours of downtime per week**—is wholly unacceptable, particularly for the 24/7 health care industry. The current CAQH CORE requirements seem particularly anemic when one considers that industries such as banking and finance deem anything less than 99.9% system availability as incompatible with supporting vital business functions. In our industry's "business" of human health, it is a huge disservice to all stakeholders and, more importantly, patients to tolerate such low system availability expectations. **The AMA urges NCVHS to recommend that any future connectivity operating rules (1) include system availability requirements that apply across all electronic transactions and (2) require at least 95% system availability.**

Conclusion

The AMA thanks NCVHS for the opportunity to present our feedback on the adoption of the PA Infrastructure and Data Content Rules and Connectivity Rule 3.1.0. **We urge NCVHS to recommend federal adoption of all three operating rules because we believe that they will meaningfully improve both patient care and physician practice efficiency. We further encourage NCVHS to include our other suggestions in its formal recommendations to ensure that the full value of the operating rules can be realized across the health care industry.** We look forward to continuing to work with NCVHS and all industry stakeholders in identifying and implementing innovative ways to improve the efficiency of health care in our country. If you would like to further discuss our comments, please contact Heather McComas, Director, Administrative Simplification Initiatives, at heather.mccomas@ama-assn.org.

Christol Green
Portfolio Manager, E-Solutions
Anthem, Inc.
(303) 435-6195

Submitted electronically to NCVHSmail@cdc.gov

August 21, 2020

National Committee on Vital and Health Statistics (NCVHS)
Hearing of the Subcommittee on Standards
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, Rm 505A
Washington, DC 20201

Good Afternoon Members of the NCVHS Board,

Thank you for the opportunity to provide testimony on behalf of Anthem, Inc. regarding our perspective on the Council for Affordable Quality Healthcare Committee on Operating Rules for Information Exchange (CAQH CORE) Prior Authorization rules. Anthem's experience serving more than 79 million people, including 41 million within its family of health plans, provides a vital perspective to consider when discussing how to improve the prior authorization process to reduce administrative burden and ensure patients receive appropriate care.

My name is Christol Green, and I support Anthem's electronic data exchange as a Clinical/Medical Records Portfolio Manager within the E-Solutions Division. I have over 30 years of extensive healthcare experience, including implementing and integrating healthcare electronic transactions and working with our industry to drive and deliver new interoperable technologies.

Overview of Anthem's Efforts to Improve the Prior Authorization Process

Prior authorization is a tool used by private and public health plans to ensure care being provided to patients is safe, effective, and consistent with medical evidence. The importance of prior authorization is supported in studies that indicate 15-30 percent of care in the U.S. is unnecessary, and prior authorization works by requiring a provider to request approval of coverage before delivering certain treatments or services. The prior authorization process plays a critical role in patient safety and protection by ensuring that the care being authorized aligns with the latest evidence-based medical research and ensuring that the patient's service is covered. Recognizing the important role prior authorization plays in driving high-value care across healthcare programs, Anthem regularly updates our processes and criteria to recognize emerging evidence and new technologies. Anthem is also continuously modernizing, improving and, when appropriate, removing prior authorization requirements for certain services, to reduce administrative costs and burdens and deliver on our mission of simplifying healthcare. While it is important to recognize that the submission of a prior authorization request does take time on the part of a provider, it is equally important to acknowledge that when

providers send all of the necessary medical information on the initial request, approvals are communicated quickly and efficiently.

Prior authorization promotes evidence-based care, reducing unnecessary services, and improving care management and coordination. Anthem's prior authorization processes promote safe and effective care for patients by helping to ensure that the choice of drugs, medical procedures, treatments, and services provided to patients are founded on the latest evidence-based, peer-reviewed literature and guidelines before they are provided.

Anthem's prior authorization processes help to ensure patients do not receive unnecessary tests and treatments (based on the latest medical evidence), particularly early in the diagnostic process for a condition. The benefits of reduction include reducing potential out-of-pocket costs for the patient and not over treating a patient, which can be harmful. Additionally, Anthem's prior authorization efforts promote information sharing from the provider to the health plan, which improves opportunities for the health plan to improve care management and coordination.

Recognizing the importance of improving the prior authorization process, Anthem continually works to ensure that our prior authorization process improves quality, is automated and as timely as possible, is informed by credible scientific evidence, and is responsive to care providers' feedback. Examples of our efforts to improve the overall care provider experience with prior authorization include the following:

- Launched an innovative provider-facing Utilization Management portal, known as the Interactive Care Reviewer (ICR), which allows providers to submit electronic prior authorization requests to Anthem 24 hours a day as well as track the status of authorizations without having to pick up a phone or fax in any information;
- Reviews its prior authorization requirements at least twice a year to ensure they are based on current clinical evidence and to identify any services or treatments with high approval rates to determine if a prior authorization requirement should be removed;
- Anthem has begun to leverage the use of analytics using stored member, care provider, and clinical data to drive automation in the prior authorization review process; and,
- Anthem is exploring opportunities to integrate electronic medical record data into prior authorization systems to improve precision and speed of prior authorization.

Anthem is also working with our provider partners to streamline prior authorization requirements when providers are in value-based contracts and taking on risk. The Prior Auth Pass pilot program is based on the provider groups' commitment to creating processes and strong internal controls for managing care and appropriate use of services. When providers are taking on risk, such as in a value-based payment arrangement, incentives to effectively manage wasteful or duplicative services are better aligned.

The Prior Auth Pass pilot program with the Cleveland Clinic (Ohio), TriHealth (Ohio), and the South Bend Clinic (Indiana), utilizes a simplified prior authorization process for many common medical procedures done in an outpatient setting. Specifically, the program's goal is to reduce administrative burden for high-performing practices by removing authorization requirements for a subset of outpatient

procedures for these select practices who have a proven track record of approvals. It is imperative that health plans retain the flexibility to test new and innovative models, such as Prior Auth Pass, rather than trying to add standards to outdated technology.

Anthem also participates in emerging technology initiatives with Health Level Seven International (HL7), Da Vinci project, and the U.S. Department of Health and Human Services' Office of the National Coordinator for Health Information Technology to support the use of Fast Healthcare Interoperability Resources (FHIR). This enables providers, at the point of service, to request authorization by providing all necessary clinical information to support the request and receive immediate authorization. Anthem is also engaged with our provider community with the X12 278 transaction requests.

Recommendations on the CAQH CORE Prior Authorization Rules

Anthem supports the comments detailed by our trade organizations, America's Health Insurance Plans and the Blue Cross Blue Shield Association, and stresses the importance of addressing their detailed concerns prior to moving forward with any mandate.

Anthem has long been an early adopter of CAQH rules and we continue to work and participate with CAQH CORE and Standard Development Organizations (SDOs) to improve the prior authorization process. While we applaud the intent of the rules, we caution that with moving forward without addressing concerns related to connectivity, data content, and infrastructure, and allowing appropriate time for implementation, the value of prior authorization will be diminished and potentially more administratively burdensome.

As NCVHS considers these rules, we caution against adding standards to an already outdated process. Rather than trying to fix the outdated current standard process with the addition of new regulations, we urge NCVHS to look towards emerging technology (such as HL7 Da Vinci) adoption process that will and can be enhanced on a timely continuous basis, bringing all stakeholders along at the same time built upon standards that are designed to support more innovative processes.

Specifically, we recommend that all stakeholders, regardless of size, move to new rules at the same time. This will ease burdens around maintaining multiple platforms to accommodate various entities who may be behind in implementation. We suggest at least 24 months for implementation after the concerns/comments are addressed in the rules to allow for sufficient time for all stakeholders to adopt and implement the new rules.

When evaluating the rules, we have concerns with the safe harbor provisions that would allow providers to elect a different connectivity methodology resulting in health plans having to maintain multiple methods. Anthem recommends that the Connectivity rule only be adopted if it is adopted across all transactions for which operating rules are in place. We have concerns that there would be the requirement to implement and support regardless of usage or solutions currently in place.

Additionally, we recommend addressing inconsistencies in the data content rule provisions to allow a dependent patient with a unique member ID to be sent as the subscriber, as allowed in the 278

Technical Report Type 3, and harmonize requirements between the patient level and service level data categories.

For X12 278 prior authorization transactions to be effective, the ability to request and receive supporting documentation electronically is critical for workflow. The lack of adoption of attachment regulations leaves the industry with an incomplete authorization process. Furthermore, healthcare systems are at varying stages of adoption of this technical workflow and, as such, some payers and providers will need to manually request and submit supporting documentation as needed follow-up for the submitted X12 728. Data content/operating rules do not address turnaround times for current business processes that cannot be conducted electronically end-to-end. We support affording flexibility to use newer business technologies such as FHIR or Extensible Markup Language (XML) via a web portal, which would allow for more efficient communication exchange between the clinical staff and the health plan.

The ownership of data content requirements and usage is the sole responsibility of the SDO and not the Operating Rule Authoring Entity (ORAE). Rules regarding data content should be communicated via the data specifications and Implementation Guides (IGs) created from the industry approved SDO process. In addition, Health Insurance Portability and Accountability Act (HIPAA) Security and Health Information Technology for Economic and Clinical Health Act (HITECH) Rules cite the National Institute of Standards and Technology (NIST) as the authoritative industry source, not the ORAE. Data content and connectivity rules should be consistent with current standards since rules created outside of and divorced from SDO IGs and NIST standards and specifications create confusion and disparity in healthcare Electronic Data Interchange (EDI) standards deployment.

Finally, current web portal operating rules, such as the CAQH CORE Prior Authorization & Referrals Web Portal Rule vPA.1.0, discourage adoption of HIPAA Electronic Transaction Standards and can be burdensome and costly to providers. Web portal operating rules addressing payer portals should align with the goals and requirements of HIPAA administrative simplification provisions.

Conclusion

Thank you for the opportunity to share Anthem's comments on CAQH CORE Prior Authorization rules that are under consideration. We look forward to our continued work with NCVHS and other stakeholders to improve the prior authorization process. Should you have any questions or wish to discuss our comments, please contact Alison Armstrong at Alison.Armstrong@anthem.com or (805) 336-5072.

Sincerely,

Christol Green
Portfolio Manager, E-Solutions

July 24, 2020

William W. Stead, MD
Chair
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: CAQH CORE Operating Rules Proposed to NCVHS – 2020

Submitted electronically to NCVHSmail@cdc.gov

Dear Dr. Stead,

Thank you for the opportunity to provide feedback on the CAQH Committee on Operating Rules for Information Exchange (CORE) Proposal to the National Committee on Vital and Health Statistics (NCVHS). athenahealth fully supports the proposal and recommends the three CAQH CORE Operating Rules to the Department of Health and Human Services (HHS) for federal adoption under HIPAA.

Over the past twenty-two years, athenahealth has built a network of over 160,000 providers in both the ambulatory and acute settings. We provide electronic health record ("EHR"), practice management, care coordination, patient engagement, data analytics, revenue cycle management, and related services to physician practices and hospitals. More than 120,000 of our clinicians utilize our single instance, continuously updated, cloud-based platform. Since announcing a combination with Virence Health in early 2019, we also support on-premise software solutions. In both hosting paradigms, athenahealth seeks out and establishes connections with partners across the care continuum, enabling our clinicians to improve the quality of care they deliver. Interoperability is part of the athenahealth DNA and we integrate with more than 1,800 insurance payers, 122,000 lab and imaging centers, and 75,000 pharmacies in the U.S.

Our mission is to create a thriving ecosystem that delivers accessible, high-quality, and sustainable healthcare for all. We regularly receive feedback from our physician customers, payers, and internal teams that the prior authorization process is overly burdensome and unnecessarily costly for the entire industry. Among other benefits, standardizing the data shared between plans and providers will increase efficiency and allow providers to prioritize patient care over administrative tasks. We believe the three proposed CAQH CORE operating rules will reduce unnecessary and duplicative tasks across stakeholders and move the industry forward towards a more connected, thriving ecosystem.

Over 125 organizations from across healthcare, including athenahealth, contributed to the proposals in an iterative, bottom up, approach. The prior authorization process has lagged

significantly behind technology solutions in other corners of healthcare. Timely adoption of these operating rules will raise the bar across the industry and encourage technology vendors to build more robust solutions alongside their provider customers. athenahealth is convinced that industry led initiatives, such as the work from CAQH CORE, help establish a strong foundation for healthcare transactions from which innovation can flourish.

We also encourage NCVHS to continue to work as a convener and collaborator with industry leaders that are improving healthcare delivery in real time. It is critical that HHS and other Government stakeholders embrace an iterative approach to innovation that enables market participants to collaborate towards their shared goals of increased information flow and a reduction in administrative work for all parties. The improvement of these back-end processes can enable a wave of innovation to tackle other problems in healthcare, such as provider burnout and cost.

We look forward to continuing to partner with your team and please do not hesitate to reach out with questions.

Sincerely,

Paul Brient
SVP, Chief Product Officer
athenahealth

From:	Turney, Amy
To:	NCVHS Mail (CDC)
Cc:	McCorquodale, Kathleen; Money, Jill; Monarch, Cynthia; Brideau, Wanda
Subject:	NCVHS Request for Public Comments on Proposed Rules
Date:	Friday, July 17, 2020 11:27:24 AM
Attachments:	NCVHS RPC-PA Op Rules_Blue Cross Blue Shield of Michigan.docx

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Good Morning,
Please find attached Blue Cross Blue Shield of Michigan's response to the NCVHS Request for Public Comment on Three CASH CORE Operating Rules. Please let me know if you have any questions. Thank you.

Amy M. Turney
Business Analyst III
e-BIG EDI Business
1-248-486-2448

NCVHS Request for Public Comment on
Three CAQH CORE Proposed Operating Rules:

For each comment, please indicate the operating rule to which it refers, i.e., Prior Authorization Data Content Rule, Prior Authorization Infrastructure Rule, or Connectivity Rule. For general comments, please note this in your statement as well. Comments must be received no later than July 24, 2020.

- Prior Authorization (278) Data Content Rule v5.0.0 (finalized April 2019)
- Prior Authorization (278) Infrastructure Rule v4.1.0 (finalized September 2015)
- Connectivity Rule 4.0.0 (finalized September 2015)

1. **Participation in development of the rules:** If your organization participated in identification and development of the proposed operating rules for prior authorization and/or connectivity, describe the skill set of the individuals involved (business or technical) and in what way they participated in the process.

   BCBSM Comments:
   Blue Cross Blue Shield of Michigan (BCBSM) participated in the CAQH CORE Prior Authorization Subgroup, the CAQH CORE Rules Work Group, and the CAQH CORE Connectivity Subgroup. The development of these Operating Rule requirements involved a coordinated review effort with business and IT individuals from our EDI and Utilization Management areas.

2. **Workflow (prior authorization rules)**: In what way(s) will the proposed operating rules for prior authorization improve workflow for your organization's industry sector? Discuss the prior authorization data content and infrastructure rules and describe how the proposed requirements from each will impact your workflow, reduce burden (if relevant) and better support patient care.

   BCBSM Comments:
   The proposed Prior Authorization rules support implementation of an automated response process for non-emergency and non-urgent prior authorization requests. The requirements support an automated workflow for pending a request due to the need for additional documentation as well as a returning a response regarding why an initial 278 request could not be successfully processed. We do recognize the potential for these to enhance the use of the 278 transaction standard and the potential to better support patient care. While time does not permit us to do an in depth impact analysis, we know these requirements will necessitate our development of new workflows to support them. Additionally, our ability to attain these benefits has great dependency on our health care providers/trading partners increasing their use of the mandated 278 transaction standard and, at this time, we do not know if the adoption of these will result in an increased use.

3. **Transaction exchange (connectivity rule):** In what way(s) will the proposed operating rule for connectivity improve the processing of transactions, message payload, connectivity, security, etc. if adopted by HHS? What are the anticipated benefits that this operating rule offers vs. the current state (please provide examples if possible)?

BCBSM Comments:

BCBSM agrees that the CAQH CORE Connectivity Rule 4.0.0 would provide benefits for all mandated transactions through enablement of newer technologies that support greater data privacy and security protocols. Additionally, we agree applying it for use with all mandated standards will support a consistent base/minimum communication method for the exchange of all administrative health care data.

4. **Improving use of transactions and/or adoption of standards (all proposed operating rules):** Describe how adopting the proposed operating rules will or could increase in the use of any of the adopted HIPAA transaction standards.

BCBSM Comments:

We agree these Operating Rules are a component to further enhancing the electronic exchange of administrative health care data. The Prior Authorization rules will provide consistency in the business and technical workflow and the Connectivity Rule enables the use of newer technologies that enhance privacy and security of the exchange. It is possible they could result in an increase of the real-time prior authorization (278) transaction standards but may minimally (or not at all) impact the exchange of batch transaction standards. The unknown is whether those entities that currently do not use the 278 transaction standard as well as those that are accustomed to using SFTP for batch standards would invest in updating their systems to enable the use of these Operating Rules.

5. **Connectivity rule implementation for your organization or industry wide (please specify)**:
   a. What are the implications, costs and benefits of implementing the new connectivity rule requirements (Rule 4.0.0) for the claims, prior authorization, premium payment and enrollment/disenrollment transactions? Providing generalized or high level information will be helpful to the Committee.

      BCBSM Comments:

      Unable to provide information at this time.

   b. Can you provide general types of costs and benefits of meeting the processing mode requirements for both real time and batch submissions?

      BCBSM Comments:

      Unable to provide information at this time.

6. **Implementation time frame for each proposed rule:**
   a. What is the anticipated lead time needed by your organization to develop, test and implement the proposed operating rules? What are the dependencies that impact the timeline, e.g., vendors, trading partners and business associates? If possible, please provide an estimate of the amount of time your vendors would require to develop their component of the solution?

      BCBSM Comments:

The Prior Authorization and Connectivity Rules will impact all health care stakeholders and require coordination amongst trading partners to ensure successful implementation. Due to the complexity and the low use of the 278 in the industry a compliance timeframe of 24 months would better serve this implementation. We recommend there be strong encouragement for trading partner testing prior to the compliance date to ensure successful industry implementation by the compliance date.

b. Should considerations be given to size or organization type for the proposed implementation timeframe? Please discuss for each of the proposed operating rules (Prior authorization content, prior authorization infrastructure and connectivity).

BCBSM Comments:

We do not recommend different timeframes for compliance based on an organizations size or type for any of these proposed Operating Rules. Doing so results in larger stakeholders having to maintain multiple processes in order to continue doing business with all of their trading partners. This increases cost and impacts return on investment.

7. **Costs (Prior Authorization rules)**: Is your organization able to provide an estimate of the implementation cost for the requirements of the two prior authorization operating rules for data content and infrastructure? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting these rules?

BCBSM Comments:

We are not able to provide an estimate of implementation cost at this time. We recognize there is a potential risk that a low percentage of health care providers will increase their use of the 278 transaction standard which will impact achieving the overall benefits. We recommend that the cost benefit determination include an analysis regarding health care providers not currently using the mandated 278 and their likelihood to use the 278 transaction standard (whether direct via their vendor or via a clearinghouse) should these rules be adopted.

8. **Costs (Connectivity rule)**: Is your organization able to provide an estimate of the implementation cost for the requirements of the connectivity operating rule? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting this rule and its requirements?

BCBSM Comments:

We are not able to provide an estimate of implementation cost at this time. With regards to the cost benefit determination, NCVHS and HHS should include consideration for the industry's present connection methods as they relate to the use of real-time standards versus batch standards. BCBSM chose to support the use of HTTPS digital certificates for the exchange of the real-time eligibility (270/271), real-time claim status (276/277), and the batch electronic remittance advice (835). All of our trading partners (i.e., 100%) that have requested the electronic exchange the 270/271 and 276/277 use this method for real-time exchange. Even though it is offered (and has been since January of 2014) we do not have any trading partners that use this connectivity method for batch electronic remittance advice. SFTP continues to be the preferred choice for batch. Based on this it is possible that adopting the CORE Connectivity Rule 4.0.0 would further support the real-time exchange of the prior authorization (278) standard but may minimally (or not at all) impact the exchange of batch standards. The cost benefit determination should take this into consideration.

9. **Additional comments:** Given that the Connectivity Rule is highly technical, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?

BCBSM Comments:

Mandating use of the Connectivity Rule for all mandated transaction standards will require a health plan to implement changes in order to support a health care provider's request. However, health care providers may elect to not change to the new connectivity method. A health plan can work with their trading partners to reduce use of SFTP (i.e., promote use of the newer connectivity method) but this adds additional cost and time and impacts ROI. Should NCVHS recommend adoption to HHS, we believe it would be beneficial to include recommendations to support industry education on the benefits of using the CORE Connectivity Rule 4.0.0.

10. **Additional comments:** For the Prior Authorization operating rules, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?

BCBSM Comments:

We ask that NCVHS consider the following in their deliberation of moving the Prior Authorization rules forward for adoption:

- The lack of a mandate for electronic attachments. Prior authorizations typically need clinical data support (i.e., clinical documentation). The mandated 278 response does support electronically communicating the type of clinical documentation needed but the industry is not yet in a position to support an electronic response (i.e., completion of the electronic workflow).
- The Prior Authorization rules include a requirement to use the X12C Health Care Insurance (999) standard for acknowledgment of a batch transaction standard or, in certain instances, for rejection of a real-time transaction standard. Until there is a mandate requiring use of the 999, we anticipate this requirement would be excluded in a mandate. In the past, having the mandate exclude this while the verbiage of the Operating Rule requires it has caused some confusion among trading partners. If NCVHS does decide to move this request forward for adoption, we ask NCVHS to again request for the adoption of electronic acknowledgment standards.

11. **General**: For each rule, please provide the rationale for your support or opposition to its adoption to inform the Committee's deliberations.

BCBSM Comments:

BCBS of Michigan supports all of these Operating Rules as there is potential to enhance the use of the mandated electronic transaction standards, particularly the 278; however, we want to reiterate that due to complexity, the low use of the 278, and the industry use of SFTP for batch standards a compliance timeframe of 24 months would better serve this implementation.

July 24, 2020

William Stead, MD
Chair, National Committee on Vital and Health Statistics
c/o Rebecca Hines
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782

Submitted electronically via NCVHSmail@cdc.gov

RE: Request for Public Comment on Three CAQH CORE Proposed Operating Rules

Dear Dr. Stead,

Blue Cross and Blue Shield of North Carolina ("Blue Cross NC") writes to comment on the three proposed operating rules developed by the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE). Specifically, the National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards, is considering the following three operating rules for federal adoption: Prior Authorization (278) Data Content Rule, Prior Authorization (278) Infrastructure Rule, and Connectivity Rule. We offer our support for adoption of the three rules. Blue Cross NC is committed to affordability and access to health care for North Carolinians. Adoption of rules like these improve the care experience for many groups touched by the health care system, including patients, providers and payers, by reducing burden and speeding up administrative processes between payers and providers.

The workflow improvements established by these rules support Blue Cross NC's goal of promoting value-based care. By encouraging electronic-based data exchange for prior authorization, we can reduce the administrative burden on payers, providers and patients. The rules allow providers to bypass phone or fax-based methods to facilitate authorizations, enable greater automation of payer systems and operations at a lower operating expense, and allow patients to receive their care in a more streamlined and timely way. In value-based care arrangements, automation of prior authorization enables more consistent, straightforward and timely population management than exists today, and will contribute to reducing total cost of care for members and patients.

Below are responses to NCVHS questions for consideration:

1. **Participation in development of the rules: If your organization participated in identification and development of the proposed operating rules for prior authorization and/or connectivity, describe the skill set of the individuals involved (business or technical) and in what way they participated in the process.**

   Blue Cross NC's involvement in the development of the rules had executive-level business support across the Information Technology and Health Care divisions, as well as technical leadership support in IT when commenting on and developing these new rules.

2. **Workflow (prior authorization rules): In what way(s) will the proposed operating rules for prior authorization improve workflow for your organization's industry sector? Discuss the prior authorization data content and infrastructure rules and describe how the proposed**

requirements from each will impact your workflow, reduce burden (if relevant) and better support patient care.

Providers utilizing this 278 prior authorization transaction will allow our systems (and corresponding automation represented by those systems) to handle prior authorization request volumes that still have large reliance on fax and phone requests, thus allowing our staff to focus on true care management as opposed to more time-consuming and labor-intensive manual processes represented by fax and phone. Additionally, system-to-system data exchange will remove keystroke error opportunities which are intrinsic in the process of manually rekeying information when received via phone and fax, thus lowering rework for those instances. These rules also help to establish a baseline of expectations on system availability and responsiveness which providers can then use to help further enable staff flexibility for performing these activities, and more rapidly respond to requests for further information thus streamlining the administrative turnaround time in this regard which should lead to increase customer (patient) satisfaction in the form of reduced wait times for authorization of procedures.

4. **Improving use of transactions and/or adoption of standards (all proposed operating rules): Describe how adopting the proposed operating rules will or could increase in the use of any of the adopted HIPAA transaction standards.**

   Historically, the prior authorization (278) transaction has been on the (far) lower end of the provider and payer adoption of the HIPAA transaction set. We believe that a lack of uniformity in connectivity, system availability, and content expectations have contributed to this lower rate of adoption. By standardizing those baseline requirements, provider health system vendors will be able to create uniform products which will enable providers to exchange these requests in a uniform manner across payers in a repeatable fashion, rather than a point-to-point integration model which is largely the reality of these integrations today. By removing these barriers to adoption and by setting these common requirements we expect to see enhanced transaction volume from providers as a result.

5. **Connectivity rule implementation for your organization or industry wide (please specify):**

   a. **What are the implications, costs and benefits of implementing the new connectivity rule requirements (Rule 4.0.0) for the claims, prior authorization, premium payment and enrollment/disenrollment transactions? Providing generalized or high-level information will be helpful to the Committee.**

      Further adoption of the connectivity rules across the claims, prior authorization, premium payment and enrollment/disenrollment transactions will allow vendors to build products which could connect to any payer through configuration as opposed to the current point-to-point custom integration model represented in today's world. The more uniform we can expect to send and receive these transactions, the more that software vendors can build products which could connect to many payers and remove costly transactional middlemen from the exchange of data. If the method of connectivity becomes ubiquitous and common across payers, we could expect administrative cost savings across stakeholders as a result.

   b. **Can you provide general types of costs and benefits of meeting the processing mode requirements for both real time and batch submissions?**

      Although the implementation of both batch and real time processing modes does represent some additional development costs, the additional value of providing the data in the manner which best suits the customer offsets the additional costs by reducing barriers to usage and

facilitating the system to system exchange of that information which in turn streamlines information flow and reduces the need for human interaction and intervention.

11. **General: For each rule, please provide the rationale for your support or opposition to its adoption to inform the Committee's deliberations.**

    Blue Cross NC supports the aforementioned CAQH rules on prior authorization as written and looks forward to working with our providers on reducing administrative expense, facilitating interoperability, and streamlining the interaction between providers and payers through the adoption of these operating rules.

We appreciate the opportunity to provide these comments and to continue serving the health care needs of individuals and families in the State of North Carolina. If you have any questions regarding our comments, please feel free to contact us.

Sincerely,

Troy Smith
Vice President
Health Care Strategy and Payment Transformation
BlueCross BlueShield of North Carolina

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

COMMENTS

to the

NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS

SUBCOMMITTEE ON STANDARDS

for the

Review of the CAQH® CORE Operating Rules for Federal Adoption

The Blue Cross Blue Shield Association (BCBSA) is a national federation of 36 independent, community-based and locally operated Blue Cross and Blue Shield companies (Plans) that collectively provide healthcare coverage for one in three Americans. For more than 90 years, Blue Cross and Blue Shield companies have offered quality healthcare coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid.

On behalf of BCBSA and the Plans, we would like to thank you for the opportunity to respond to the Subcommittee on Standards' questions and provide our perspective on the proposed operating rules for the prior authorization transaction. We continue to strongly support the goals of HIPAA Administrative Simplification to promote efficiency and reduce the costs of administrative transactions.

Blue Plans vary widely in size, markets and geography. However, despite these differences, Plans report little variation in experience for a particular transaction: the challenges and barriers to adoption of that transaction by trading partners, and the overall adoption rate of mandated standards, are fairly consistent across the Plans. Therefore, our responses to the Subcommittee's questions are applicable to Blue Plans generally.

Before responding to the Subcommittee's questions, we wish to briefly address the following overarching points:

- We continue to uphold the adoption of operating rules that support the implementation of standards, not to supplement what is already defined by the standards organizations -- operating rules should replace neither their front matter nor conflict with general usage information contained in the implementation guides.

- The CAQH CORE Prior Authorization and Connectivity Operating Rules appropriately focus on infrastructure requirements, meeting the objective of business rules, which are "the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specification." However, the final published versions still raise a few concerns related to potential cost and business impacts that merit continued consideration by the NCVHS.

- We suggest that any information technology (IT) requirements, including these operating rules, must be considered in the context of the broader environment of mandates and requirements with significant IT implications, including the interoperability rules.

The proposed Prior Authorization and Connectivity Operating Rules do address the exchange of transactions and connectivity between trading partners. Plans indicate that the operating rules in general are likely to increase the reliability and performance of data exchange without affecting the data content

of the standard. Plans have identified, however, concerns that these operating rules are likely to add to administrative costs for both Plans and their providers. Plans anticipate that the connectivity provisions, which limit submitter authentication to a single method of digital certificates, will be costly to implement with little return on investment. The total costs to implement will vary depending on the submitter authentication methods Plans have implemented currently. Most providers continue to opt for the login/password option from earlier phases of operating rules. The version C3.1.0 connectivity rule safe harbor provisions allow providers to continue to use other methods even when Plans must implement digital certificates to be in compliance. Plans are then faced with using contracts or participation agreements to move providers towards the newer method. Providers choosing to move to this methodology for some or all transactions will need system changes also. Maintaining multiple methods as they vary across Operating Rule Phases creates additional system impacts for all trading partners.

Plans also expressed concerns that the security protocols named within the connectivity rule are outdated and considered insecure. We suggest that further, broader research on the timing and costs associated with all stakeholders moving to a more secure methodology for all transactions, needs conducted. While this is ultimately preferable to better address security concerns, it is essential that such a move is orchestrated across all standards and all trading partners rather than applying to some of the parties and a few transactions.

Plans continue to face a multitude of health information technology imperatives, both from federal mandates and programs as well as from their own strategic goals. Plans indicate that implementing administrative simplification standards requires time and resources that are incommensurate with the business value achieved (in part, because business partners are not required to use the standards, and sometimes interpret standards differently). To free up resources while accelerating other standards/specifications, which enable greater interoperability and the exchange of clinical data, the timing of any adoption of additional provisions of administrative simplification must be done with consideration to the timing of other regulatory requirements

We will now address the specific questions posed by the Subcommittee.

1. **Participation in development of the rules:** If your organization participated in identification and development of the proposed operating rules for prior authorization and/or connectivity, describe the skill set of the individuals involved (business or technical) and in what way they participated in the process.

   BCBSA participated in the subgroups where the operating rules were developed as schedules accommodated participation. Our representative comes from a business background but also has technical knowledge about the prior authorization standard as well as the operational impacts of processing prior authorizations. Several Plans have representatives with various business and technical expertise within the subgroups as well.

2. **Workflow (prior authorization rules):** In what way(s) will the proposed operating rules for prior authorization improve workflow for your organization's industry sector? Discuss the prior authorization data content and infrastructure rules and describe how the proposed requirements from each will impact your workflow, reduce burden (if relevant) and better support patient care.

   Plan feedback indicated that the operating rules as currently published are not likely to add any value to current workflows. For some Plans, current automation of prior authorizations, in which final determinations are able to be returned to provider today, would need to be reverted back to previous pending of the request in order to meet the timeframes in the infrastructure rule. It is unclear if the automated systems can be revamped to meet a 20-second round trip real-time requirement. Due to the complexity involved with the processing of prior authorizations, often involving multiple backend systems or the need to "converse" back and forth more than once, the 20-second time requirement is unrealistic.

   Plans also indicated that in the batch environment, the one-hour response time requirement for a 999 might not be achievable depending on transaction volumes and processing queues.

   While we absolutely support improving the prior authorization processes, we would suggest that real world testing to document realistic and achievable timeframes is warranted.

3. **Transaction exchange (connectivity rule):** In what way(s) will the proposed operating rule for connectivity improve the processing of transactions, message payload, connectivity, security, etc. if adopted by HHS? What are the anticipated benefits that this operating rule offers vs. the current state (please provide examples if possible)?

   BCBSA and the Plans do not believe the connectivity rule will improve the processing or exchange of prior authorizations. Implementing these rules while also having to maintain prior connectivity methods due to the safe harbor provisions adds overhead and investment with little return. Coupled with the concern that the security protocols contained within the rule are considered outdated protocols, a requirement to implement these protocols is concerning given that the data being exchanged is protected health information (PHI).

4. **Improving use of transactions and/or adoption of standards (all proposed operating rules):** Describe how adopting the proposed operating rules will or could increase in the use of any of the adopted HIPAA transaction standards.

   Plans do not believe adoption of these operating rules will increase the adoption of the 278 prior authorization transaction. Plans still report much lower volumes of 278 transactions from providers and the value proposition for implementation is very low. The barriers to adoption continue to include the complexity of the transaction and the lack of an attachment standard. Prior authorizations often require a more conversational approach to exchanging information between the provider and the

health plan. Initial requests may prompt follow-up "questions" which are not as readily exchanged in an EDI environment, especially when providers use a batch approach. Even when providers use a real-time approach, Plans found that some inquiries required responses that were not processable for approval in an automated real-time fashion, due to the need for manual medical review. While a real-time prior authorization can be a little more conversational, Plans indicate their providers find having that exchange through a web portal more convenient to their office workflows. The 278 has greater clinical data content and necessitates greater involvement by clinical staff than administrative staff to see greater benefit. Flexibility to use newer business technologies to exchange information, e.g. FHIR or XML via a web portal, would accommodate the need for a more iterative process for authorizations as there is often the need for additional questions and follow-up, i.e. an ongoing exchange between the clinical staff and the health plan. This would enable the focus of EDI resources on other transactions with much heavier use by providers. Plans also indicated they believe that adoption rates might increase when the health claim attachment standard is adopted.

5. Connectivity rule implementation for your organization or industry wide (please specify):

a. What are the implications, costs and benefits of implementing the new connectivity rule requirements for the prior authorization, eligibility & benefits, claim status and electronic remittance advice transactions? Providing generalized or high-level information will be helpful to the Committee.

   Plans indicate that the cost to implement the connectivity requirements as significant, with little return due to the safe harbor provisions and the need to maintain all current connectivity methods simultaneously. Plans are unable to provide detailed estimates without in depth analyses but indicated it could mirror prior implementations of operating rules for the eligibility transaction, including data content and infrastructure along with the connectivity requirements at that time.

b. Can you provide general types of costs and benefits of meeting the processing mode requirements for both real time and batch submissions?

   Plans did not indicate there was any difference in the impacts for real-time vs. batch from a connectivity perspective.

6. Implementation time frame for each proposed rule:

a. What is the anticipated lead time needed by your organization to develop, test and implement the proposed operating rules? What are the dependencies that impact the timeline, e.g., vendors, trading partners and business associates? If possible, please provide an estimate of the amount of time your vendors would require to develop their component of the solution?

BCBSA and the Plans see 24 months as the time needed to implement any data content, infrastructure and connectivity requirement. Prior authorization processes include multiple backend systems, which requires extensive gap analysis and review. Information technology projects are scoped out 18-24 months in advance in terms of release schedules and with a greater magnitude of systems, the longer timeframe is critical

b. Should considerations be given to size or organization type for the proposed implementation timeframe? Please discuss for each of the proposed operating rules (Prior authorization content, prior authorization infrastructure and connectivity).

We recommend that any requirement be applied at the same time to all covered entities. Staggering implementation by size or organization type creates additional burdens on entities exchanging transactions with trading partners that have different implementation timeframe requirements.

7. **Costs (Prior Authorization rules):** Is your organization able to provide an estimate of the implementation cost for the requirements of the two prior authorization operating rules for data content and infrastructure? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting these rules?

Plans are not able to provide detailed cost estimates at this time, but as indicated earlier, it can potentially be equivalent to the full implementation of data content, infrastructure and connectivity rules for the eligibility transaction. We can say that it is likely to be in the millions of dollars for implementers, and costs vary above that based on systems involved and connection points, etc.

It is difficult to suggest ways to determine cost benefits without going through detailed project planning, analysis and review. Any cost benefit analysis, however, must include all covered entity stakeholders.

8. **Costs (Connectivity rule):** Is your organization able to provide an estimate of the implementation cost for the requirements of the connectivity operating rule? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting this rule and its requirements?

   Plans are not able to provide detailed cost estimates at this time, but indicated the connectivity rule alone would be a significant cost in and of itself.

   It is difficult to suggest ways to determine cost benefits without going through detailed project planning, analysis and review. Any cost benefit analysis, however, must include all covered entity stakeholders.

9. **Additional comments:** Given that the Connectivity Rule is highly technical, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?

   We would look for a connectivity rule to be explicit as to the transactions it applies to, move all trading partners to the same methodology without safe harbor provisions and utilize current security protocols.

10. **Additional comments:** For the Prior Authorization operating rules, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?

    BCBSA and the Plans have concerns that there are some conflicts within the data content rule with the 278 Technical Report Type 3 (TR3). Section 4.2.2.1 requires returning a request from an out-of-network provider with the AAA request validation segment, which is defined in the TR3 for use when the request is invalid. A request for prior authorization from an out-of-network provider is not invalid. A member's benefits may require a prior authorization for a particular service, regardless of the network status of the provider involved.

    Also, many Plans issue unique member identifiers to dependents and therefore in transactions, including eligibility, claims and prior authorizations, the information on these members are sent within the subscriber loops. This is identified in Section 1.12.2 of the 278 TR3. Section 4.1.1 of the data content operating rule, however, requires sending information on both the subscriber and the dependent when the patient is a dependent.

11. **General:** For each rule, please provide the rationale for your support or opposition to its adoption to inform the Committee's deliberations.

    For the reasons outlined above, we do not support the adoption of the prior authorization data content and infrastructure rules nor the adoption of the connectivity rule version 3.1.0 as they are currently published.

Conclusion

BCBSA supports in general the adoption of operating rules. We recognize their value in achieving the overall goal of quality and affordable healthcare. Affordability and quality necessitates the exchange of patient information.

It is important, however, to avoid using operating rules to resolve problems created by use of noncompliant transactions. Such problems need to be resolved through education, the enforcement process, or both. Moreover, the value of such standards and operating rules would be enhanced if the industry developed a timelier and more predictable maintenance cycle. Future predictable cycles would also facilitate the coordination and communication that will be essential to keep standards and operating rules consistent with one another as we move forward.

Given the number of mandates with implementation dates in the next few years, we continue to encourage CMS to consult the National Committee on Vital and Health Statistics to develop a strategic road map for Administrative Simplification provision implementations. This road map should balance all mandates, including the ONC and CMS Interoperability rules and other federal mandates, to work towards avoiding bottlenecks and overlapping resource commitments. We would also request that the NCVHS work with industry stakeholders in developing such a road map.

We appreciate the opportunity to submit comments in advance of the hearing. Gail Kocher, Director, Commercial Markets will be available as part of the August 25-26, 2020 hearing to address any questions the Subcommittee might have. Otherwise, please contact Lauren Choi, Director, Managing Director, Office of Policy and Representation at lauren.choi@bcbsa.com.

July 24, 2020

William W. Stead, MD
Chair
National Committee on Vital and Health Statistics
3311 Toledo Road Hyattsville, MD 20782-2002

Re: Request for Public Comment on Three CAQH CORE Proposed Operating Rules: Revised Instructions for Submission

Submitted electronically at NCVHSmail@cdc.gov

Dear Dr. Stead:

Centene appreciates the opportunity to provide feedback on the Council for Affordable Quality Healthcare (CAQH)'s Committee on Operating Rules for Information Exchange (CORE)'s proposed operating rule package, consisting of the Prior Authorization Data Content Rule, the Prior Authorization Infrastructure Rule, and the Connectivity Rule. As a CORE board member, we broadly support efforts to modernize and streamline prior authorization (PA) to drive automation and bi-directional electronic information exchange. Prior authorization remains a critical tool to deliver appropriate and safe care as well as cost-effective formulary management, and the movement toward electronic prior authorization (ePA) will greatly improve the PA process. Centene continues to work with our provider partners to implement electronic and automated processes that efficiently responds to PA requests while minimizing administrative burden. We are committed to enhancing interoperability to facilitate more timely data sharing and improve care delivery. We believe these core rules have great potential to not only streamline processes but improve overall care delivery, experience, system efficiency, and healthcare outcomes.

Founded in 1984, Centene has established itself as leading multi-national healthcare enterprise with a commitment to helping people live healthier lives. The company takes a local approach – with local teams and solutions - to provide fully integrated, high-quality, and cost-effective services to government-sponsored and commercial healthcare programs, focusing on under-insured and uninsured individuals. Centene offers affordable and high-quality products to nearly 1 in 15 Americans across all 50 U.S. states, including Medicaid and Medicare members (including close to 1 million Medicare members and nearly 4 million members in Medicare Prescription Drug Plans) as well as individuals and families served by the Health Insurance Marketplace, the TRICARE program, and individuals in correctional facilities. The Company also serves several international markets, and contracts with other healthcare and commercial organizations to provide a variety of specialty services focused on treating the whole person. Centene offers a comprehensive portfolio of innovative, flexible solutions that demonstrate our commitment to delivering results to better serve our members, providers, local communities, and government partners.

Centene's comments are organized in the following order framed by the Committee in their Request for Public Comment.

2. Workflow Improvement

The CAQH CORE Prior Authorization (278) Data Content Rule enhances and standardizes data elements needed between payers and providers that could lead to significant process. Prior Authorization is one of most burdensome and costly processes for providers. By reducing overall back and forth and addressing a key data issue in PA requests (medical necessity), these standardized data elements could reduce burden and improve overall care experience.

8. Implementation time frame

Centene has launched auto-determination pilots with our partners and continues to work towards developing and improving our electronic and automated PA processes. This undertaking has been a gradual process to accommodate for shared learnings, as well as provider outreach and education, among other resource and cost considerations. To this end, plans and providers should be given reasonable time to implement the proposed changes from the three rules. A restrictive time frame would greatly impede the ability of health plans and providers to effectively deliver utilization management decisions.

10. Additional Comments (Prior Authorization operating rules)

Centene commends NCVHS for considering the federal adoption of streamlined ePA processes, which represents an improvement from current state-by-state variations in PA requirements. However, at the more granular level, the new requirements outlined in the Prior Authorization Data Content and Infrastructure rules require varying levels of system migrations and upgrades to implement. As it stands, the operations, systems, and process changes required by the rules could create substantial upfront administrative burden for both plans and providers who lack the necessary resources and expertise to administer complex technical changes. Accordingly, as stated above, Centene requests that the proposed updates be gradually implemented, with a reasonable time frame for plans and providers to implement and familiarize themselves with these changes.

11. General Comments to Inform Committee's Deliberations

As health plans continue to work on initiatives to streamline and automate our PA processes, we rely on flexibilities in designing PA criteria to reinforce evidence-based guidelines in order to generate greater value in our healthcare system. These flexibilities account for different populations and provider variation, and can further help to reduce administrative burden. For example, in a process known as gold-carding, physicians that are consistently using evidence-based practices may be granted exemption from PA requirements, which has the effect of removing provider burden and incentivizing high-quality care. As the PA process undergoes operational changes, it is critical that these flexibilities are protected so that health plans can continue to design utilization management tools that delivers improved outcomes while reducing costs.

We remain a committed partner in working with the Administration to streamline PA transactions and promote interoperability and automation to enable timely reviews and improve overall care delivery. If you have questions or need more information on the attached detailed comments, please contact Kim Henrichsen at kimberlee.henrichsen@centene.com or 314.320.2716.

Sincerely,

Centene Corporation

CENTENE Corporation

Transforming the health of the community, one person at a time

SUBMITTED TO:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS SUBCOMMITTEE ON STANDARDS

August 25 & 26, 2020

Presented By: Crystal Ewing, Director of Product, eSolutions

Board Chair, Cooperative Exchange: *The National Clearinghouse Association*

Members of the Subcommittee, I am Crystal Ewing, Board Chair of the Cooperative Exchange (CE), representing the National Clearinghouse Association and Director of Product, eSolutions. I would like to thank you for the opportunity to present testimony today on behalf of the Cooperative Exchange membership concerning the proposed Operating Rules.

Please refer to prior Cooperative Exchange NCVHS June 6, 2015[1] and February 16, 2016[2] testimonies regarding Health Care Attachment Transaction Standards and CAQH CORE Phase IV Operating Rules, in which many of the our 2020 NCVHS testimony comments below, reflect the same industry issues as identified in 2015 and reiterated in the 2016 NCVHS testimonies, still have not been addressed today.

Cooperative Exchange Background

Cooperative Exchange is the nationally recognized resource and representative of the clearinghouse industry for the media, governmental bodies and other interested parties

Cooperative Exchange 23[3] clearinghouse member companies, represent over 90% of the clearinghouse industry and process annually over 6 billion plus claims representing $1.1 trillion, from over 750,000 provider organizations, through more than 7,000 payer connections and 1,000 HIT vendors. The Cooperative Exchange ***truly represent the healthcare industry EDI highway infrastructure*** and

[1] Cooperative Exchange, NCVHS Testimony June 6, 2015;Proposed Phase IV Operating Rules; https://www.ncvhs.hhs.gov/wp-content/uploads/2015/04/Cooperative-Exchange-Panel-3-Binder1.pdf

[2] Cooperative Exchange, NCVHS Testimony February 16,2016; Health Care Attachments Transaction Standards https://www.cooperativeexchange.org/site_page.cfm?pk_association_webpage_menu=2891&pk_association_webpage=15408

[3] The Cooperative Exchange (CE) is comprised of 23 of the leading clearinghouses in the US. The views expressed herein are a compilation of the views gathered from our member constituents and reflect the directional feedback of the majority of its collective members. CE has synthesized member feedback and the views, opinions and positions should not be attributed to any single member and an individual member could disagree with all or certain views, opinions and positions expressed by CE.

maintains hundreds of thousands of highways and the majority of the on and off ramp connections across all lines of healthcare business in this country.

Cooperative Exchange member clearinghouses support both administrative and clinical industry interoperability by:

- Managing tens of thousands of connection points
- Securely manage and move complex data content including administrative and clinical information
- Receive and submit both real time and batch transactions
- Provide interoperability by normalizing disparate data to industry standards
- Provide flexible solutions to accommodate the different levels of stakeholder EDI readiness (low tech to high tech)
- Actively participates and provides strong representations across all the national standard organization with many of our members holding leadership positions.

Therefore, we strongly advocate for EDI standardization and compliance within the healthcare industry. We are committed to promote and advance electronic data exchange for the healthcare industry by improving efficiency, advocacy, and education to industry stakeholders and government entities.

Summary of Recommendations

The Cooperative Exchange, the National Clearinghouse Association DOES NOT support federal adoption of the Prior Authorization Infrastructure, Data Content, or Connectivity Operating Rules as proposed.

- The infrastructure rule does move the industry closer to a partially automated process. However, since critical business processes are not fully automated, providers will still need to break workflow to manually submit supporting documentation requests and needed follow-up.
- We strongly recommend that NCVHS advise to wait for the Connectivity vC.4.x Operating Rule rewrite effort to conclude as this is expected to imminently replace the proposed Connectivity vC3.1.0 rule.
- As previously testified, we continue to oppose all operating rules involving data content and encourage the Operating Rule Authoring Entity (ORAE) to more effectively partner and align efforts with their Standards Development Organization (SDO) peers.

Response to Subcommittee Questions

The following are the Cooperative Exchange responses to the NCVHS questions regarding the request received on February 24, 2020, from the Council for Affordable Quality Healthcare (CAQH), Committee on Operating Rules for Information Exchange (CORE) Board, to consider the following three new operating rules for federal adoption:

- Prior Authorization (278) Data Content Rule
- Prior Authorization (278) Infrastructure Rule
- Connectivity Rule

1. **If your organization participated in identification and development of the proposed operating rules for prior authorization and/or connectivity, describe the skill set of the individuals involved (business or technical) and in what way they participated in the process.**

   Rule-writing and voting is done by CAQH CORE Participating Organizations and limits industry involvement in the rule development process.

   - 60% of our members are also CAQH CORE participating organizations.
   - The Cooperative Exchange does have member organizations who are actively participating in the rule development process.
   - Except for Standards Organizations and Government Entities, an annual fee is required to participate and vote in rule development. The fee is based on the participating organization's annual revenue.
   - The skill set and level of participation varies by participating organization.

2. **In what way(s) will the proposed operating rules for prior authorization improve workflow for your organization's industry sector? Discuss the prior authorization data content and infrastructure rules and describe how the proposed requirements from each will impact your workflow, reduce burden (if relevant) and better support patient care.**

   Critical Business Processes and Technical Workflow Inefficiencies Still Not Addressed.

   The Cooperative Exchange does see value in the CAQH CORE proposed infrastructure rules, which includes establishing consistent standard infrastructure and national turnaround timeframes for a health plan, payer or its agent when responding to a 278 request. The Cooperative Exchange also finds value in the transparency of system availability expectations, uniform use of acknowledgements, and processing mode and response timeframes.

   - The infrastructure rule does move the industry closer to a partially automated process. However, since critical business processes are not fully automated, providers will still need to break workflow to manually submit supporting documentation requests and needed follow-up.
   - For the ASC X12 278 Prior Authorization transaction to be effective, the ability to send and receive supporting documentation electronically is needed. Without the adoption of attachment regulations, the industry is left with an incomplete prior authorization workflow that does not meet stakeholder business needs.
   - Additionally, healthcare systems and applications are at varying levels of adoption and maturity required to support these critical business functions and technical workflow.

- No data content or operating rules can address turnaround times for current business processes that are not be conducted electronically (such as peer-to-peer medical reviews).
- The AMA's 2018 survey[4] indicated 21 principles grouped into 5 broad categories: • Clinical validity • Continuity of care • Transparency and fairness • Timely access and administrative efficiency • Alternatives and exemptions.
    - As an industry, we need to address all 5 categories, of which connectivity and maximum turnaround times are just a subset. If the results of the provider's request are not successful or continue to be burdensome, then we continue to facilitate the same industry barriers that impede adoption.

We do not support ANY and ALL Operating Rules involving data content.

- Consistent with prior testimony, the Cooperative Exchange does not support rules involving data content requirements or usage. Our position is that the ownership of data content requirements and usage is the sole responsibility of the standards development organization (SDO), not the operating rule authoring entity (ORAE).
- Rules regarding data content need to be communicated single source via the implementation guides/data specifications created from the industry vetted Standards Development Organization (SDO) process.
- Data content rules created outside of and divorced from SDO guides/data specifications create confusion and disparity in healthcare EDI standards deployment.
- If CAQH CORE workgroups identify data content needs/enhancements, they should be submitted via the established data maintenance process to the applicable SDO for consideration.
- The Cooperative Exchange continues to support the recommendations in the February and December 2019 NCVHS letters to the HHS secretary outlining actions to facilitate a "more nimble" approach to standards development aligned with federal policy objectives, industry business requirements, and emerging technologies.

3. In what way(s) will the proposed operating rule for connectivity improve the processing of transactions, message payload, connectivity, security, etc. if adopted by HHS? What are the anticipated benefits that this operating rule offers vs. the current state (please provide examples if possible)?

The timeline for development and approval and adoption of Connectivity rules does not allow for the alignment of mandated Industry Privacy and Security rules and standards and would require the implementation of outdated and costly systems regardless of the availability of new technology.

[4] AMA Prior Authorization NCVHS Full Committee, Nov13,2019: https://ncvhs.hhs.gov/wp-content/uploads/2019/12/Presentation-Prior-Authorization-AMA-Update-Heather-McComas.pdf

- SSL v3.0 is included in the proposed version C3.1.0 Connectivity Rule as a minimum standard despite known and publicly published security vulnerabilities. SSL has effectively been replaced by TLS. Federally mandating support of a vulnerable standard will continue to hinder efforts to encourage trading partners to upgrade.
- HHS, OCR, ONC and NIST in their publications and guidance recognize that security solutions require standard guidelines as well as a flexible framework as one "blueprint" may not accommodate all stakeholders and scenarios. As an example, the NIST Special Publication (SP) 800-63 [5]suite provides technical requirements for federal agencies implementing digital identity services. The publication includes: an overview of identity frameworks; using authenticators, credentials, and assertions in a digital system; and a risk-based process to select assurance levels. Organizations have the flexibility to choose the appropriate assurance level for their needs.
- HIPAA Security and HITECH Rules cite the National Institute of Standards and Technology (NIST) as the authoritative industry source, not the Operating Rule Authoring Entity.
- Connectivity rules created outside of and divorced from the NIST standard guides/specifications create confusion and disparity in healthcare EDI standards deployment.
- The proposed operating rule for connectivity only allows stakeholders one option for authentication, X.509 Digital Certificates, and if adopted, would require stakeholders to support this option. Per prior testimony by multiple organizations, the cost of implementing X509 certificates will be passed on to providers and will merely be a shift in the transaction cost along with creating additional administrative burden for stakeholders required to comply with this operating rule.
- The Cooperative Exchange finds limiting authentication to only one solution does not provide flexibility to meet different stakeholder business needs and may result in additional change costs that will impede EDI adoption.
- The proposed Connectivity rule limits the inclusion of new and emerging technology such as restful API's, OAUTH, SAML authorization and Identity Services that address many of the business issues that the proposed Connectivity Rule would limit. Some of these are identified in the proposed connectivity rule as not being addressed due to time constraints or deferred for future consideration.
- The Cooperative Exchange recommends that the industry wait for the 2020 CAQH CORE Connectivity Operating Rules version C4.x rewrite process to conclude (expected by the end of 2020) and revisit at that time to ensure that this is addressed and mitigate unnecessary industry implementation costs and resources.
-

4. Describe how adopting the proposed operating rules will or could increase in the use of any of the adopted HIPAA transaction standards.

Although the proposed Infrastructure operating rules could increase the usability of the 278 prior authorization transaction if adopted, there are many other barriers and concerns that have been previously identified which need to be addressed and solved for.

[5] National Institute of Standards and Technology SP800-63 Series Digital Identity Guidelines; https://www.nist.gov/itl/tig/projects/special-publication-800-63

- Web Portal Operating Rules discourage adoption of HIPAA Electronic Transaction Standards
  - We acknowledge that web portals have been utilized in the industry as a bridge strategy for low-tech providers and lack of industry adoption and maturity of EDI automation.
  - Operating rules regarding payer portals, such as the CAQH CORE Prior Authorization & Referrals Web Portal Rule vPA.1.0, are not aligned with the goals/requirements of HIPAA administrative simplification provisions and are burdensome and costly to providers.
  - Web portals disintermediate the need and use of HIPAA adopted transactions and discourage efforts towards establishing fully systematic, interoperable, and automated EDI workflows.
  - The term "CORE Operating Rule" should only be used and applied specific to federally mandated operating rules supporting health care transaction standards.
- An attachment standard has still not been adopted as a HIPAA named transaction yet is foundationally required to support the prior authorization business function.
- To date, despite a great deal of industry time and resources consumed, there continues to be minimal measurable action or change related to the Prior Authorization process.
  - Numerous, concise NCVHS letters to the HHS secretary.
  - Focused Prior Authorization initiatives by the AMA, eHI, MGMA, WEDI and others.

5. **Connectivity rule implementation for your organization or industry wide (please specify):**
   a. **What are the implications, costs and benefits of implementing the new connectivity rule requirements for the prior authorization, eligibility & benefits, claim status and electronic remittance advice transactions? Providing generalized or high-level information will be helpful to the Committee. [Note, this question has been revised to remove reference to claims, enrollment/disenrollment, and premium payment transactions for which operating rules have not been adopted by HHS.]**

No perceived benefits versus cost and required resource commitments.

- Required to implement & support regardless of usage or current solutions.
- A federal connectivity mandate could supersede other business development initiatives which are based on an organization's defined product roadmap and client needs.

Costs and Resources of implementing the proposed connectivity rule.

- Development – Required for all that did not implement X.509 Digital Certificate based authentication over SSL/TLS and SOAP 1.2 + WSDL 1.1 and MTOM (for both Real Time and Batch).
  - Cost and resources vary by product and architecture.
  - May need to implement for multiple products based on product delivery and past acquisitions.
- Testing – Required for all.

- At our non-recoupable expense, resources must be allocated, and a complete testing environment must be staged.

- Core Certification[6] – Can be required for proof of adoption or compliance by third parties
  - Fees range from $750 to $9,000 dependent on type of business and net annual revenue. Government entities are exempt.
  - Recertification every 3 years. Fees range from $375 to $4,500 (1/2 of the initial certification fee).

b. **Can you provide general types of costs and benefits of meeting the processing mode requirements for both real time and batch submissions?**

The industry already supports real-time and batch submission where appropriate and possible.

- Delivery of the modes varies by transaction type.
- Additional Costs may be incurred (Development, Processing, etc.) if both modes must be supported over a single transport.

6. **Implementation time frame for each proposed rule: a. What is the anticipated lead time needed by your organization to develop, test and implement the proposed operating rules? What are the dependencies that impact the timeline, e.g., vendors, trading partners and business associates? If possible, please provide an estimate of the amount of time your vendors would require to develop their component of the solution? b. Should considerations be given to size or organization type for the proposed implementation timeframe? Please discuss for each of the proposed operating rules (Prior authorization content, prior authorization infrastructure and connectivity).**

The Cooperative Exchange believes that industry sector implementation timeframe estimations and considerations are premature at this time.

7. **Costs (Prior Authorization rules): Is your organization able to provide an estimate of the implementation cost for the requirements of the two prior authorization operating rules for data content and infrastructure? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting these rules?**

Clearinghouses act as a network transport for Prior Authorization workflows and are generally not as impacted by infrastructure rules. Clearinghouses often must bring awareness to our trading partners and mediate data content operating rules that are divorced from the X12 TR3 specifications. This leads to trading partner frustration due to inconsistent EDI deployments and costly and unnecessary support burdens.

- The Cooperative Exchange is concerned about the implementation cost to the industry as a whole. We strongly recommend that estimating implementation and recurring support costs

[6] CAQH CORE Certification Process; https://www.caqh.org/core/core-certification-process

from the Provider, Vendor, Clearinghouse, and Payer stakeholders be considered if the proposed rules are recommended by NCVHS for adoption.

8. **Costs (Connectivity rule): Is your organization able to provide an estimate of the implementation cost for the requirements of the connectivity operating rule? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting this rule and its requirements?**

   The Cooperative Exchange believes that a cost/benefit analysis of the proposed Connectivity Rule is not warranted and should be deferred.

   - 2020 CAQH CORE Connectivity Operating Rules version C4.x rewrite is currently in process and is expected to conclude by the end of 2020.

9. **Additional comments: Given that the Connectivity Rule is highly technical, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?**

The Cooperative Exchange recommends that the Connectivity Rules scope and timeline be re-evaluated to ensure that the industry can focus on evolving security risks as well as emerging technology solutions.

- Waste of cost and resources to implement, test, and support outdated standards.
- Current process is not agile and prevents the ability to adjust rapidly to a changing environment.

10. **Additional comments: For the Prior Authorization operating rules, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?**

The Cooperative Exchange feels that the overall implementation and value of the proposed Prior Authorization operating rules cannot be properly evaluated at this time.

- Per the NCVHS letter [7] to the Secretary of HHS entitled "Recommendations for the Proposed Phase IV Operating Rules" dated July 6, 2016, NCVHS heard testimony both during the February 2016 hearing, as well as at previous hearings (including the Review Committee hearing in June 2015) noting that the level of implementation of Prior Authorization across the industry is extremely low (less than 5% of all prior authorizations being done across the board). The benefit of adopting the proposed Phase IV Operating Rules for Prior Authorization is not clear when there is such low use, and there might be the risk of creating additional barriers to its adoption.

- To date, this has not changed and there is no more clarity nor less risk with these proposed operating rules.

[7] NCVHS 2016 Letter of Recommendation to HHS for Proposed Phase IV Operating Rules; https://ncvhs.hhs.gov/wp-content/uploads/2018/03/NCVHS-REV-Phase-IV-Ltr-July-1-2016-Final-Chair-CLEAN-for-Submission-Publication-REV-Jul-6.pdf

11. General: For each rule, please provide the rationale for your support or opposition to its adoption to inform the Committee's deliberations.

The Cooperative Exchange, the National Clearinghouse Association DOES NOT support federal adoption of the Prior Authorization Infrastructure, Data Content, or Connectivity Operating Rules as proposed.

Prior Authorization Infrastructure Rule

- In general, we support the new Operating Rule structure and transition to a business transactions-based vs. phase-based model. We agree that a single and uniform Safe Harbor connectivity rule and updated prior authorization & referral infrastructure rules are directionally sound and could provide benefit/value; however, along with the concerns outlined previously, we do not support a "piece-meal" approach when federally mandating Operating Rules specific to a business transaction. The associated industry cost and resource effort to implement the proposed Operating Rules significantly outweighs the potential industry benefit/value/ROI.

Connectivity Operating Rule

- Some of our members are actively participating in the Connectivity Rule rewrite which is positioned to address several longstanding concerns. We strongly recommend that NCVHS advise to wait for the vC.4.x rewrite effort to conclude as this is expected to imminently replace the proposed vC3.1.0 rule.

Data Content Operating Rule

- We will continue to oppose any and all operating rules involving data content and we strongly encourage the Operating Rule Authoring Entity (ORAE) to more effectively partner and align efforts with their Standards Development Organization (SDO) peers.

Conclusion

Aligned with prior Cooperative Exchange testimony, the Cooperative Exchange feels that many of the findings and recommendations outlined in the July 2016 NCVHS letter to the HHS secretary remain outstanding and have not been effectively addressed. We also agree with and support the findings and recommendations in the February 13[8] and December 10[9], 2019 NCVHS letters to the HHS secretary outlining actions to improve the adoption of standards under HIPAA. We are concerned that despite numerous, concise NCVHS letters to the HHS secretary, backed by industry consensus and support including focused Prior Authorization initiatives by the AMA, eHI, MGMA, WEDI and others, there continues be minimal measurable action or

[8] NCVHS Letter to HHS February 13, 2019; Re: NCVHS Recommendations on New Approaches to Improve the Adoption of National Standards for the Health Care Industry; https://ncvhs.hhs.gov/wp-content/uploads/2019/02/Recommendation-Letter-Predictability-Roadmap.pdf

[9] NCVHS Letter to HHS December 10, 2019;Re: Additional recommendations for HHS actions to improve the adoption of standards under the Health Insurance Portability and Accountability Act (HIPAA) of 1996; https://ncvhs.hhs.gov/wp-content/uploads/2019/12/NCVHS-Recommendation-Letter-HHS-Actions-to-Improve-the-Adoption-of-Standards-Under-HIPAA-December-2019.pdf

change (e.g. Attachments, Prior Authorization, Acknowledgments). Our collective resource investment costs incurred over the years with minimal or no realized progress or ROI is of great industry concern. The Cooperative Exchange will continue to support NCVHS and we offer our assistance to determine how we can expedite and achieve measurable and timely results aligned with the HIPAA Administrative Simplification's original stated purpose to improve the efficiency and effectiveness of the health care system through the establishment of standards and requirements for the electronic transmission of certain health information.

Respectfully Submitted,

Crystal Ewing
Board Chair, Cooperative Exchange

From:	Wilderman, David L CTR (USA)
To:	NCVHS Mail (CDC)
Cc:	Sawyer, Daniel W CIV DHA J-5 (US); Tyler, Paul A Jr CTR DHA BUS OPS J-5 (USA); Nawabi, Mostafa A CTR (USA); Khatta, Manisha CTR (USA)
Subject:	Comments on CAQH CORE Proposed Operating Rules
Date:	Friday, July 24, 2020 12:57:01 PM

Good afternoon,

On behalf of Mr. Danny Sawyer, Defense Health Agency, thank you for providing the opportunity to submit comments. Our comment relates to the required implementation time frame for the proposed rules. When developing the regulatory requirement(s), please provide covered entities with enough time to successfully implement in light of other respective organizational priorities. The Defense Health Agency budgeting process is completed well in advance of a given Fiscal Year, so any unanticipated "year-of-execution" requirements are more challenging to implement. Please let us know if you have any questions or need additional information.

Very respectfully,

Dave

David Wilderman

DHA HIPAA Support

571-814-7904

From:	Burckhardt, Laurie
To:	NCVHS Mail (CDC)
Subject:	CORE Operating Rules
Date:	Friday, July 24, 2020 12:53:39 PM

I am Laurie Burckhardt, Chair of the Designated Standards Maintenance Organizations (DSMO) Committee. Thank you for the opportunity for the DMSO to provide comments on the proposed CORE Operating Rules for Prior Authorization. The committee has reviewed the questions and have no comments to submit at this time.

If any questions or concerns, please contact me at laurie.burckhardt@wpsic.com.

Laurie Burckhardt
EDI Regulatory and National Standards Administrator
Corporate Services - EDI
WPS Health Solutions

e: laurie.burckhardt@wpsic.com

William W. Stead, MD
Chair
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: CAQH CORE Operating Rules Proposed to NCVHS – 2020

Dear Dr. Stead,

Edifecs greatly appreciates the opportunity to provide feedback to the National Committee on Vital and Health Statistics (NCVHS) with regard to the CAQH Committee on Operating Rules for Information Exchange (CORE) Prior Authorization and Connectivity Operating Rules proposed. We fully support advancing a national agenda with the goal of reducing industry burden and promoting administrative automation in healthcare. We strongly believe that this proposal will significantly increase adoption of electronic Prior Authorization and recommend the operating rules to NCVHS and the Department of Health and Human Services (HHS) for federal adoption under HIPAA.

Edifecs has an extensive customer base of payers across the US in both the commercial and public sectors. We support hundreds of payers in meeting their HIPAA compliance requirements and have specifically worked with many of them to implement electronic Prior Authorization. We feel these proposes rules with play an important part in advancing the adoption and implementation of this critical process that benefits all stakeholders, most importantly patients and consumers.

Edifecs actively participated with over 125 organizations in the development of the proposed operating rules through a collaborative, consensus-based process. We feel the process fairly and adequately represented a broad cross-section of interests and priorities and sets and important minimum bar that supports a critical standards-based approach for addressing many of the concerns expressed by patients, providers, payers and other important voices.

For the past two decades and more, Edifecs has participated in many collective forums and with individual stakeholders to work on making the Prior Authorization process more effective and efficient. The process is broadly acknowledged to be overly burdensome and unnecessarily costly. The operating rule package proposed by CAQH CORE will drive greater automation, increase efficiencies, and enhance health plan and provider data exchange. The proposed rules represent meaningful steps that healthcare stakeholders can take now to support the move toward automation of prior authorization. Specifically:

- The CAQH CORE Prior Authorization Operating Rules form the foundation of a roadmap to move the industry toward an end-to-end automated workflow for prior authorization adjudication. The rules reduce the unnecessary back and forth between providers and health plans, accelerate adjudication timeframes, and reduce provider resources spent on manual follow-up.

- The CAQH CORE Connectivity Rule vC3.1.0 enhances security and promotes uniform interoperability requirements across administrative transactions. A single, updated safe harbor connectivity method for the industry will simplify data exchange and eliminate the need to support the older, outdated versions of CAQH CORE Connectivity that are currently mandated.

Edifecs believes that the proposed CAQH CORE Operating Rules will set a universal floor for process standardization that will spur further innovation and stakeholder compromise that will bring about a more rapid convergence of administrative and clinical data streams in healthcare and in many ways accelerate the migration to new standards and technologies.

Edifecs strongly encourages NCVHS in its commitment to promote the adoption of standards and, when necessary, recommend that the Secretary use the authority of HHS to move the industry to adopt universal efforts among industry stakeholders to address the goals of security, automation, efficiency and interoperability of health data and systems. We encourage NCVHS to promote industry progress by supporting and advancing industry-driven efforts like the CAQH CORE Operating Rules.

Thank you for the opportunity to provide comment. Please do not hesitate to reach out with questions.

Sincerely,

Gupreet (Sunny) Singh

CEO & President
Edifecs, Inc.

July 28, 2020

William W. Stead, MD
Chair
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782

Re: CAQH CORE Operating Rules Proposed to NCVHS for Federal Adoption

Dear Dr. Stead:

Thank you for the opportunity to provide feedback on the CAQH Committee on Operating Rules for Information Exchange (CORE) Prior Authorization and Connectivity Operating Rules proposed to the National Committee on Vital and Health Statistics (NCVHS).

Epic is a leading health IT developer that works with some of the largest health systems and health plans across the United States. We have worked extensively with health systems, payers, and other vendors to automate the prior authorization process including by incorporating HIPAA's mandated X12 standards for prior authorization in provider workflows in Epic's software. However, inconsistent support of the standards across the health ecosystem as well as the varying interpretations of the standards has acted as a barrier to greater adoption across providers and plans, and prevented the industry from realizing the full benefits of streamlined electronic communication.

We support federal adoption of the proposed CAQH CORE Prior Authorization and Connectivity Operating Rules as required transactions under HIPAA. Standardizing the data content and exchange infrastructure used for X12 278 Request and Response transactions would result in significant progress in removing the barriers identified above. This will enable greater automation of prior authorization processes, which will ultimately increase the timeliness of care, and reduce administrative burden for all healthcare stakeholders.

As NCVHS moves to finalize a requirement to adopt CAQH's proposed operating rules, it must ensure that stakeholders have enough time adapt to the new requirements. Health IT developers must enough time to design, code, and test updates to their software, and create documentation and training materials for users. Provider organizations will need time to implement the updated software, adjust their workflows and business processes, and train users. We recommend the requirement take effect no less than 24 months after finalization.

We are happy to answer any questions you have on our feedback, and serve as an ongoing collaborative partner with NCVHS on this topic. Please contact us at info@epic.com.

Thank you for your consideration.

Sincerely,

Sreevinas Pasumarthi
Software Development Lead, Epic

Harvard Pilgrim Health Care

July 27, 2020

William W. Stead, MD
Chair
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: CAQH CORE Operating Rules Proposed to NCVHS for Federal Adoption

Dear Dr. Stead,

Thank you for the opportunity to provide feedback on the CAQH Committee on Operating Rules for Information Exchange (CORE) Prior Authorization and Connectivity Operating Rules proposed to the National Committee on Vital and Health Statistics (NCVHS). Harvard Pilgrim Health Care fully supports the proposal and recommends the operating rules to NCVHS and the Department of Health and Human Services (HHS) for federal adoption under HIPAA.

Harvard Pilgrim Health Cares is a regional not-for-profit health plan and a CAQH CORE participant. Harvard Pilgrim was the first health plan to be CORE I and CORE II certified in 2009. Representative of the plan participated extensively in the developed of the proposed Prior Authorization and Connectivity Operating Rules.

Over 125 organizations, including Harvard Pilgrim, participated in the development of the proposed operating rules through a collaborative, consensus-based process. The operating rule package proposed by CAQH CORE will drive greater automation, increase efficiencies, and enhance health plan and provider data exchange. The proposed rules represent meaningful steps that healthcare stakeholders can take now to support the move toward automation of prior authorization.

Harvard Pilgrim commends NCVHS efforts to accelerate the adoption of standards and operating rules to achieve the purposes of security, automation, efficiency and interoperability of health data and systems. We encourage NCVHS to promote industry progress by supporting and advancing industry-driven efforts like the CAQH CORE Operating Rules.

Thank you for the opportunity to provide comment. Please do not hesitate to reach out with questions.

Sincerely,

Rhonda E. Starkey
Director eBusiness Services
Harvard Pilgrim Health Care

HARVARD PILRIM HEALTH CARE COMMENTS – NCVHS ADOPTION CAQH CORE OPERATING RULES

For each comment, please indicate the operating rule to which it refers, i.e., Prior Authorization Data Content Rule, Prior Authorization Infrastructure Rule, or Connectivity Rule. For general comments, please note this in your statement as well.

1. **Participation in development of the rules: If your organization participated in identification and development of the proposed operating rules for prior authorization and/or connectivity, describe the skill set of the individuals involved (business or technical) and in what way they participated in the process.**

   Harvard Pilgrim Health Care, a regional non-profit health plan and CAQH CORE Participant, participated in the development and review of all three proposed operating rules. Rhonda Starkey, Director eBusiness Services, served as co-chair for the following work groups and subgroup:

   a. CAQH CORE Phase IV Response Time Rules & Technical Work Group
   b. CORE Prior Authorization Rules Work Group
   c. CAQH CORE Prior Authorization Subgroup

   Ms. Starkey has been a contributor to Harvard Pilgrim's design, development, and operations of business processes and technology to support referral and prior authorization services for the last 15 years. This spans web portal use, 278 request and response transaction, 278 inquiry and response transaction, centralized referral/authorization rules engine, and authorization related clinical attachments.

2. **Workflow (prior authorization rules)**: **In what way(s) will the proposed operating rules for prior authorization improve workflow for your organization's industry sector? Discuss the prior authorization data content and infrastructure rules and describe how the proposed requirements from each will impact your workflow, reduce burden (if relevant) and better support patient care.**

   The proposed data content and infrastructure rules clarify expectations for prior authorization submission and response between payers and providers. By creating common data content standards, all parties are aware of information initially expected to process a prior authorization request (patient information, diagnosis/procedure/revenue codes), as well as subsequent to a submission should additional information be needed (health care service decision reason codes, PWK codes). Clear expectations should impact both the constituent's workflow and operational burden. When consistent expectations are defined, workflows and business processes can be intelligently redesigned to meet those expectations. As the system/administrative aspects of the prior authorization request are automated, resource allocations and costs can be eliminated or shift from administrative to clinical support services.

   The adoption of infrastructure rules offers the same benefits of clear expectations for response timeframes. We believe the combination of the infrastructure response timeframes and use of the real time prior authorization transaction will serve to improve patient care. When providing a real time 278

response, the patient and provider's interaction and the patient's care are more efficiently and effectively supported. Whether the request's final outcome or next steps are provided, the outcome can be assessed, and additional planning immediately engaged. The focus is on the individual patient, not engaging in administrative work waiting for or checking/confirming if the batch response has been received, and potentially sorting through the batch responses/outputs for an individual patient response. When a real time response has been provided, there is no guessing as to what and when the outcome will be known.

Harvard Pilgrim has utilized the 278 real time request and response transaction for nearly 20 years as the referral and authorization requirements and standards for: 1) our provider web portal, 2) our participation in the Massachusetts based New England Healthcare EDI Network multi-payer web portal, and 3) direct EDI transactions.

In concert with the design of the 278 request transaction as the business standard, Harvard Pilgrim has undertaken multiple iterations to refine external and internal clinical and administrative requirements needed to complete a referral or authorization. Consistently, 85% of all requests received as 278 transaction result in an immediate response that the transaction is approved or partially approved, no plan action is required, or the request is denied (with denials at 1%). The remaining 15% of requests, which include initial, extension or other edit requests, pend for additional clinical information.

The efforts to streamline request requirements, in concert with the standard transaction use, afforded us the opportunity to reduce referral and authorization administrative staff over time by 14 FTEs. For the plan, this represented an organizational value through administrative cost reduction.

This example is of the benefits of the standard transaction use, our expectation is further definition of submission and response data requirements would add additional incremental administrative relieve to us through growth of adoption in the provider community and direct 278 transaction exchange.

We have also seen previously that the failure to rationalize requirements of the 278 request transaction among payers impedes utilization. Home care providers have the highest rate of 278 authorization use with our plan. A local home health care and health plan collaborative designed a defined home care authorization form. Upon confirmation the 278 transactions would support all administrative and clinical items identified within the common form, and guidance on how to provide that information within the request standard, home care providers then implemented the use of the web portal and the resulting 278 transaction. Rates of 278 requests increased through 2014 to a plateau at two-thirds for home care requests. The common, consistent standard implementation resulted in significant conversion from paper, reduced inbound faxes by 45% and reduced the average response turnaround time to providers from two days to one day.

An additional note regarding the proposed infrastructure operating rule. The HIPAA mandate requires implementation of the 5010X217 278 Request and Response transaction; however, it did not include the implementation of the 5010X215 278 Inquiry and Response transaction. This results in an incomplete work cycle for those requests that receive a pended prior authorization response. The provider and/or payer must then engage in some manual work to confirm the final transaction request result. The infrastructure rule component requiring an outbound unsolicited 278 response with finalized authorization result closes that gap; doing so within the standard that is mandated by HIPAA requirements.

3. **Transaction exchange (connectivity rule): In what way(s) will the proposed operating rule for connectivity improve the processing of transactions, message payload, connectivity, security, etc. if adopted by HHS? What are the anticipated benefits that this operating rule offers vs. the current state (please provide examples if possible)?**

The most anticipated benefits of the connectivity operating rule are transmission security and an industry-wide common method for transaction exchange.

Historically we have found trading partners may delay adopting new transaction security levels without significant industry requirements or mandates. Example: We moved trading partners from SHA-1 to SHA-2 in 2019. One trading partner did not meet our defined time window in which to change and was inactive for an extended timeframe; they subsequently found it necessary to renew their transaction exchange at the improved security standard in order to meet the needs of their provider constituents.

Adopting the connectivity rule to an industry-wide common method will reduce a plan's complexity in supporting transaction exchange. Removing an enveloping method (HTTP-MIME) moves connectivity to a single standard. Harvard Pilgrim currently supports both enveloping methods for connectivity; each requires unique infrastructure support. Moving to one enveloping standard will reduce operational resources and costs associated with the HTTP-MIME enveloping method.

4. **Improving use of transactions and/or adoption of standards (all proposed operating rules): Describe how adopting the proposed operating rules will or could increase in the use of any of the adopted HIPAA transaction standards.**

Adopting the proposed operating rules can move transactions from standards to best practices with consistent rather than variable processes.

The 278 operating rules detail requirements that are improvements from current individual state mandates or requirements for mandated response times. Consistent maximum response times allow providers to implement processes that meet one standard rather than manage multiple payer specific standards. For payers, standards would be across all services and requests rather than potentially variable by state. Having consistent standards and processes across constituents can incent both providers and payers to embrace those standards and their use.

Massachusetts, our major marketplace, has previously established a two business day response requirement for prior authorization requests. Other states within our marketplace detail longer response times. To rationalize work effort within our organization, business processes and technology support are designed to meet the shortest response time requirements, the two business days. As previously noted, we have undertaken multiple iterations to refine external and internal clinical and administrative requirements needed to complete a referral or authorization, ensuring we continue to meet or exceed the two business day response time applied. Through combined business process and authorization rules engine, we routinely see 85% of 278 transaction requests result in an immediate response that the transaction is finalized, 15% pend for additional information. When the additional information is provided, whether in combination with the initial request, or subsequent to the request, processes continue to meet the two business days response time.

Continued lack of standards and inconsistent process requirements serve to foster fractured interactions for both the provider and payer, greater work effort and friction between parties.

5. **Connectivity rule implementation for your organization or industry wide (please specify)**:

   a. **What are the implications, costs and benefits of implementing the new connectivity rule requirements for the prior authorization, eligibility & benefits, claim status and electronic remittance advice transactions? Providing generalized or high-level information will be helpful to the Committee. [Note, this question has been revised to remove reference to claims, enrollment/disenrollment, and premium payment transactions for which operating rules *have not been* adopted by HHS.]**

   Adopting the connectivity rule to an industry-wide common method can reduce a plan's costs and resources required in supporting transaction exchange.

   Through use of current connectivity standards, including the prior Phase IV CAQH CORE 470 Connectivity Rule v4.0.0, Harvard Pilgrim has reduced the number of connectivity methods for transaction exchange for the identified transactions from four (4) to three (3) methods. Implementing the proposed connectivity standards will allow us to plan to decommission additional methods, reducing our connectivity standards from three (3) to one (1) when all other parties support the vC.3.1.0 standards. Each connectivity standard requires unique infrastructure services and operational support. Moving to one enveloping standard will reduce application and operational resources (staffing to perform development and enhancements, manage/monitor alert and reporting systems, manage downtime and recovery, and complete problem resolution and infrastructure work), including those associated with the HTTP-MIME enveloping method. Operational costs reduction would be roughly commensurate with the reduction in connectivity methods; capital costs would remain largely the same regardless of the reduction in connectivity standards (infrastructure such as servers remain).

   b. **Can you provide general types of costs and benefits of meeting the processing mode requirements for both real time and batch submissions?**

   If a plan is already processing eligibility and claims status transactions in real time and batch processing modes, costs to implement the additional transaction to the existing processes and infrastructure should be lower than initial development and implementation. This is the addition of a transaction on existing infrastructure and operational costs, as an incremental cost, rather than a new effort and cost. For the 278 transaction, only one mode is required, and if only one mode is implemented it should further serve to minimize the incremental cost.

   A new cost to implement 278 transactions, whether in batch or real time mode, may be clinical system integration. The model a payer or provider may use to implement may require new costs for this component. Within our organization, a freestanding rules engine is used for a referral and prior authorization decisions – both those from 278 submissions and those entered by the plan manually.

We have already integrated with the clinical management systems as needed; there is no further system integration required. However, other payer and plan design models may include the new integration with clinical systems as a new implementation costs for the mode of submission as well as all other operating rules.

Our organization has long valued the benefits of real time transactions over those of batch for eligibility, claims status and prior authorization. The use of real time transaction provides immediate response to providers with either a final action or next steps. Particularly in eligibility and prior authorization, the real time response can more effectively support the patient and provider's interaction and the patient's care when the final outcome is rendered, or next steps are provided, either can be immediately assessed when working on the patient's plan of care. The focus is on the individual patient rather than time on administrative work checking/confirming if the batch response has been received, and potentially sorting through the batch responses/outputs for a particular patient sometime after the care request was started.

6. Implementation time frame for each proposed rule:

a. What is the anticipated lead time needed by your organization to develop, test and implement the proposed operating rules? What are the dependencies that impact the timeline, e.g., vendors, trading partners and business associates? If possible, please provide an estimate of the amount of time your vendors would require to develop their component of the solution?

Harvard Pilgrim would anticipate a nine-month to one year implementation. That would be to assess for gaps and implement the operating rules as enhancements to our existing 278 transaction use, where the 278 represents 70% of referrals and prior authorizations submitted to Harvard Pilgrim (submissions through portals and direct EDI). We recently completed a major 278 authorization enhancement project that included: changes by one of our portal vendors, development of new authorization business rules, development of new internal business processes, changes to our central authorization rules engine, and development of attachment infrastructure. This project spanned nine (9) months. Implementation of the operating rules would involve thesee same components and processes.

The major external dependencies would include portal vendors (two). In our most recent prior authorization related project, the portal vendor had previously designed much of the authorization attachment module; this served to reduce the overall project time. We would estimate an implementation of additional operating rules by the portal vendor would be at least nine (9) months for development and implementation and potentially one year for multiple vendors to be implemented.

We would reduce external dependencies and schedules on trading partners and business associates by implementing the operating rule changes within the plan and support external trading partners to phase in their implementation in a defined subsequent window. We would plan for trading partner migration over time, which may increase project implementation costs, but would smooth the transition to new rules and reduce friction in the implementation with trading partners. A similar migration has been done in previous efforts such as implementation of version 5010 for all transactions.

We would expect those new to the 278 transaction to require additional time to implement both the 278 transaction itself and the operating rules.

b. Should considerations be given to size or organization type for the proposed implementation timeframe? Please discuss for each of the proposed operating rules (Prior authorization content, prior authorization infrastructure and connectivity).

We have no comment at this time.

7. **Costs (Prior Authorization rules)**: **Is your organization able to provide an estimate of the implementation cost for the requirements of the two prior authorization operating rules for data content and infrastructure? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting these rules?**

An estimate by our organization could not be provided at this time. The data content and infrastructure rule require gap analysis of clinical and technical business processes as well as some reassessment of technology infrastructure. With 70% of our current auths received as 278 transactions, both our costs and growth potential may be different than other organizations. Health plan support of the 278 has been federally mandated for many years, most plans should have the basic technology infrastructure in place to support operating rule implementation.

8. **Costs (Connectivity rule): Is your organization able to provide an estimate of the implementation cost for the requirements of the connectivity operating rule? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting this rule and its requirements?**

Our organization could provide an estimate of implementation costs for the requirements upon direct request.

The estimate can include:

- The size of the plan (membership)
- The number of trading partners engaged in exchange of the EDI transactions applicable to the connectivity rule using vC.2.2.0 and those exchanging in the formerly defined v4.0.0 version
- The volume of all EDI transactions applicable to the connectivity rule that are performed annually by real time and batch using vC.2.2.0 and those exchanging in the formerly defined v4.0.0 version
- Allocation of resources by real time versus batch transaction for each applicable transaction type
- Operational vs. capital implementation costs (or capital as a % of costs)
- Reduction in operational costs for decommission of the HTTP-MIME enveloping support

9. **Additional comments: Given that the Connectivity Rule is highly technical, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?**

As previously noted in response to items number 3 and 5.a., we are able to identify cost and resource reductions for the payer to adopt the connectivity rule. We would expect providers, or their vendors, could also realize a cost and resource benefit through implementing one common connectivity standard across the identified transactions for all payers with whom they exchange transactions.

10. **Additional comments: For the Prior Authorization operating rules, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?**

The HIPAA mandate requires implementation of the 5010X217 278 Request and Response transaction; however, it did not include the implementation of the 5010X215 278 Inquiry and Response transaction. This results in an incomplete work cycle for those requests that receive a pended prior authorization response. The provider and/or payer must then engage in some form of manual work to confirm the final transaction request result. The infrastructure rule component requiring an outbound unsolicited 278 response with finalized authorization result closes that gap; doing so within the standard that is mandated by HIPAA requirements.

11. **General**: **For each rule, please provide the rationale for your support or opposition to its adoption to inform the Committee's deliberations.**

Harvard Pilgrim supports the adoption of all three proposed operating rules:

- CAQH CORE Prior Authorization & Referrals (278) Data Content Rule vPA.1.0
- CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule vPA.2.0
- CAQH CORE Connectivity Rule vC3.1.0

Together the proposed rules form cohesive, uniform requirements that serve to reduce administrative burden and associated costs and enhance interactions between constituents.

Health plan support of the 278 has been federally mandated for many years; plans, vendors and providers should have the basic technology infrastructure in place to support operating rule implementation. This should be an incremental effort to adopt the operating rules.

In the absence of other standards proposed for common assessment, we recommend these operating rules be implemented to fill the need for consistency in advancing prior authorization capabilities in health care services. The importance of timely delivery of patient care should lead us to move forward and adopt uniform requirements as expeditiously as possible.

Laboratory Corporation of America® Holdings
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July 24, 2020

Via E-Mail: NCVHSmail@cdc.gov

U.S. Department of Health and Human Services
National Committee for Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: National Committee on Vital and Health Statistics (NCVHS)
Hearing of the Subcommittee on Standards
Request for Public Comments on Three CAQH CORE Proposed Operating Rules

Ladies and Gentlemen:

In a Federal Register notice dated June 23, 2020, the National Committee on Vital and Health Statistics (NCVHS or the Committee), Subcommittee on Standards, announced that at its August 25–26, 2020 hearing, NCVHS will address a request received on February 24, 2020, from the Council for Affordable Quality Healthcare (CAQH), Committee on Operating Rules for Information Exchange (CORE) Board, to consider three new operating rules for federal adoption: (1) CAQH CORE Prior Authorization Data Content Rule; (2) CAQH CORE Prior Authorization Infrastructure Rule; and (3) CAQH CORE Connectivity Rule. At this hearing, the Subcommittee on Standards will hear from invited industry stakeholders and review written testimony received in advance from interested individuals and organizations. NCVHS developed specific questions to ensure industry comments address key issues under consideration by the Committee.

Please accept the comments of Laboratory Corporation of America Holdings (LabCorp) on the above-referenced NCVHS questions. LabCorp is a global life sciences company that is deeply integrated in guiding patient care through its comprehensive clinical laboratory and end-to-end drug development services.

Our comments on specific NCVHS questions are provided below.

1. **Participation in development of the rules: If your organization participated in identification and development of the proposed operating rules for prior authorization and/or connectivity, describe the skill set of the individuals involved (business or technical) and in what way they participated in the process.**

LabCorp has appointed a liaison to interact with the different healthcare standard setting organizations. This individual has "boots on the ground" experience with the laboratory or indirect provider business model and is from the business sector with a strong understanding of the technical sector. The liaison role is intended to brief, translate and educate both the business and technical subject matter experts on industry initiatives.

For CAQH CORE, the liaison participates in the workgroup sessions. When it is time to gather work group consensus, the CAQH CORE process is to use on-line straw polls. When a straw poll is issued by CAQH CORE, the LabCorp liaison pulls together an internal cross functional team of subject matter experts. This team is briefed on the CAQH CORE work group purpose, scope and the discussions to date. The team examines, considers and responds to the straw poll questions. The liaison files the straw poll response for the company. All information from the team meetings is used to guide the liaison during CAQH CORE work group meetings.

2. **Workflow (prior authorization rules): In what way(s) will the proposed operating rules for prior authorization improve workflow for your organization's industry sector? Discuss the prior authorization data content and infrastructure rules and describe how the proposed requirements from each will impact your workflow, reduce burden (if relevant) and better support patient care.**

For the laboratory, as an indirect provider, the prior authorization process is slightly different from practitioners who meet face to face with patients. When a laboratory receives a specimen for testing, the primary focus is patient care. Regardless of available administrative information, testing is performed as quickly as possible. In many cases, services that require prior authorization may drive life changing decisions. A one-day delay in delivering test results could alter the treatment plan.

In most cases, the date the specimen was collected was prior to anyone knowing if a prior authorization is needed. For the majority of testing, the laboratory receives a test request from an ordering provider with a specimen. In general, the date of service for diagnostic laboratory tests is the date of specimen collection. This means the date of service will be prior to the prior authorization request. Within the CAQH CORE Infrastructure rule this scenario is known as a retrospective prior authorization. Retrospective prior authorizations are out of scope for the Infrastructure rule. Therefore, laboratories are excluded from the rule unless there is a way to delay the collection of a specimen until an authorization is obtained for the laboratory services.

By excluding retrospective prior authorizations from the Infrastructure rule, laboratories will still have to wait as few as 3 days and as many as 60 days for an authorization

determination. The authorization request will be returned to the laboratory long after the test results have been delivered to the ordering provider. Chances that the laboratory will receive an authorization decrease each day after the ordering provider receives the test results. There is no incentive for the ordering provider to supply any additional documentation that the payer may need once the ordering provider has the test results. Without supporting documentation from the ordering provider, the payer will deny the authorization request. Without authorization, payment to the laboratory will be denied. Therefore, workflow and payment for laboratories will not be improved with the Infrastructure rule as currently drafted.

For the Data Content rule, LabCorp has a concern with several rules. First, 4.1.1, "Patient Identification," requires that when the patient is the dependent, the subscriber's last name, first name, and date-of-birth be supplied along with the dependents' demographic information. Laboratories are indirect providers and typically do not meet face to face with patients. Laboratories must depend on the ordering provider to supply the required demographic information. If a subscriber's date of birth is needed for an authorization request, a laboratory may not be able to obtain this information without reaching out to the patient. Given that the laboratory did not see the patient face to face, the subscriber, for security reasons, may not be willing to disclose personal information such as date of birth to the laboratory. The eligibility transaction will only confirm the date of birth for the subscriber if a date is sent. The subscriber's date of birth is not on the member ID card.

Regarding rule 4.2.2.1, "Out-of-network Requester, Service Provider or Specialty Entity," there are times, such as for esoteric testing, that a laboratory may need to request authorization for a test when our organization may be out of network. It is beneficial to be alerted that LabCorp is out of network during the process. The alert allows for the estimated charges presented to the patient to reflect the use of an out of network provider and prevent surprise bills. The Data Content rule, as written, seems to prevent further action on the authorization request once the payer determines the provider is out of network.

Rules in section 4.2.3, "Requesting Additional Documentation for a Pended Response" have the potential to improve the current workflow for the industry. Knowing, all at one time, what documentation the payer requires to support the authorization request is beneficial. This allows for the laboratory to determine the information that should be supplied by the ordering provider and submit just one request for information to that provider. Multiple requests for information decrease the likelihood that all requests will receive a response.

3. **Transaction exchange (connectivity rule): In what way(s) will the proposed operating rule for connectivity improve the processing of transactions, message payload, connectivity, security, etc. if adopted by HHS? What are the anticipated benefits that this operating rule offers vs. the current state (please provide examples if possible)?**

The benefit of the proposed operating rule is the turnaround time, the rapid exchange/processing of data over real-time connected systems, and, to a lesser degree, the standardization of connectivity and security protocols across the healthcare industry. However, transaction and message structures are already well defined and largely subscribed to by many healthcare organizations, especially those that have adopted and implemented systems under the HIPAA guidelines. The dominant connectivity protocol adopted across HIPAA practitioners is sFTP/SSH (batch). However, there are also relevant exceptions, such as TLS 1.x.

HL7 transaction/message standard adherence is variable across vendor platforms, but the connectivity and security protocol is the largely adopted TCP/IP (MLLP) message-based protocol over VPN tunnels. Furthermore, interconnecting across organizations has never been a "one-size-fits-all" model that can be expected to be followed by all organizations. LabCorp currently processes millions of transactions and files each day across two B2B platforms supporting over 85,000 interfaces.

To add some additional clarity, the standardization benefit of the proposed operating rule for batch and real-time connectivity for organizations like LabCorp does not offer tangible connectivity and security benefit. There is no existing problem to solve there from LabCorp's perspective. Fortunately, the Safe Harbor of the proposed operating rule addresses the utilization of existing standards noted above. However, connectivity and security protocols continue to evolve, such as the x509 certificate-based authentication rule segment, and must be adopted to protect sensitive healthcare data moving across connected organizations. In addition, there is benefit to be realized by the rule for additional transactions that add business value to the industry and enhanced messaging and error reporting.

4. **Improving use of transactions and/or adoption of standards (all proposed operating rules): Describe how adopting the proposed operating rules will or could increase in the use of any of the adopted HIPAA transaction standards.**

The Prior Authorization & Referrals (278) Infrastructure Rule and Data Content Rules could propel the use of the Prior Authorization transaction (278) forward by establishing guiderails for authorization requests and responses. Unfortunately, there is not a standard to trade additional documentation that may be required with an authorization. In addition, laboratories are not able to utilize the Infrastructure rule. The benefits the rest of the industry may enjoy will be denied to laboratories due to the necessity of generating a date of service prior to knowing an authorization is required.

The adoption of the connectivity rule will, for the most part, not increase the use of the HIPAA standards. Very seldom is the electronic connection method a barrier to trading information with our referring providers or payers. The current connections maintained by LabCorp enjoy greater security protocols, have manageable maintenance processes, and both trading partners are able to deploy quickly if a new connection or update is needed. The only

benefit from adoption of the connectivity rule is that new trading partners will have the ability to invest in technology they know the whole healthcare industry will support.

5. **Connectivity rule implementation for your organization or industry wide (please specify):**
   a. **What are the implications, costs and benefits of implementing the new connectivity rule requirements (Rule 4.0.0) for the claims, prior authorization, premium payment and enrollment/disenrollment transactions? Providing generalized or high level information will be helpful tc the Committee.**
   b. **Can you provide general types of costs and benefits of meeting the processing mode requirements for both real time and batch submissions?**

The costs of real-time submissions for LabCorp may include the following:

- LabCorp has the technology in place to support proposed rules, so the costs we face are predominately related to labor to establish any new connections. This cost is part of the investment our organization makes when standing up a new trading partner.

- In some cases, proposed rule implementation may require additional engineering resources to scale infrastructure (hardware) and build interfaces to deploy (e.g., building and implementing interfaces that will support FHIR protocols/services).

- EHR and EMR vendors, as well as healthcare practitioners, may not have needed capital to support adoption, which will slow down LabCorp's progression to adopt the new rule (latency cost). However, a federal mandate and financial support should help facilitate needed change by vendors/trading partners.

The costs of batch submissions for LabCorp may include the following:

- Similar to real-time expected costs to support real-time proposed rule requirements, batch costs for LabCorp will be predominately related to labor, but, to a lesser degree, could also require additional hardware for scaling the platform. This cost is part of the investment our organization makes when standing up a new trading partner.

- Platform scaling for batch submissions is expected to be significantly less costly for LabCorp since most, if not all, of the system infrastructure and technical skills required are already on staff. However, normal business growth requires additional manpower periodically to ensure project throughput meets/exceeds service level agreement commitments. Adoption of proposed rule batch processing requirements could also result in a need for additional B2B platform engineer headcount due to protocols that are more labor intensive to update security protocols and patch software. However, the labor and potential hardware cost increases are expected to be approximately 25% less than that required to build extensive real-time submission capabilities.

The benefits of moving to a more real-time centric interfacing model may include the following:

- The obvious benefit of moving to a more real-time centric interfacing model is more rapid exchange and processing of data supporting critical needs for patient care/wellbeing, as well as time-sensitive transactions/payload for strategic business units of the organization. For example, implementation of prior authorization across the industry will ensure that expected revenue for laboratories is significantly more predictable.

- Moving to a more real-time centric interfacing model may also improve the turnaround time of error/exception correction and data resubmission. For example, real-time exchange of data will enable organizations' business and operational units to focus on exception mitigation at the point of impact with real-time submission of problematic transactions, coupled with rapid responses from the transaction originating organization.

- Payload size would be largely reduced in a real-time model, which would represent a generally more consistent/predictable flow of data and processing demand across organization platform daily processing cycles.

- The federal mandate to close automation gaps will promote widespread adoption across the industry.

6. **Implementation time frame for each proposed rule:**
   a. **What is the anticipated lead time needed by your organization to develop, test and implement the proposed operating rules? What are the dependencies that impact the timeline, e.g., vendors, trading partners and business associates? If possible, please provide an estimate of the amount of time your vendors would require to develop their component of the solution?**

For the Connectivity rule, LabCorp is heavily dependent on EHR and EMR Vendor support to implement new system functionalities required to support system changes to optimize organization data/information integration. It is expected that there will be some latencies to overcome from vendors, trading partners, and business associates (external to LabCorp) related to implementing the proposed operating rules. For LabCorp, which supports 85,000 connections, a one-year window would be required for implementation and another year for testing. This equates to a two-year period to fully implement the rules.

For the Prior Authorization operating rules, LabCorp would need approximately two years to develop, test and implement the rules. We work with more than 3,000 different commercial and government payers. The prior authorization landscape is very dynamic and we could find that some payers may contract with utilization management organizations to take on the prior authorization process. We may see this change as payers try to reduce costs. Moreover, the

service level agreements within the rules could create costs that are better managed by organizations that have the infrastructure in place. Payers that convert to utilization management services will require additional testing to ensure adherence to the payer's policies.

b. Should considerations be given to size or organization type for the proposed implementation timeframe? Please discuss for each of the proposed operating rules (Prior authorization content, prior authorization infrastructure and connectivity).

No consideration should be given for the size of an organization. Most small organizations use vendors to support their offices. These vendors will be making the changes and should be able to apply the changes to all of their clients during the implementation window. Dividing the industry by size adds unneeded complexity to the project plan.

7. Costs (Prior Authorization rules): Is your organization able to provide an estimate of the implementation cost for the requirements of the two prior authorization operating rules for data content and infrastructure? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting these rules?

We are not able to determine a cost to implement the authorization rules. The best cost benefit determination could be calculated by potential collection of payment for services. If a provider can reduce collection time for services performed by four to 60 days, the investment to implement the operating rules would be a true benefit. Claims are generally more difficult to collect the longer they remain outstanding. Collecting payments more quickly can help reduce the risks of incurring losses and reduces a company's borrowing requirements. Unfortunately, laboratories would not benefit from the turnaround time rules, so there is not a cost benefit for LabCorp.

8. Costs (Connectivity rule): Is your organization able to provide an estimate of the implementation cost for the requirements of the connectivity operating rule? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting this rule and its requirements?

LabCorp has set forth its projected costs of implementation for the requirements of the connectivity operating rule in its response to Question 5 above.

9. Additional comments: Given that the Connectivity Rule is highly technical, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?

There is a need to have options to support both machine-to-machine interchange and machine-to-human interchange as the healthcare industry continues to mature and technology evolves.

Connectivity must have the ability to stand up to GDPR Security requirements as well as other privacy and security requirements.

10. Additional comments: For the Prior Authorization operating rules, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?

Just as the HIPAA law, problematically, did not include acknowledgements as a named transaction, it would be problematic to exclude retrospective prior authorizations for laboratory testing from the infrastructure rule, a major service that drives clinical decisions. The infrastructure rule, as written, has the potential to change the paradigm of the current industry workflow. If laboratories have to wait up to 60 days for a prior authorization response, the ordering provider may choose to request the authorization for the laboratory. Currently, some payers and utilization management organizations prohibit this process.

LabCorp suggests a modification to the infrastructure rule. If a retrospective prior authorization request is received by the payer, and the place of service code represents a laboratory, the request should enjoy the same benefits of the operating rule as the ordering provider community.

11. General: For each rule, please provide the rationale for your support or opposition to its adoption to inform the Committee's deliberations.

LabCorp nominally supports the Connectivity rule. The rule provides a safe harbor if needed. It does not prevent current protocols that are in place today between trading partners. However, the rule is barely adequate for the privacy and security environment the healthcare industry finds itself working in today.

LabCorp does not support the prior authorization rules. We are disappointed in the exclusion of the laboratory business model from the Infrastructure rule. The rule has the potential to improve the current workflow for authorizations, improve patient care, and save money for both the payer and provider communities. However, the rule also has the potential to create an unexpected paradigm shift in the current workflow. Also, by excluding retrospective prior authorization for testing from the infrastructure rule, a major tool that drives clinical decisions will still have to wait as many as 60 days for an authorization determination that will be returned to the laboratory long after the test results have been delivered to the ordering provider.

LabCorp has several concerns with the Data content rule. There is a need to seek authorization even if our organization is out of network for a patient. The demographic information that is defined in the rule is often not readily available to indirect providers such as laboratories, generating a need to contact the patient for the required information. If the laboratory did not see the patient face-to-face, a patient may not be willing to disclose personal information such as date of birth to the laboratory.

It appears that retrospective prior authorizations were left out of the rules by CAQH CORE because CAQH CORE was trying to put forth rules that cover 80% of the workflow. We are unaware of other standard setting organizations whose rules cover just a portion of the workflow. It is a concern that CACH CORE has proposed operating rules that do not address the entire workflow.

Thank you for the opportunity for LabCorp to submit written testimony regarding the three CAQH CORE proposed operating rules. Our organization believes in the process to vet proposed standards prior to being included in regulation. We respectfully request that NCVHS consider the unintended adverse consequences that may be associated with the prior authorization rules as drafted. We look forward to NCVHS' August 25–26, 2020 hearing.

Very truly yours,

Donald E. Horton, Jr.
Senior Vice President, Global Government Relations & Public Policy

Marshfield Clinic
Health System

1000 North Oak Avenue
Marshfield, WI 54449

August 14, 2020

William W. Stead, MD
Chair
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: CAQH CORE Operating Rules Proposed to NCVHS for Federal Adoption

Dear Dr. Stead,

Thank you for the opportunity to provide feedback on the CAQH Committee on Operating Rules for Information Exchange (CORE) Prior Authorization and Connectivity Operating Rules proposed to the National Committee on Vital and Health Statistics (NCVHS). The Marshfield Clinic Health System (MCHS) fully supports the proposal and recommends the operating rules to NCVHS and the Department of Health and Human Services (HHS) for federal adoption under HIPAA.

MCHS is an integrated health system serving northern, central, and western Wisconsin. Our 1,270 providers accommodate 3.5 million patient encounters each year across our 9 hospitals and almost 60 clinical sites. The Marshfield Clinic Research Institute is the largest private medical research institute in Wisconsin with more than 30 Ph.D. and M.D. scientists and 150 physicians engaged in medical research. We also are a teaching health system, providing over 1,300 students with over 2,300 educational experiences throughout our system. Our primary service area encompasses over 80 percent of the rural population of the state of Wisconsin. In fact, over half of our 60+ facilities are located in communities of less than 2,000 people. And, we are the largest provider of primary and specialty care in our region. Most importantly, throughout our century plus history of providing high-quality and accessible care, we have been leaders in creating value-based models that reduce costs and improve coordinated care for our patients.

Over 125 organizations, including MCHS, participated in the development of the proposed operating rules through a collaborative, consensus-based process. As the former Chair of the CAQH CORE Board, and the current Immediate Past Chair, I have invested significant time in using my clinical and executive experiences to inform the development of these principles. These standards are an important advancement and reflect best practices from across our industry.

The healthcare industry has lamented for many years that the prior authorization process is overly burdensome and unnecessarily costly. The operating rule package proposed by CAQH CORE will drive greater automation, increase efficiencies, and enhance health plan and provider data exchange. The

proposed rules represent meaningful steps that healthcare stakeholders can take now to support the move toward automation of prior authorization. Specifically:

- The CAQH CORE Prior Authorization Operating Rules form the foundation of a roadmap to move the industry toward an end-to-end automated workflow for prior authorization adjudication. The rules reduce the unnecessary back and forth between providers and health plans, accelerate adjudication timeframes, and reduce provider resources spent on manual follow-up.

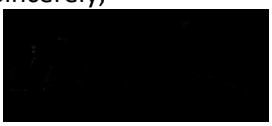
- The CAQH CORE Connectivity Rule vC3.1.0 enhances security and promotes uniform interoperability requirements across administrative transactions. A single, updated safe harbor connectivity method for the industry will simplify data exchange and eliminate the need to support the older, outdated versions of CAQH CORE Connectivity that are currently mandated.

Further, the proposed CAQH CORE Operating Rules set the stage for future innovation to further enable the critical convergence of administrative and clinical data and support the use of new technologies with existing standards.

MCHS applauds NCVHS efforts to accelerate the adoption of standards and operating rules to achieve the purposes of security, automation, efficiency and interoperability of health data and systems. We encourage NCVHS to promote industry progress by supporting and advancing industry-driven efforts like the CAQH CORE Operating Rules.

Thank you for the opportunity to provide comment. Please do not hesitate to reach out with questions.

Sincerely,



Susan L. Turney, MD
Chief Executive Officer
Marshfield Clinic Health System

Testimony by the Medical Group Management Association

To:

The National Committee on Vital and Health Statistics
Subcommittee on Standards

Submitted July 24, 2020

The Medical Group Management Association (MGMA) is pleased to submit the following testimony to the National Committee on Vital and Health Statistics on the issue of prior authorization. We commend the Committee for recognizing the need to improve prior authorization and for reviewing the Council for Affordable Quality Healthcare (CAQH), Committee on Operating Rules for Information Exchange (CORE) proposal to adopt the Prior Authorization (278) Data Content Rule, Prior Authorization (278) Infrastructure Rule, and Connectivity Rule Version PA 2.0 under the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

MGMA is the premier association for professionals who lead medical practices. Since 1926, through data, people, insights, and advocacy, MGMA empowers medical group practices to innovate and create meaningful change in healthcare. With a membership of more than 58,000 medical practice administrators, executives, and leaders, MGMA represents more than 12,500 organizations of all sizes, types, structures, and specialties that deliver almost half of the healthcare in the United States.

Health plan prior authorization requirements are a significant burden for physician practices-costing time and money for the organization and delaying the delivery of patient care. Although HIPAA mandated and the Department of Health and Human Services implemented an electronic transaction standard for prior authorization, it continues to be woefully underused. Practices typically rely on fax, mail, or logging into proprietary web portals to conduct prior authorizations. As you will see from our testimony, while we are supportive of the three sets CORE operating rules under discussion, we assert that additional steps must be taken to improve the current prior authorization environment.

Key Recommendations

- MGMA is supportive of the CAQH CORE Prior Authorization (278) Data Content and Infrastructure Rules (PA Version 2.0) being federally mandated. We believe adoption of these operating rules will improve the current prior authorization by standardizing the data content of the electronic transaction and requiring a maximum time for health plans to respond to authorization requests.

- We recognize that the two-business day requirement for the plan to request additional information from the provider and the two-business day requirement for the health plan to provide a final determination was a compromise between providers and health plans. While an improvement over the current lengthy and non-standardized plan response times, we urge that these maximum timeframes be significantly shortened to improve the care delivery process.

- MGMA asserts that while these operating rules will impose important new requirements on health plans, additional reforms are needed to substantially improve the prior authorization process. These reforms include eliminating prior authorization for services that are routinely approved and for providers in risk contracts, promulgating the regulation for electronic attachments, exploring new standards to automate the authorization process, and increasing enforcement against non-compliant health plans.

MGMA Response to Committee Questions

1. *Participation in development of the rules: If your organization participated in identification and development of the proposed operating rules for prior authorization and/or connectivity, describe the skill set of the individuals involved (business or technical) and in what way they participated in the process.*

MGMA Response: MGMA was one of more than 125 organizations that collectively contributed to the development of the proposed operating rules. These entities represent a range of stakeholders including providers, health plans, vendors, clearinghouses, associations, standards development organizations, and government agencies.

MGMA staff participated on all calls and completed all of the polls throughout the development process for each of the operating rule sets. MGMA's representative for the CORE operating rules development process has more than 20 years' experience in standards development environment, leads industry administrative simplification efforts, and has participated in CORE since its inception in 2005.

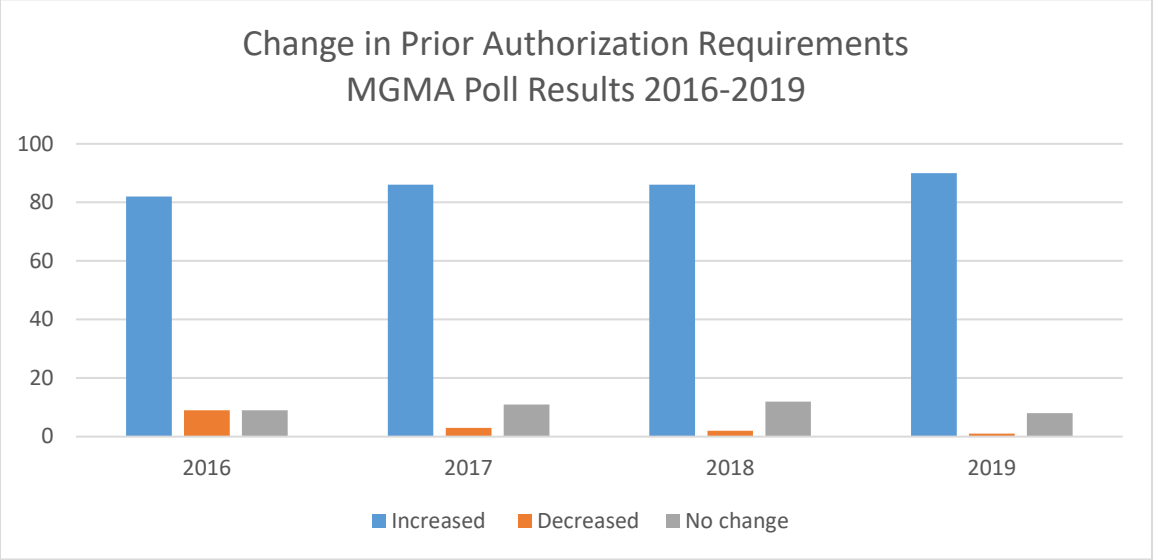
We want to commend CAQH CORE staff for their professionalism during the rule development process and for their willingness to engage and collaborate with impacted stakeholders. We also wanted to applaud CORE's recent revision of its operating rule structure and its transition to a business transactions-based model. This new approach structures the operating rules into logical categories and should facilitate a faster rule updating process.

2. *Workflow (prior authorization rules): In what way(s) will the proposed operating rules for prior authorization improve workflow for your organization's industry sector? Discuss the prior authorization data content and infrastructure rules and describe how the proposed requirements from each will impact your workflow, reduce burden (if relevant) and better support patient care.*

MGMA Response: Before we can discuss how new operating rules could impact physician practice workflow, it is important to understand the current prior authorization environment. Prior authorization continues to be one of the most onerous administrative processes faced by physician practices. As a cost-control process requiring providers to qualify for payment by obtaining approval before performing a service, prior authorization is overused, costly, inefficient, and can be responsible for delays in patient care.

Documentation requirements from health plans for items and services associated with prior authorization and ordering for certain medical services are also significant sources of administrative burden. Congress and the Administration can play an important role in evaluating and addressing administrative processes and clinical workflow factors contributing to this burden. While electronic health records, practice management system software vendors and other health IT solutions can also play a role in reducing this burden, prior authorization processes clearly suffer from a lack of standardization and common approaches from health plans.

Not only are prior authorization requirements challenging, but MGMA members also report that the requirements from health plans are actually increasing. In a poll conducted in September 2019 with almost 1,000 respondents, 90 percent reported that prior authorization requirements had increased in the past year, 9 percent stated that requirements had stayed the same, and one percent indicated they had decreased. Over the past few years, MGMA members have reported a consistent spike in prior authorization requirements (see below).



To put prior authorization into perspective and to compare this task with other administrative burdens facing medical practices, the 2019 MGMA regulatory burden survey asked practice executives to rate a number of administrative challenges from not burdensome to extremely burdensome. The survey results were released October 2019 and included responses from executives representing over 400 group practices.

Two-thirds of respondents are in practices with less than 20 physicians and 14 percent are in practices with over 100 physicians. Three-fourths of respondents are in independent practices. Survey respondents identified prior authorization as the leading regulatory burden facing their practice in 2019 (see below).

	Not burdensome	Slightly burdensome	Moderately burdensome	Very burdensome	Extremely burdensome	Very + Extremely
Prior authorization	2%	5%	10%	22%	61%	83%
Medicare quality payment program (MIPS/APMs)	4%	2%	17%	30%	47%	77%
Audits and appeals	1%	9%	23%	35%	32%	67%
Lack of EHR interoperability	5%	10%	20%	33%	32%	65%
Medicare Advantage chart audits	6%	10%	23%	26%	35%	61%
Translation and interpretation requirements	8%	14%	24%	26%	28%	54%
Medicare and Medicaid credentialing	4%	18%	31%	24%	23%	47%
HIPAA privacy and security	8%	15%	35%	28%	14%	42%
Federal fraud and abuse law	17%	22%	37%	18%	6%	24%

Prior authorization approval rates and practice costs

The utilization of medical services and medications should not significantly increase if prior authorization requirements are relaxed due to the fact that the majority of authorization requests are ultimately approved. In October 2019, MGMA took a poll of almost 200 physician practice executives asking a series of questions regarding prior authorization requests. We received the following responses:

- Seventy-two percent of prior authorization requests submitted to their health plans are approved during the first submission.
- Seventy-five percent of prior authorization requests that are not approved during the first submission process and are subsequently appealed are approved by their health plans following the appeal.
- Eighty-five percent of prior authorizations that require a peer-to-peer (practice clinician to health plan clinician) discussion are approved by your health plans.

Respondents reported that the majority of authorization requests are approved by the health plan the first time they are submitted and for those that are appealed by the practice following a denial by the health plan, again, the majority are approved. In those cases where the appeal requires a peer to peer (direct discussion between the practice clinician and a clinician designated by the health plan) consultation, the vast majority of authorizations are approved by the health plan.

Practice costs related to prior authorization include:

- Clinical and administrative staff time spent determining if an authorization is necessary for a specific service, test, or medication. Each health plan has their own proprietary medical necessity requirements, thus adding additional burden for practice staff. Some

practices report they are forced to have staff assigned to specific health plans to conduct prior authorizations.
- Clinical and administrative staff time determining what documentation is required to support the individual plan's medical necessity requirements.
- Administrative staff time transmitting the prior authorization request and support documentation to the health plan (most often via mail, facsimile, or uploaded through a health plan's proprietary website).
- Clinical and administrative staff time spent responding to an authorization denial, which may include compiling and transmitting additional clinical documentation.
- Clinical staff time to engage in a peer-to-peer discussion of the clinical issues.

The 2019 CAQH Index reports that prior authorization is the costliest and most time-consuming administrative transaction for providers. On average, providers can save more than $9 per transaction by moving from fully manual to fully electronic transactions (X12 278) and more than $2 per transaction by moving from web portals to fully electronic.

It is important to note that the Office of the National Coordinator for Health Information Technology (ONC) final report "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs," released February 21, 2020, also identifies prior authorization as a critical challenge facing clinicians. On page 14, the report correctly states "EHRs and other health IT solutions can also help to mitigate this burden, but prior authorization processes suffer from a lack of standardization and common approaches." The report makes recommendations aimed at alleviating the burdens associated with practices meeting health plan prior authorization requirements, including supporting automation of prior authorization processes through adoption of standardized templates, data elements, and real-time standards-based electronic transactions.

Support for the Proposed CAQH CORE Operating Rules

The CAQH CORE Prior Authorization (278) Data Content and Infrastructure operating rules take a modest step toward realizing the goals set out in the ONC final report by enhancing the X12 278 by closing automation gaps, reducing administrative burden, and reducing maximum adjudication timeframes. The Prior Authorization (278) Data Content Rule further standardizes the data shared between health plans and providers. The rule targets one of the most significant problem areas in the prior authorization process: the pending of authorization requests from health plans for what they claim is missing or incomplete documentation. The rule should reduce somewhat the unnecessary back and forth between providers and health plans that often occurs when confirming medical necessity, enabling shorter adjudication timeframes and less manual follow-up. We concur with CAQH CORE that there are content areas addressed in this Rule that could have a positive impact on the prior authorization workflow. These include:

- Receipt and processing of diagnosis/procedure/revenue codes for specified categories of services and detection and display of all code descriptions should assist in auto adjudication.
- Consistent patient identification and verification should reduce common errors and denials by providing a complete set of demographic data to ensure a better patient/subscriber match.
- Return of specific AAA error codes and action codes (used to identify security validation requirement issues and to indicate plan business edits) when certain errors are detected on the authorization request should improve electronic communication between practices and plans and reduce the need for manual follow-up.

- Return of Health Care Service Decision Reason Codes should provide a clearer explanation to the practice of plan required next steps.
- Use of PWK01 Code (or Logical Identifiers Names and Codes & PWK01 Code) should provide direction on status and what additional clinical information is needed for health plan adjudication of the prior authorization request.
- Detection and display of all code descriptions could reduce the burden of interpretation on the provider.
- "Requesting Additional Documentation for a Pended Response" has potential to improve the current workflow for the industry. Knowing, all at one time, what documentation the health plan requires to support the authorization request is beneficial. This allows for the downstream provider to determine the information that should be supplied by the ordering provider and submit just one request for information to that provider. Multiple requests for information decrease the likelihood that all requests will receive a response.

We do have a concern with the Patient Identification rule (4.1.1) that requires that when the patient is the dependent, the subscriber's last name, first name, date-of-birth to be supplied along with the dependents demographic information. Certain types of providers (i.e., laboratories) do not meet face to face with patients and are dependent on the ordering practice to supply the demographic information. Requiring the subscriber's date of birth for the authorization request would force the provider to find the information, including potentially reaching out directly to the patient. This would add considerable administrative burden, especially if the patient is reluctant to share that information over the phone.

There has been much discussion regarding what industry entity should be responsible for developing data content for the electronic transactions. Optimally, a single entity should be responsible for data content, most likely the appropriate Standards Development organization (SDO). Yet this presupposes that the SDO will exhibit certain characteristics, including actively soliciting input from providers, incorporating modifications that increase the usefulness of the transaction, and acting quickly to meet industry needs. When one or more of these characteristics are not met, it is imperative that another entity step up to ensure that the transactions are responsive to the needs of practices and improved in a timely manner. With the long gap between mandated transaction versions, it was important that CAQH CORE fill the void with its data content and infrastructure operating rules. We do note, however, that an improved standards development process would most likely negate the need for operating rules.

3. *Transaction exchange (connectivity rule): In what way(s) will the proposed operating rule for connectivity improve the processing of transactions, message payload, connectivity, security, etc. if adopted by HHS? What are the anticipated benefits that this operating rule offers vs. the current state (please provide examples if possible)?*

MGMA response: Updating the federally mandated connectivity requirements from vC1.1.0 and vC2.2.0 for the eligibility, claims status, and ERA transactions to an updated version for prior authorization could offer the following benefits:

- Moving to an updated CAQH CORE Connectivity version has the potential of enhancing interoperability, efficiency and security by defining technical requirements for the exchange of the electronic transactions between trading partners so entities can be assured of a common connectivity method–effectively creating a safe harbor.
- Mandating this updated version could assist in ensuring a common connectivity method for the exchange of eligibility, claim status, ERA and prior authorization transactions which reduces the need to support multiple connectivity methods.

However, we do not support the mandating of Connectivity Rule C3.1.0 at this time. CAQH CORE is currently working on an updated set of Connectivity operating rules (Version C4.x). CAQH CORE expects this version to be completed by the end of 2020. Rather than potentially require the industry to update an already outdated rule (C3.1.0), we recommend NCVHS wait until CAQH CORE finalizes and approves this new version before revisiting this issue and potentially including it in a set of federal mandates.

4. *Improving use of transactions and/or adoption of standards (all proposed operating rules): Describe how adopting the proposed operating rules will or could increase in the use of any of the adopted HIPAA transaction standards.*

MGMA response: We are optimistic that the requirements in the proposed rules will improve the value of the 278 transaction by specifying and standardizing the transaction infrastructure and the data shared between practices and health plans. Potential improvements include:

- The data content requirements could assist a practice more accurately request member-specific information needed for a prior authorization and enable a health plan to clearly communicate next steps in the prior authorization process to the practice, including what additional documentation is needed.
- The availability of enhanced data content has the potential of streamlining the review of prior authorization requests, facilitate faster response times, and provide for an automated adjudication of a final determination.
- Additionally, the timeframe requirements in the infrastructure rule could act as an incentivize for practice adoption as they can be more assured of a maximum response time when utilizing the 278 transaction. A federal mandate would also reduce the need for health plans to comply with varying state requirements.

5. *Connectivity rule implementation for your organization or industry wide (please specify):a. What are the implications, costs and benefits of implementing the new connectivity rule requirements for the prior authorization, eligibility & benefits, claim status and electronic remittance advice transactions? Providing generalized or high-level information will be helpful to the Committee. [Note, this question has been revised to remove reference to claims, enrollment/disenrollment, and premium payment transactions for which operating rules have not been adopted by HHS.] b. Can you provide general types of costs and benefits of meeting the processing mode requirements for both real time and batch submissions?*

MGMA response: CAQH CORE is proposing Connectivity Rule V PA 2.0 for the HIPAA-mandated eligibility, claim status, and ERA transactions. CAQH CORE is also proposing the CAQH CORE Connectivity Rule apply to the prior authorization transaction for federal mandate per the CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule.

As a result of the CAQH CORE Connectivity Rules vC1.1.0 and vC2.2.0 becoming federally mandated by the Department of Health and Human Services (HHS) in 2013, a large industry installed base of these connectivity rules exists among HIPAA-covered entities that exchange administrative transactions. The CAQH CORE Connectivity Rule vC2.2.0 includes requirements addressing the message envelope, corresponding envelope metadata, vocabularies and semantics, real time and batch processing modes, authentication, and transport security.

The only new processing mode requirements proposed by CAQH CORE are in the CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule. This rule requires that a health plan or its agent implement server requirements for either real time or batch processing mode

for the 5010X217 278 Request and Response transactions. Building off existing infrastructure for real time and batch processing in place for eligibility, claim status and ERA, implementation of the 5010X217 278 can be expediated given implementation of currently mandated operating rules. Leveraging existing efforts greatly reduces costs of implementation.

However, development of a revised version is currently underway at CORE. Updating the CAQH CORE Connectivity Rule to a more appropriate version will improve security and simplify interoperability across administrative transactions (see also the answer to Question 3).

6. *Implementation time frame for each proposed rule: a. What is the anticipated lead time needed by your organization to develop, test and implement the proposed operating rules? What are the dependencies that impact the timeline, e.g., vendors, trading partners and business associates? If possible, please provide an estimate of the amount of time your vendors would require to develop their component of the solution? b. Should considerations be given to size or organization type for the proposed implementation timeframe? Please discuss for each of the proposed operating rules (Prior authorization content, prior authorization infrastructure and connectivity*). 6 a. Should considerations be given to size or organization type for the proposed implementation timeframe?

Practices themselves will likely not be required to implement the technical portions of the Rules. For the Connectivity rule, practices will be heavily dependent on their EHR vendors to implement new system functionalities required to support system changes to optimize organization data/information integration. We expect some challenges to overcome from smaller EHR vendors and other trading partners related to implementing the proposed operating rules. Practices could be impacted by the data content and infrastructure provisions of the Rules and prior authorization workflows may need to be modified. However, we expect these changes will should not take very long to complete.

We note that the CAQH CORE Certification process typically takes between three to six months, depending on an organization's readiness and resources committed to the project. All covered entities, regardless of their size or type, should be given 24 months to comply with this federal mandate-the same amount of time provided covered entities for implementing he operating rules for the 270/271, 276, 835, and electronic funds transfer transactions.

7. *Costs (Prior Authorization rules): Is your organization able to provide an estimate of the implementation cost for the requirements of the two prior authorization operating rules for data content and infrastructure? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting these rules?*

MGMA response: While we are not able to provide an estimate of the specific implementation costs for the requirements of the two prior authorization operating rules for data content and infrastructure, we urge NCVHS to leverage data from the 2019 CAQH Index to determine the potential savings for the industry of the proposed rules.

We expect that adoption of the proposed prior authorization operating rules should accelerate increased use of the 278 transaction and somewhat reduced administrative costs. Prior authorization is the costliest and most time-consuming manual transaction tracked by the CAQH Index. According to the most recent Index, the industry could save $12.31 per prior authorization transaction by moving from manual processing to use of the HIPAA-mandated 278 Request and Response.

A cost-benefit determination could be calculated by potential improvement in the overall collection of payment for services and delivery of patient care. Streamlining and accelerating the process will result in reduced staff time processing authorizations. As many practices rely on retrospective authorizations to speed up patient care, moving more authorizations to the front of the delivery process should reduce accounts receivable.

8. *Costs (Connectivity rule): Is your organization able to provide an estimate of the implementation cost for the requirements of the connectivity operating rule? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting this rule and its requirements?*

MGMA response: While we are not able to provide an estimate of the implementation cost for the requirements of the connectivity operating rule on covered entities we note that covered entities that were required to implement the CAQH CORE Connectivity Rule vC2.2.0 will not be required to fully implement all requirements due to commonalities in transport, envelope, authentication standards, and metadata. We expect that implementation costs for these organizations will be less due to only needing to support one submitter authentication standard.

9. *Additional comments: Given that the Connectivity Rule is highly technical, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?*

MGMA response: Updating the currently mandated CAQH CORE Connectivity requirements for eligibility, claim status, and ERA transactions will ensure a modern and secure connectivity method is available for industry and reduce the need for continued industry support for multiple authentication standards. Additionally, a single (appropriate) connectivity rule across all transactions is easier to update, reduces confusion, and promotes industry alignment on best practices.

10. *Additional comments: For the Prior Authorization operating rules, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?*

MGMA response: We are supportive of the proposed CAQH CORE Data Content and Infrastructure operating rules for prior authorization and believe they will help to streamline the current prior authorization process. However, we urge the Committee to consider the following recommendations for augmenting and improving these operating rules:

- Prior authorizations deemed urgent should have a maximum response time of 24 hours once the provider has supplied the health plan with all the supporting documentation they require.

- The CORE infrastructure rule PA Version 2.0 currently stipulates response times for initial health plan response and final health plan response as 2 "business" days. We assert that this should be changed to 48 hours for each response. Healthcare delivery is not a Monday through Friday event. Business days do not include weekends or federal holidays. In practical terms, 2 business days could translate to a full 5 days between health plan responses-leading to unacceptable delays in patient care.

- The CORE infrastructure rule PA Version 2.0 (Time Requirement for a 5010X217 278 Response Close Out Due to a Lack of Requested Information/ Documentation) currently stipulates that providers have a maximum of 15 business days to respond

to a health plan's request for additional supporting documentation before the request is closed by the plan. This timeframe does not adequately take into account the current care delivery process. For some authorizations, providers will be required to order additional tests, requiring patient action and follow up on the part of the practice. We urge the Committee to extend to 30 business days the maximum time providers have to respond to a health plan's request for additional supporting documentation.

- We also recommend the following modification to the CORE infrastructure rule PA Version 2.0. If a retrospective authorization request is received by the health plan, and the place of service code is "laboratory," the request should follow the same requirements for the operating rule as the ordering provider.

The NCVHS has, on numerous occasions, held hearings and issues recommendations to the HHS Secretary on prior authorization and related issues. As the Committee views these operating rules as a chance to modestly streamline the current prior authorization process, we offer the following recommendations for achieving more significant reform of prior authorization:

1. **Health plan transparency**. Health plans should be required to make available on a public section of its website a list of all items and services that are subject to a prior authorization requirement under the plan and a template of the clinical information the plan requires in order to fully adjudicate the prior authorization request for all items and services that are subject to a prior authorization requirement. Full transparency of what items and services require a prior authorization and the specific clinical documentation the practice is required to submit to support a prior authorization request will significant decrease the administrative burden associated with these processes.

   Further, access to this information will permit EHR and other vendors to develop automated prior authorization solutions that will decrease burden for the practice and reduce delays in the care delivered to patients.

2. **Establishment of programs excluding clinicians from prior authorization requirements**. Health plans should be required establish programs to exempt providers from the prior authorization process upon a provider's demonstration of compliance with the plan's coverage, coding and payment rules. Plans should exempt providers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during a designated assessment period. Excluding clinicians who adhere to a plan's coverage, coding and payment rules from prior authorization requirements not only rewards those clinicians with decreased administrative burdens but can also serve as an incentive for other clinicians to more closely adhere to coverage, coding, and payment rules.

3. **Adoption of policies excluding clinicians who are participating in a risk-based contracts from prior authorization requirements**. Health plans should be required to establish programs exempting providers from any prior authorization requirements if they enter into a contract with the plan that requires the clinician take on one or two-sided risk.

   Excluding clinicians who have entered a risk-based contract from prior authorization requirements is appropriate for two reasons. First, clinicians who are in an at-risk contract are already inherently incentivized to furnish cost-effective, high quality care

and avoid overutilization of services. Second, waiving burdensome prior authorization requirements that are unnecessary in risk-based contracts will serve as an incentive to establish these contracts.

4. **Adoption of the X12 275 electronic attachments standard**. In four separate letters, NCVHS has recommended that HHS move forward with issuing a final regulation establishing a national standard for electronic clinical documentation attachments. Plan adoption and support of the X12 275 electronic attachment standard will significantly decrease administrative burden and cost for the practice and reduce delays in the care delivered to patients. Absent this electronic attachment standard, we assert widespread use of the 278 transaction will be significantly suppressed.

5. Enforcement of standards and operating rules. HHS

6. **Improvement of the standards development process.** The current process to develop and mandate electronic standards does not permit the rapid adoption of modifications necessary to keep up with the ever-changing healthcare environment. The NCVHS 2019 "Predictability Roadmap" outlined opportunities to improve the standards development process. We urge the Committee to continue working with the physician practice community and other impacted stakeholders to identify to HHS an appropriate pathway toward administrative simplification.

We thank you for your consideration of these comments and recommendations. We look forward to continuing to work with the Committee to identify opportunities to reduce the volume of prior authorization requirements and automate the remainder. Should you have any questions regarding this testimony, please contact Robert Tennant, Director of Health Information Technology Policy, at 202.293.3450 or rtennant@mgma.org.

From:	Fuller, Diana (DHHS)
To:	NCVHS Mail (CDC)
Cc:	Veverka, Charles (DTMB-Contractor); Hinkle, Lori (DHHS); Scott, Karen (DHHS); Bond, Alexis (DHHS); Fuller, Diana (DHHS)
Subject:	Response to Request for Public Comment on Three CAQH CORE Proposed Operating Rules: Revised Instructions for Submission
Date:	Thursday, July 23, 2020 4:22:02 PM
Attachments:	Comments on CAQH PA 278 Proposed Rules For NCVHS Review.docx Sample Letter Language.docx

Good afternoon,

Here are our responses to your request for public comment on the three CAQH-Core Proposed rules for 278: PA 278 Data Content Rule, PA 278 Infrastructure Rule, and the Connectivity Rule. Attached you will find a document with our responses to your questions and a document with sample letter language we use.

Thank you,

Diana L Fuller
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Department of Health and Human Services
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Comments on CAQH PA 278 Proposed Rules for NCVHS Review

NCVHS Questions:

1. **Participation in development of the rules:** If your organization participated in identification and development of the proposed operating rules for prior authorization and/or connectivity, describe the skill set of the individuals involved (business or technical) and in what way they participated in the process.

Answers:

Our organization selected a 3-person team to participate with CAQH throughout the development of these Proposed Rules, a team which has also been engaged with the WEDI Prior Authorization (PA) Work Group since its inception. Consisting of a subject matter expert with 25 years' PA operations experience; a business process and systems expert having 18 years' experience; and an EDI analyst contributing over 9 years' experience on HIPAA transaction exchange and processing, this group attended all conference calls, prepared documentation for work group review, provided survey materials, completed questionnaires, and engaged leadership of CAQH and WEDI Work Groups in one-on-one telephone and in-person discussions for the sharing of perspective and to consider potential improvements. Our team worked off-line to evaluate all aspects of the Proposed Rules regarding both anticipated effectiveness for the Payer community as a whole, and Payer business process and system revisions needed to support the PA improvement initiative. To the best of our knowledge, we are the only organization that devoted a multi-disciplinary team to the investigation of all CAQH-CORE and WEDI PA-related initiatives for over four years, which also engaged with CAQH throughout development of these Proposed Rules.

2. **Workflow (prior authorization rules): A.** In what way(s) will the proposed operating rules for prior authorization improve workflow for your organization's industry sector? B. Discuss the prior authorization data content and infrastructure rules and describe how the proposed requirements from each will impact your workflow, reduce burden (if relevant) and better support patient care.

Answer:

A. As a Medicaid Payer organization that has continually worked for the improvement of PA request handling, the Proposed Rules are not expected to improve our workflow, will instead increase the burden on our Provider/Payer PA business process, and raises concern on potential negative impact on timeliness of decisions related to patient care.

Please note that in our environment, there are very few inpatient services that require PA, and those that do require PA are typically are not urgent/emergent and a PA determination should be obtained prior to the patient being admitted to the hospital. The majority of our PA requirements apply to in-home and Durable Medical Equipment requests. Our agency does not require PA for emergency inpatient care. We have a process supporting urgent decisions for in-home care within a 24-hour turnaround time. Our stated processes allow urgent/emergent services after-hours, on weekends or on holidays, with the Provider's submission of a follow-up call to the prior authorization division on the next business day.

In recent years, our organization has conducted extensive reviews of our PA requirements, and we continue to do so on a periodic basis. Our goal is to minimize workload for Providers and our PA unit, by only retaining or adopting PA requirements where our policy requires us to perform a manual review of a Provider's request.

Any remaining quantity, frequency or diagnosis related requirements/limitations have already been evaluated and put into our system, this allows the provider to provide the services that fall within established boundaries without obtaining PA. This information is available to the provider online and within our system.

We have previously invested in the development and implementation of an online system that includes a robust Web portal and PA online tool for use by our entire Provider community. Our Providers can readily verify patient eligibility; access PA requirements and our specific document needs on-line; prepare/submit a PA Request; upload supporting documents; download a pre-encoded fax cover sheet (linked to the PA) if they prefer to send faxed documents; immediately obtain the PA request number; check the status of any previously-submitted PA; and retrieve our customized response letters, status, and final decisions for any current or previous request their organization has submitted.

Consequently, we do not see the Proposed Rule as improving workflow for our, nor our Providers' organizations.

B. <u>Data Content Rule and Use of LOINC Codes</u>

We have the ability through a combination of technology and manual staff review to prepare customized and detailed response letters to the Provider and Beneficiary, at the line level, in response to a PA request. Our responses requesting additional documentation from the submitter are thus specific to each request in regard to the type of information needed (not just a document type) in an effort to focus the PA submitter's subsequent reply on the minimum necessary information required to reach a decision on a PA request. A review of the attached sample of actual information-request responses reveals the specificity of our documentation requests, and makes it apparent that even use of LOINC codes cannot match the level of detail we routinely issue in reply to a submitter's request, as shown in the following examples:

1. "The documentation and prescription submitted list multiple accessories for the requested gait trainer that are not present on the PA. Please clarify what is requested as only those items requested on the PA can be considered for coverage."
2. "What is the medical necessity for the requested bed and features? Please note: Enclosed bed systems are not covered when the purpose is to restrain the beneficiary due to behavioral conditions, caregiver need or convenience, etc."
3. "MDHHS has no record of approving this power wheelchair for this beneficiary. Please submit a copy of the documentation that was submitted at the time this chair was purchased for consideration of coverage of the requested repair per section 1.9.C. of the Medical Suppliers chapter of the Medicaid Provider Manual."
4. For additional examples of letter language please see attached Sample Letter Language document.

LOINC codes work very well for requesting a specific document when a beneficiary is in a hospital, but they do not allow for the level of specification and customization in the responses that we presently send to our Providers (as shown above). When we updated our system, our Providers told us they wanted us to continue our customized response letters because they contain exceptional specificity and clarity on the information needed, and helps them send only the information necessary for us to reach a determination on their PA requests.

Although the Proposed Rule states the 278-217 PWK segment can be used in lieu of LOINC codes, the segment is not of sufficient size for us to include the detailed specificity and clarity that our Providers have requested we maintain.

Conversion to the use of LOINC codes to request additional information in reply to a submitted request is expected to actually reduce efficiency compared to our current information-request process for the types of requests we process; resulting in a communication scenario that would be more complicated, less detailed, less effective, and more time-consuming, when compared to our present practices.

<u>Infrastructure Rule and Response Time Requirements</u>

Concerns on Proposed Rule Regarding 2-day Payer Decision Response

As a Medicaid Payer organization that performs 100% manual review of submitted PA requests, we have concern on the proposed two-day decision (or Payer's response requesting additional information from the Provider) response requirement. Complying with this requirement will create a serious financial burden in the area of staffing resources.

A Submitter's Prior Authorization request seeks an exception to our organization's published coverage policy, and therefore requires a manual review, not an automated system reply. Our organization has already removed PA requirements for most services, so all remaining services require Provider documentation to enable manual evaluation by our staff. Further, the documentation required from the Provider in support of the PA request exceeds a simple Physician's order.

To evaluate a submitted PA request, Payer staff members must: (1) review the requested service or equipment and accompanying documents; (2) determine if additional documentation is needed from the Provider; (3) if necessary, request, receive, and match the documentation with the original submitted request and review; (4) determine coverage for the proposed requested service; and (5) compose and issue a final decision to the request submitter and to the beneficiary. These activities are performed by staff members educated in the specific service area. Review of a single PA request may appear to be an easy task to perform on the surface; however, our organization must process thousands of requests in a given time-frame, and must balance our staff resources to accommodate typical daily volume, and also address surges in volume resulting from seasonal or environmental factors.

In order to comply with the proposed two-day response requirement, our organization will incur significant and ongoing increased costs for additional staff (including office space, computers, phones, etc.), in addition to the anticipated costs for system processing revisions that will be required to support the Proposed Rules.

Concerns on Proposed Rule Regarding 15-day Provider Documentation Response:

As a Payer organization we have concern on the proposed fifteen-day documentation response period allowed the PA submitter, following a request for supporting documentation from the Payer.

When a Provider submits a PA request for a particular service, the Provider should already have documented observations, test results, or other substantiation for the necessity of the proposed service. By separating the submitted PA request from the documentation to evaluate that request complicates, and increases, the Payer resources needed to make a final decision on the PA request. Allowing up to three weeks to elapse before sending supporting documentation to the Payer creates a situation in which the Payer staff member processing the request will need to re-investigate the original PA request, Pertinent Payer Policy, any intervening communications exchanged with the submitter, the newly-received documentation, and then proceed to a final determination decision. In many instances, the documentation provided may not fulfill the information need of the Payer, and alternative documentation will then need to be requested from the Provider.

Essentially, delaying receipt of the necessary documentation from the time when the original PA request is received imposes two reviews of the same request on the Payer. In some instances, an additional re-acquaintance and review occurs when the documentation subsequently sent by the submitter does not fulfill the information needed to evaluate the request, and another iteration of Payer information request occurs, thus creating a later, third review situation for the Payer.

A more expeditious, focused response by the PA submitter, to a Payer's response seeking additional documentation, would help reduce the Payer's resources needed to reach a final decision on each PA request.

Establishing a mechanism for the PA submitter to combine a 278 PA request and the supporting documentation in a single event/transaction would greatly resolve this situation for the Payer. This mechanism will likely only occur when an attachment standard is adopted and implemented by the industry.

Accordingly, the fifteen-day Provider documentation response period delays the Payer's final determination on a PA request.

Summary:

Our investment in the above-described combination of (1) reduction of Required Prior Authorizations, (2) deployment of a current-technology solution for our Providers, and (3) extremely specific current request

responses, benefits both our Providers and our staff by creating a minimum current workload commitment for the processing of PA requests.

A detailed study and our resulting understanding of the Proposed Rules indicate that adopting the Rules will not benefit our manual workflow, will be less focused in the area of information exchange, and may actually increase the number of back-and-forth information-exchange (iterations) needed to reach a determination on individual PA requests. Our concern is that the end result will be an increase in overall process time, which would act as a detriment in reaching request decisions and will not achieve the desired improvement in timeliness of patient care.

Lack of alternatives

Adoption of the Proposed Rules will impose shortened response timing requirements that, although intended by CAQH to improve *automated* PA processing, do not accommodate the corresponding impact on *manual* processing.

During the course of the CAQH PA Rules Development initiatives, it became apparent there are differences in the Prior Authorization review process between what may be considered Commercial and Governmental Payers. Governmental Payers such as our organization have a stated public-sector responsibility to review proposed care considering both the patient's medical necessity and the ability to obtain care at a reasonable cost, and work to fulfill these obligations through a manual assessment of the information related to each request. When this distinction became apparent, we requested consideration be given to including exception language in any Proposed Rule, possibly for organizations that have continually reduced and actively streamlined their remaining PA requirements, or for Governmental Payers, or for organizations that perform a 100% manual review of PA requests. Since the CAQH ballot and voting procedures rely on a majority rule approach, and few Payers were outspoken on these exception suggestions, no mention of proposed alternatives or exception conditions appear in the Proposed Rules.

3. Transaction exchange (connectivity rule): In what way(s) will the proposed operating rule for connectivity improve the processing of transactions, message payload, connectivity, security, etc. if adopted by HHS? What are the anticipated benefits that this operating rule offers vs. the current state (please provide examples if possible)?

Answer:

4. **Improving use of transactions and/or adoption of standards (all proposed operating rules):** Describe how adopting the proposed operating rules will or could increase in the use of any of the adopted HIPAA transaction standards.

Answer: We do not believe adoption of the Proposed Rules will help the industry adopt the PA 278 Transaction. We anticipate that an attachment standard is a required enabler for increased adoption of the PA 278 transaction within the industry. When an attachment is required for the evaluation of a submitted PA request, most entities currently need to revert to a non-HIPAA exchange. We also believe adoption of an attachment standard would aid in the use of the 837 Claims transactions.

Within our organization, all remaining PA requirements require the submission of documents for review and determination of a decision on the submitted request. Consequently, the adoption of an attachment standard represents a precursor requirement for the adoption of the PA 278 transaction.

5. **Connectivity rule implementation for your organization or industry wide (please specify)**: a. What are the implications, costs, and benefits of implementing the new connectivity rule requirements for the prior authorization, eligibility & benefits, claim status and electronic remittance advice transactions? Providing

generalized or high-level information will be helpful to the Committee. **[Note, this question has been revised to remove reference to claims, enrollment/disenrollment, and premium payment transactions for which operating rules *have not been* adopted by HHS.]**

Answer: Unfortunately, the costs and burden for implementing this connectivity rule as a replacement approach for both Realtime and Batch transaction exchanges arrive at a time when discretionary funds are not available to replace standards and/or technology that works and serves the needs of current users.

The COVID-19 response has increased the financial burden on all payers, hospitals, and providers. As a State Medicaid Agency, our budget (and also the systems development budget) is determined by the state legislature based on projected tax revenues. Given the very high unemployment rate due to the pandemic, the corresponding decrease in tax revenue this will cause, and the ongoing financial burden of the pandemic response, devoting limited state funds to install this Proposed Rule does not appear to be a prudent financial expenditure for the foreseeable future.

b. Can you provide general types of costs and benefits of meeting the processing mode requirements for both real time and batch submissions?

Answer: We suggest that NCVHS or HHS publish a requirements strawman as a model for evaluation, and solicit critique and implementation cost estimates for that model, from the industry.

6. **Implementation time frame for each proposed rule: a.** What is the anticipated lead time needed by your organization to develop, test, and implement the proposed operating rules? What are the dependencies that impact the timeline, e.g., vendors, trading partners and business associates? If possible, please provide an estimate of the amount of time your vendors would require to develop their component of the solution? **(NOTE: 25 months is the standard time given after final rule for implementation).**

Answer: Our assessment revealed that a complete overhaul of the Prior Authorization subsystem within our claims processing solution will be required in order to support the capabilities specified in the Proposed Rules.

Our system vendor requires us to provide the specifications related to any new requirements to enable their preparation of cost and timing estimates for the identified system revisions. Following the specification and design cycle approvals and resource commitment, planning for the necessary system changes must be integrated within our system maintenance release development and deployment schedule. We anticipate a need to coordinate with our Vendors, Providers, and Trading Partners to establish a common understanding on scope and extent of the required changes; for initiatives of this scope, we typically engage on a business partner outreach effort, while system design, development, and testing are underway. We then engage in formal internal User Acceptance Testing; and engage our Business Partners in testing prior to actual implementation of the changes, to verify all parties are ready to deploy on a specified implementation date.

However, the most critical enabler for such a project will be obtaining necessary funding. The COVID-19 response has increased the financial burden on State operations. As a State Medicaid Agency, our budget (and also the systems development budget) is determined by the state legislature based on projected tax revenues. Given the very high unemployment rate due to the pandemic, the corresponding decrease in tax revenue this will cause, and the ongoing financial burden of the pandemic response, obtaining limited state funds to support the Proposed Rules will be difficult for the foreseeable future.

We estimate a minimum 3 year overall schedule should be considered for the adoption of any approved changes of this type.

b. Should considerations be given to size or organization type for the proposed implementation timeframe? Please discuss for each of the proposed operating rules (Prior authorization content, prior authorization infrastructure and connectivity).

Answer: For all three rules: Yes, the type and size of the organization should be considered in preparing an implementation timeline. Larger organizations with complex systems will likely provide the major thrust for implementing revisions, especially within the Payer segment of the industry. Vendors will need time to coordinate revisions across their client base, and Providers will need to develop or acquire the necessary software. Organizations having more trading partners, vendors, or providers, and organizations with more complex and integrated systems will require more time and investment to support the revisions.

7. **Costs (Prior Authorization rules):** Is your organization able to provide an estimate of the implementation cost for the requirements of the two prior authorization operating rules for data content and infrastructure? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting these rules?

Answers:

It is doubtful that any health care entity will be able to forecast with accuracy how long it will take or how much money it will cost to implement this rule, until the rule is finalized and development and migration requirements can be evaluated.

We suggest that NCVHS or HHS publish a requirements strawman as a model for evaluation, and solicit critique and implementation cost estimates for that model, from the industry.

Additionally, the COVID-19 response has increased the financial burden on all payers, hospitals, and providers. As a State Medicaid Agency, our budget (and also the systems development budget) is determined by the state legislature based on projected tax revenues. Given the very high unemployment rate due to the pandemic, the corresponding decrease in tax revenue this will cause, and the ongoing financial burden of the pandemic response, devoting limited state funds to install these Proposed Rules does not appear to be a prudent financial expenditure for the foreseeable future.

8. **Costs (Connectivity rule)**: Is your organization able to provide an estimate of the implementation cost for the requirements of the connectivity operating rule? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting this rule and its requirements?

It is doubtful that any health care entity will be able to forecast with any accuracy how long it will take or how much money it will cost to implement this rule, until the rule is finalized and migration requirements can be evaluated.

We suggest that NCVHS publish a requirements strawman as a model for evaluation, and solicit critique and implementation cost estimates for that model, from the industry.

Additionally, the COVID-19 response has increased the financial burden on all payers, hospitals, and providers. As a State Medicaid Agency, our budget (and also the systems development budget) is determined by the state legislature based on projected tax revenues. Given the very high unemployment rate due to the pandemic, the corresponding decrease in tax revenue this will cause, the ongoing financial burden of the pandemic response, devoting limited state funds to install these Proposed Rules does not appear to be a prudent financial expenditure for the foreseeable future.

9. **Additional comments:** Given that the Connectivity Rule is highly technical, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?

Answer:

10. **Additional comments:** For the Prior Authorization operating rules, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?

Comments: We do not see improvement in either processing workflows or response times resulting from implementation of these Proposed Rules, when compared to our web portal solution. In fact, we see the opposite. Our web portal capabilities already exceed what is described in the "Data Content" and "Infrastructure" Proposed Rules.

The simplicity, timeliness, communications capabilities, and document exchange functionality of our web portal solution fully meets the PA needs of our Provider community. We believe the majority of our Provider community will want to continue using our current solution, rather than the PA 278 transaction.

Until an attachments standard has been adopted, we do not believe the PA 278 transaction will be fully adopted by the industry as a whole. Any system changes to accommodate these Proposed Rules, without an accepted attachments solution, would be premature.

Additionally, the COVID-19 response has increased the financial burden on all payers, hospitals, and providers. As a State Medicaid Agency, our budget (and also the systems development budget) is determined by the state legislature based on projected tax revenues, and we do not have the ability to "raise premiums" with the next contract year as commercial insurances do. Given the very high unemployment rate due to the pandemic, the corresponding decrease in tax revenue this will cause, the ongoing financial burden of the pandemic response which will not be going away any time soon, and the fact that adopting these Proposed Rules would be a functional "step backwards" from our current system's capabilities, devoting limited state funds to install these Proposed Rules is not a prudent financial expenditure for the foreseeable future.

From a value perspective, spending funds to reduce functional capabilities in our present systems does not appear to make good economic sense.

11. General: For each rule, please provide the rationale for your support or opposition to its adoption to inform the Committee's deliberations.

Answer:

As our previous comments above state, comparing our organization's current PA workflow environment to that resulting from adoption of the Proposed Rules creates a PA-handling scenario that we expect to be more time-consuming, less explicit, and therefore more costly, than our current practices.

PA 278 Data Content Rule

Our organization's efforts, presented in our response to Question 2, have resulted in the earlier-described combination of our: (1) reduction of Required Prior Authorizations; (2) deployment of a current-technology solution for our Providers; and (3) extremely specific information request responses; which benefit our Providers and our staff by reducing workload in the submission and processing of PA requests.

Our detailed study and resulting understanding of the Proposed Rules indicate that for our organization, adopting the 278 Data Content Rule requirements related to use of LOINC codes and the PWK Segment for requesting documentation from a PA submitter will not benefit our manual workflow, will reduce focus and specificity in requesting supporting information or documents (compared to our current procedures), and

may actually increase the number of information/documentation requests needed to reach a determination on individual PA requests. Our concern is that a resulting increase in overall process time would detract from reaching timely request decisions, will increase Payer cost, and yet fail to achieve the desired improvement in timeliness of patient care.

Although we do support, and helped craft, portions of the PA 278 Data Content Rule relating to Data Normalization, we consider conversion to exclusive use of LOINC codes and the PWK Segment to request additional documentation from a Provider detrimental to the specificity required to obtain information needed to reach a final determination in a manual PA review workflow.

We therefore oppose adoption of the PA 278 Data Content Rule.

PA 278 Infrastructure Rule

Adoption of the Proposed PA 278 Infrastructure Rule will impose shortened response time requirements that, although intended by CAQH to improve *automated* PA processing, do not accommodate the corresponding impact on *manual* processing.

During the course of the CAQH PA Rules Development initiatives, it became apparent there are differences in the approach to Prior Authorization reviews by different types of Payers. Governmental Payers, such as our organization, have a stated public-sector responsibility to review proposed care considering both the patient's medical necessity and the ability to obtain care at a reasonable cost; our organization works to fulfill these responsibilities through a manual assessment of the information related to each request. When this distinction became apparent, we requested consideration be given to adding exception language in any final Proposed Rule, possibly for organizations that have continually reduced and actively streamlined their remaining PA requirements, or for Governmental Payers, or for organizations that perform a 100% manual review of PA requests. Since the CAQH ballot and voting procedures rely on a majority rule approach, and few Payers were outspoken on these exception suggestions, no mention of proposed alternatives or exception conditions appear in the Proposed Rules.

Although we do support, and helped craft, portions of the Infrastructure Rule relating to advising partners of system availability, and announcements regarding unexpected downtime, we find that we (1) cannot support the one-size-fits-all approach inherent in the Proposed Rule in regard to the 2-day Payer decision response requirement, and also (2) consider the 15-day Provider response window to submit Payer-requested supporting documentation as detrimental to a Payer reaching a final determination on a PA request.

We therefore oppose adoption of the PA 278 Infrastructure Rule.

Return reasons:

1. Please complete information re: status of current prosthesis in sections #19 and #22 on the MSA 115 form. Document the approximate month and year of previous prosthesis placement. Document the reason for replacement.
2. Please resubmit with clinical documentation from the ordering physician that describes the necessity for this test. How will the results of this test impact treatment and prognosis for this patient?
3. The submitted CMN is for a patient other than the beneficiary identified on this PA request, please resubmit with CMN for the correct beneficiary.
4. The coverage of a pediatric mobility device requires it to accommodate growth and adjustments for seating systems a minimum of 3in depth and 2in width. Provide the requested wheelchair's initial seat width and depth and growth adaptability as is required on the MSA-1656 Addendum A.
5. Please resubmit with the brand, model, product number of the item requested.
6. The documentation and prescription submitted list multiple accessories for the requested gait trainer that are not present on the PA. Please clarify what is requested as only those items requested on the PA can be considered for coverage.
7. What is the medical necessity for the requested bed and features? Please note: Enclosed bed systems are not covered when the purpose is to restrain the beneficiary due to behavioral conditions, caregiver need or convenience, etc.
8. MDHHS has no record of approving this power wheelchair for this beneficiary. Please submit a copy of the documentation that was submitted at the time this chair was purchased for consideration of coverage of the requested repair per section 1.9.C. of the Medical Suppliers chapter of the Medicaid Provider Manual.
9. An approved treatment plan for a dental facility with the same NPI currently exists on CHAMPS. Please clarify if you are requesting a change to the treatment plan or a new treatment.
10. Please provide the medical need for both a recline and a tilt feature for this beneficiary.

Denial Reasons:

1. The documentation submitted indicates the beneficiary is not adhering to the physician's plan of treatment. Physician orders state beneficiary is to test blood glucose levels 4-6 times per day; the submitted blood glucose logs indicate the beneficiary is testing an average of 1.4 times per day. The submitted clinic note from 05/07/2019 states beneficiary is testing 0-3 times per day, "John Doe's Blood Glucose checks are inadequate" and "He is entering Blood Glucose into (insulin) pump infrequently". The documentation also states the beneficiary has a Dexcom G5 but he is not wearing/using it. Items for a beneficiary who is non-compliant with a physician's plan of care ae not covered. The provider is welcome to submit a new PA request if/when beneficiary is compliant with the physician's plan of treatment as required in policy.
   Refer to the Medical Supplier chapter, section 1.11 of the Medicaid Provider Manual.
2. The documentation provided for this beneficiary has been discrepant. Comments provided with the current PA request state: "New motorized wheelchair arrived with tilt feature, guest has never used an electric wheelchair before and needs training on how to operate all the controls safely both inside and outside the SNF and in the community." Medicaid approval of a power wheelchair is contingent on the beneficiary's ability to independently operate the chair. Please refer to PA# 1XXXXXXXXX, approval was granted for CPT code 97542 (wheelchair management), where the occupational therapist has stated "Pt assessed using power w/c with good safety

awareness and problem solving skills", and PA# 1XXXXXXXXX for the power wheelchair, where the occupational therapist has checked "yes" to the statement "Beneficiary is able to drive a power wheelchair independently 2000+ feet, turns around, maneuvers the chair to a table, bed, toilet, negotiates a minimum of a 3% grade, maneuvers on rugs and over door sills", and has written "Trial of powerchair in therapy with successful completion." Your current request for 97542 is denied per Medicaid Provider Manual, Therapy Services Chapter, Section 4.1, Standards of Coverage. Please note that if the beneficiary is to be billed, providers must notify the beneficiary prior to rendering services that are not covered by Medicaid, otherwise the beneficiary is not financially responsible for the services provided that were not covered by Medicaid.

3. MDHHS records show the beneficiary was provided with a Kimba stroller-style mobility device with multiple positioning accessories to allow for mobility and positioning in the home and community. The documentation does not support the medical necessity for the requested mobile activity chair in addition to the mobility device already provided. Please note: A second wheelchair for beneficiary preference or convenience is not covered. Duplicate equipment is not covered. Equipment requested for play, social, or recreational activities is not covered. Refer to the Medical Supplier chapter sections 1 - Program Overview, 1.4, 1.6, 1.11, 2.7, and 2.48 of the Medicaid Provider Manual.
4. The prior authorization request was received on 12/5/19; unable to backdate for the dates 10/15/19 through 12/3/19. The beneficiary has established eligibility with this nursing facility provider. To permit backdating to the initial date of service, documentation must be received within 10 days of discharge from the acute care facility. Please refer to the Medicaid Provider Manual, Therapy Services Chapter, Section 3.2, Retroactive Prior Authorization.
5. This PA has been denied for the following reasons:
   *The required MSA-1656 and MSA-1656 Addendum B forms were not submitted.
   *The standing plan of care for caregivers including frequency and duration of standing frame use was not provided.
   *Results of trials with the stander, including documentation of the length of standing tolerated, the beneficiary's reported pain level during standing, and the number of times per day the stander was used were not provided.
   *The medical need for the requested accessories was not provided.
   *The accessibility of the home for use of the requested sit-to-stand stander was not provided.
   Please refer to the Medical Supplier Chapter, Sections 1.6, 1.8, 1.11 and 2.7 of the Medicaid Provider Manual.
6. This PA has been denied for the following reasons:
   * Transit options are not covered. Transit options are not required by federal or state transportation regulations, including for student transportation on school buses; transportation options are not considered medical in nature.
   * The documentation does not address the medical necessity for the requested abduction frame option.
   Please refer to the Medical Supplier chapter, sections 1.6, 1.11, and 2.48 of the Medicaid Provider Manual.
7. This PA has been denied for the following reasons:
   *No prior authorization is required for procedure code K0040. Please refer to the Medicaid Code and Rate Reference database.
   *Procedure code E1028 is included in the nursing facility per diem rate for beneficiaries in a long term care setting.

*Medical need is not substantiated for the requested Accu-track motor technology.
*The document submitted does not support medical need for an Attendant Control.
Please refer to Medical Supplier Manual section 1.6, 1.8, and 2.48 and to the Nursing Facility Coverages Chapter Sections 10.8.A and 10.8.B.1 of the Medicaid Provider Manual.

8. The progress note from 9/17/2019 states the beneficiary is "Stable on nocturnal ventilatory support...". The documentation submitted does not support the medical necessity for a portable ventilator in addition to the approved stationary ventilator. A back-up ventilator is the responsibility of the DME. The provider is welcome to resubmit this request with physician documentation if a portable ventilator is indeed medically necessary.
Please refer to the Medical Supplier chapter, section 2.48 of the Medicaid Provider Manual.

Other:

1. This prior authorization is being end-dated 09/30/2019 because the beneficiary is enrolled in a health plan effective 10/01/2019. Please contact ABC Health Plan at (888) 123-4567 for authorization of services continuing after 9/30/2020.
2. MDCH/CSHCS does not prior authorize non-emergent services to out of state/beyond borderland providers if the service is available within the State of Michigan. The beneficiary must take their prescriptions to a durable medical equipment provider located within the state.

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August 14, 2020

William W. Stead, MD
Chair
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: CAQH CORE Prior Authorization & Connectivity Operating Rules Proposed to NCVHS for Federal Adoption

Dear Dr. Stead,

Thank you for the opportunity to provide comment on the CAQH Committee on Operating Rules for Information Exchange (CORE) Prior Authorization & Connectivity Operating Rules proposed to the National Committee on Vital and Health Statistics (NCVHS). Montefiore fully supports the proposal and encourages NCVHS to recommend the rules for federal adoption under HIPAA.

Montefiore Health System is one of New York's premier academic health systems and is a recognized leader in providing exceptional quality and personalized, accountable care to approximately three million people in communities across the Bronx, Westchester, and the Hudson Valley. It is comprised of 10 hospitals, including the Children's Hospital at Montefiore, Burke Rehabilitation Hospital, and close to 200 outpatient care sites. The advanced clinical and translational research at its medical school, Albert Einstein College of Medicine, directly informs patient care and improves outcomes. From the Montefiore-Einstein Centers of Excellence in cancer, cardiology and vascular care, pediatrics, and transplantation, to its preeminent school-based health program, Montefiore is a fully integrated healthcare delivery system providing coordinated, comprehensive care to patients and their families.

The mission of Montefiore is to heal, to teach, to discover and to advance the health of the communities we serve. The current state of prior authorization – a highly burdensome, costly, and manual process is antithetical to this mission and results in unnecessary care delays across our system. Today, Montefiore employs approximately

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175 full time equivalent staff across the health system to manage prior authorizations via web portals, phone, and faxes, adding up to approximately $11M in annual FTE costs.

Adoption of the proposed CAQH CORE Prior Authorization and Connectivity Operating Rules will drive greater automation, increase efficiencies, improve access to timely patient care, enhance health plan and provider data exchange, and significantly reduce industry spend on prior authorization processes.

Montefiore supports NCVHS efforts to drive automation through the adoption of standards and operating rules. We encourage NCVHS to consider the immediate industry need to improve the prior authorization process and overall delivery of patient care by recommending the CAQH CORE Operating Rules to the Secretary of the U.S. Department of Health and Human Services for federal adoption.

Detailed comments on the specific questions posed by NCVHS are included below. Thank you for the opportunity to provide feedback. Please do not hesitate to reach out with questions.

Sincerely,

Noam Nahary, MS, RHIA
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Montefiore Health System

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1. **Participation in Development of the Rules: If your organization participated in identification and development of the proposed operating rules for prior authorization and/or connectivity, describe the skill set of the individuals involved (business or technical) and in what way they participated in the process.**

CAQH CORE rule development is a collaborative, consensus-based iterative process with multiple levels of balloting with quorum requirements. More than 125 CAQH CORE Participating Organizations representing health plans, providers, vendors, clearinghouses, associations, standards development organizations, and government agencies contributed to the development of the proposed operating rules. Individuals that engaged in the development of the operating rules represented a variety of functions including business, clinical, technical, and leadership. Each of the three proposed rules received at least 80 percent support in the CAQH CORE all Participant Vote.

Noam Nahary, MS, RHIA, and Senior Director, Health Service Receivables, participated directly in the development of all three proposed operating rules on behalf of Montefiore Health System, including serving as the Co-Chair of the CAQH CORE Rules Work Group for the prior authorization rules. Additionally, Stephen Rosenthal, MBA, Senior Vice President, Population Health Management and President of CMO, Montefiore Care Management, serves on the CAQH CORE Board.

2. **Workflow (prior authorization rules): In what way(s) will the proposed operating rules for prior authorization improve workflow for your organization's industry sector? Discuss the prior authorization data content and infrastructure rules and describe how the proposed requirements from each will impact your workflow, reduce burden (if relevant) and better support patient care.**

Today, Montefiore Health System employs approximately 175 staff to manage prior authorizations via web portals, phone, and faxes adding up to approximately $11M in annual FTE costs. Staff are continually relying on data entry into web portals, phone calls, and fax machines to address each request. This applies to initiation, submission, and confirmation of each authorization. Current health plan response times to initial prior authorization requests at Montefiore range from 1-14 days.

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Implementation of the proposed operating rules by all HIPAA-covered entities will enable Montefiore to transition away from web portals and manual prior authorizations and implement greater automation via the X12 278. With a higher volume of electronic transactions, Montefiore can create efficiencies in its workflows and reduce staffing costs.

Altogether, Montefiore expects that the operating rule package proposed by CAQH CORE will drive greater automation, increase efficiencies, enhance health plan and provider data exchange, and potentially reduce overall spend on prior authorization processes by $6M through savings in staffing, with additional reductions in denials and write-offs.

The CAQH CORE Prior Authorization (278) Data Content Rule will reduce the unnecessary back and forth between Montefiore Health System and health plans when confirming medical necessity, resulting in shorter adjudication timeframes and less manual follow-up. The rule enhances and further standardizes the data shared between plans and providers. For example, use of the Health Care Services Decision Reason Codes will provide greater clarity on the reason for an authorization decision, enabling Montefiore to appropriately respond. Other codes in the PWK segment will enable Montefiore to understand exactly what additional documentation is needed, expediting the approval process. Enhanced use of error codes will ensure rapid resolution.

The CAQH CORE Prior Authorization (278) Infrastructure Rule aligns with other federally mandated infrastructure rules for eligibility, claim status, and electronic remittance advice. Infrastructure requirements enable common expectations for data exchange across Montefiore's trading partners. The rule specifies prior authorization requirements for system availability, acknowledgements, companion guides, and response timeframes. Additionally, the connectivity requirements will enhance the security of data exchange.

In 2019, Montefiore participated in and co-chaired an update to this rule which included three new response time requirements. Specifically, the updates create national response timeframe expectations for the exchange of electronic prior authorization rather than each state having its own regulations. In its research, CAQH CORE found that 30 states have prior authorization response time requirements that vary from 24 hours to 15 business days with differences in definitions and applicability across states. At Montefiore, current health plan response time to prior authorization requests can take up to 14 days. These timeframe requirements will improve scheduling and minimize

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rescheduling, as well as reduce wait times for certain procedures. Shorter turnaround times will incentivize providers like Montefiore to adopt and utilize the X12 278 transaction, resulting in better, faster patient care.

3. **Transaction exchange (connectivity rule**): **In what way(s) will the proposed operating rule for connectivity improve the processing of transactions, message payload, connectivity, security, etc. if adopted by HHS? What are the anticipated benefits that this operating rule offers vs. the current state (please provide examples if possible)?**

Currently the CAQH CORE Connectivity Rule vC1.1.0 is federally mandated for the eligibility transaction and the CAQH CORE Connectivity Rule vC2.2.0, which builds on vC1.1.0, is mandated for eligibility, claim status, and electronic remittance advice transactions. When initially developed more than 10 years ago, these connectivity rules represented cutting-edge security and connectivity protocols. However, the industry had advanced significantly since this time. Compared to the current state (vC2.2.0), the CAQH CORE Connectivity Rule vC3.1.0 will reduce complexity by moving to a single SOAP standard, enhance security through the use of certificate-based authentication instead of username and password, and improve the communication of errors.

Updating the connectivity requirements for these three transactions, in addition to mandating support for the prior authorization transaction, will ensure consistent, best practice security and connectivity methods across administrative transactions that can be updated over time. The CAQH CORE Connectivity Rule vC3.1.0 will enable Montefiore to use a common connectivity method across EDI transactions and trading partners. Security will be strengthened, and onboarding costs reduced.

4. **Improving use of transactions and/or adoption of standards (all proposed operating rules): Describe how adopting the proposed operating rules will or could increase in the use of any of the adopted HIPAA transaction standards**.

The requirements in the proposed operating rules greatly enhance the X12 278 by creating common expectations for the infrastructure and data content shared between providers and plans. With more required information and consistent expectations for data exchange resulting from mandated operating rules, Montefiore expects to increase

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use of the X12 278 and update existing workflows given the benefits outlined in Questions #2 and #3.

It is evident, given the current state of prior authorization, that more than just goodwill is necessary to drive efficiencies and automation. A federal mandate will accelerate industry adoption beyond early implementers by making investment dollars and resources available to ensure compliance. CORE Certification data suggests that federal mandates drive adoption and certification, enabling prioritization and vendor development.

5. **Connectivity rule implementation for your organization or industry wide (please specify):**
    a. **What are the implications, costs and benefits of implementing the new connectivity rule requirements for the prior authorization, eligibility & benefits, claim status and electronic remittance advice transactions? Providing generalized or high-level information will be helpful to the Committee.**

The connectivity infrastructure at Montefiore Health System is designed to support the CAQH CORE Connectivity Rules, so updating to vC3.1.0 for eligibility, claim status, electronic remittance advice and adding X12 278 volumes will require minimal resources due to commonalities in transport, envelope, authentication standards, and metadata. Benefits of transitioning to vC3.1.0 include consistent connectivity across EDI transactions which will minimize onboarding costs and maximize efficiencies. Where possible Montefiore will consider connecting directly with health plans rather than through a clearinghouse to reduce transaction fees, given the connectivity safe harbor.

    b. **Can you provide general types of costs and benefits of meeting the processing mode requirements for both real time and batch submissions?**

This rule requires a health plan to implement server requirements for either real time or batch processing mode for the 5010X217 278 Request and Response transactions. Montefiore may upgrade our platform to support real time if more health plans offer real time via the X12 278. With existing real time infrastructure for eligibility and claim status, Montefiore can leverage existing implementations.

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6. **Implementation time frame for each proposed rule:**
    a. **What is the anticipated lead time needed by your organization to develop, test and implement the proposed operating rules? What are the dependencies that impact the timeline, e.g., vendors, trading partners and business associates? If possible, please provide an estimate of the amount of time your vendors would require to develop their component of the solution?**

Montefiore Health System estimates 9-12 months of lead time to implement the proposed operating rules. Montefiore is currently working with its EMR vendor on X12 278 implementation. Incorporating the new required data elements into the 278 file generation process, tracking trading partner conformance to the infrastructure requirements, and updating connectivity protocols are key components of the implementation.

    b. **Should considerations be given to size or organization type for the proposed implementation timeframe? Please discuss for each of the proposed operating rules (Prior authorization content, prior authorization infrastructure and connectivity).**

Many providers are dependent on vendor solutions for transaction support, but organization size could impact the resources available to implement the operating rules.

7. **Costs (Prior Authorization rules): Is your organization able to provide an estimate of the implementation cost for the requirements of the two prior authorization operating rules for data content and infrastructure? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting these rules?**

According to the 2019 CAQH Index, the industry could save $12.31 per prior authorization transaction by moving from manual processing to use of the HIPAA-mandated X12 278 transaction. Federal adoption of the proposed prior authorization operating rules will facilitate greater automation, faster response times, and reduce administrative costs associated with the electronic transaction.

The operating rule package proposed by CAQH CORE will reduce overall spend on prior authorization processes at Montefiore through efficiency gains and standardization.

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Montefiore will rely in its EHR vendor to complete development for integration into its workflows. Generally, an update of this nature does not incur additional costs other than those related to ongoing system maintenance/upgrades. Implementation costs for Montefiore include support for technical teams to build, connect and test electronic transactions. For Montefiore only, it would take an estimated 12 months to implement.

Today, Montefiore Health System employs approximately 175 staff to manage prior authorizations via web portals, phone, and faxes adding up to approximately $11M in annual FTE costs. Staff are manually entering data into portals one request at a time. Current health plan response times to initial prior authorization requests at Montefiore range from 1-14 days. Montefiore estimates $6M in savings with a federal mandate of the proposed operating rules through reductions in resources, with additional reductions in denials and write-offs.

8. **Costs (Connectivity rule): Is your organization able to provide an estimate of the implementation cost for the requirements of the connectivity operating rule? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting this rule and its requirements?**

Montefiore Health System, and many of our trading partners, have already implemented CAQH CORE Connectivity Rule vC2.2.0, given it is federally mandated for eligibility, claim status, and ERA. Therefore, we have already implemented some of the CAQH CORE Connectivity Rule vC3.1.0 requirements due to overlap in metadata, transport, envelope, and authentication standards. Less administrative support for multiple connectivity rules and improved security and network authentication in the vC3.1.0 requirements would lower our ongoing costs.

9. **Additional comments: Given that the Connectivity Rule is highly technical, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?**

A single connectivity rule across all transactions is easier to update, reduces confusion, and promotes industry alignment on best practices. For providers, it offers assurance of

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a common method to connect across administrative transactions that is innovative and secure.

10. Additional comments: For the Prior Authorization operating rules, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?

Patient experience is a cornerstone of the care model employed at Montefiore. Delays and inefficiencies in the current prior authorization process have a direct, negative impact on patient care. The industry must address this challenge now. The proposed operating rules enable greater automation, reducing and eliminating unnecessary delays and inefficiencies.

11. General: For each rule, please provide the rationale for your support or opposition to its adoption to inform the Committee's deliberations.

Montefiore fully supports the proposal and recommends the three CAQH CORE Prior Authorization and Connectivity Operating Rules to NCVHS and the Department of Health and Human Services (HHS) for federal adoption under HIPAA. Specifically:

- The prior authorization operating rules improve automation and timeliness of the prior authorization process, reducing costs and improving access to timely patient care.
- The connectivity operating rule enhances security and promotes uniform interoperability requirements across administrative transactions.
- Without a federal mandate, implementation of the operating rules will lag, resulting in continued inefficiencies and delays and ultimately, poorer patient outcomes.
- These operating rules set the stage for future operating rules to further enable the critical convergence of administrative and clinical data and support the use of new technologies with existing standards.

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From: Brad Smith
To: NCVHS Mail (CDC)
Cc: Michael Herd
Subject: CORE Operating Rules
Date: Thursday, July 23, 2020 10:32:15 AM
Attachments:

Attached are our comments on the CORE Operating Rules for the NCVHS Hearing. Please let me know if you have any questions.

Sincerely
Brad Smith, AAP
Nacha
(Standards Organization)
bsmith@nacha.org

Brad Smith, AAP
Senior Director, ACH Network Administration & Industry Verticals
Nacha
bsmith@nacha.org
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Nacha, as an expert in private-sector rulemaking, greatly appreciates the effort and cooperation of the healthcare industry to collaboratively develop a robust set of operating rules to improve pain points in these specific CAQH CORE Rules:

- Prior Authorization (278) Data Content Rule v5.0.0
- Prior Authorization (278) Infrastructure Rule v4.1.0
- Connectivity Rule 4.0.0

We appreciate the opportunity to provide feedback to the National Committee on Vital and Health Statistics (NCVHS) on the CAQH CORE Proposal.

As a general comment, Nacha is very supportive of the CAQH CORE rulemaking process that brings together diverse stakeholders to achieve consensus on industry standards and rules.

Topics for Public Comments

1. **Participation in Development of the Rules: If your organization participated in identification and development of the proposed operating rules for prior authorization and/or connectivity, describe the skill set of the individuals involved (business or technical) and in what way they participated in the process.**

   Nacha actively participated in the development of the proposed rules. Our participation was from the Senior Director level and higher, representing almost 50 years of rules making and payments experience and attended 75 subgroup and workgroup calls that discussed the proposed improvements to the CAQH CORE rules. Additionally, we submitted comments on 35 straw polls and ballots pertaining to these rules.

We look forward to our continued participation in the improvement of the CAQH CORE rules.

Sincerely

Bradley W. Smith
Sr. Director, ACH Network Administration
Nacha

July 20, 2020

Alexandra (Alix) Goss, Co-chair, Subcommittee on Standards
Richard Landen, Co-chair, Subcommittee on Standards
National Committee on Vital and Health Statistics
Via email: NCVHSmail@cdc.gov

Dear Ms. Goss and Mr. Landen,

Founded in 1977, the National Council for Prescription Drug Programs (NCPDP) is a not-for-profit, ANSI-Accredited Standards Developer (ASD) consisting of more than 1,700 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

NCPDP supports the federal adoption of the following Council for Affordable Quality Healthcare (CAQH), Committee on Operating Rules for Information Exchange (CORE) operating rules:

- Prior Authorization (278) Data Content Rule
- Prior Authorization (278) Infrastructure Rule
- Connectivity Rule

Even though there is very little use in the pharmacy industry of the X12 278 transaction, NCPDP observed the meetings and reviewed the Prior Authorization (278) documents. The Prior Authorization (278) Data Content Rule and the Prior Authorization (278) Infrastructure Rule exclude the pharmacy benefit electronic prior authorization.

- From the Prior Authorization (278) Data Content Rule, "Pharmacy benefit electronic prior authorization is out-of-scope for this rule set, i.e., pharmacist- or prescriber initiated prior authorizations for drugs/biologics/other treatments covered under a pharmacy benefit are not a function of the web portals addressed in this rule as drug authorizations covered under the pharmacy benefit are the function of the National Council for Prescription Drug Programs (NCPDP)."
- From the Prior Authorization (278) Infrastructure Rule, "Retail pharmacy benefit electronic prior authorizations are out of scope for this rule, i.e., pharmacist-and/or prescriber initiated prior authorization for drugs/biologics and other treatments covered under a pharmacy benefit."

While there is some use in the pharmacy industry of the X12 transactions covered in the Connectivity Rule Version C3.1.0, it is a Safe Harbor and therefore only needs to be used if mutually agreed to by the

trading partners. It does not require trading partners to discontinue using existing connections that do not match the rule. NCPDP reviewed the Connectivity Rule as it was being developed.

For direct inquiries, assistance or questions related to this letter, please contact:
Margaret Weiker, Vice President, Standards Development
NCPDP
Email: standards@ncpdp.org

Sincerely,

Lee Ann C. Stember
President & CEO
NCPDP
9240 East Raintree Drive
Scottsdale, AZ 85260
(480) 477-1000, ext. 108
(602) 321-6363 cell

NMCC
New Mexico Cancer Center
New Mexico Oncology Hematology Consultants, Ltd.

August 14, 2020

William W. Stead, MD
Chair
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: Proposed CAQH CORE Prior Authorization & Connectivity Operating Rules

Dear Dr. Stead,

New Mexico Cancer Center (NMCC) appreciates the opportunity to provide feedback to the National Committee on Vital and Health Statistics (NCVHS) on the proposed CAQH CORE Prior Authorization and Connectivity Operating Rules. NMCC fully supports the three proposed operating rules and encourages NCVHS to recommend the rules to the Secretary of the U.S. Department of Health and Human Services (HHS) for federal adoption.

NMCC is an independent, multi-disciplinary, multi-site practice operated by New Mexico Oncology Hematology Consultants Ltd. Founded in 1987, NMCC is dedicated to providing the highest quality, most compassionate, comprehensive, patient-centered cancer care in New Mexico, focusing first on patients and their needs. During the past fifteen years, the practice has grown statewide. In 2002, NMCC opened its flagship comprehensive cancer center in Albuquerque offering medical and radiation oncology, chemotherapy infusion, radiation therapy, imaging, laboratory, and pharmacy services in one site. Several years later, NMCC opened a second comprehensive cancer care facility in Gallup, NM, for the first time bringing cancer care to western New Mexico and the Navajo Nation, saving patients many hours of difficult and often prohibitively expensive travel that in years past had resulted in many receiving incomplete and inadequate care and poor outcomes.

As a CAQH CORE Participant and former Board member, NMCC has consistently advocated for CAQH CORE to address issues related to automating prior authorization. Too often at NMCC patient care is delayed due to inefficient and manual prior authorization processes. Our patients travel great distances for care, and it can be devastating when we cannot get a timely authorization for medically necessary services.

Specifically, the “two-day” response time requirements in the CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule will reduce care delays. A federal mandate requiring health plans to provide an electronic final determination within a defined timeframe will directly improve patient outcomes and drive provider (and therefore vendor) adoption of the X12 278 transaction. In fact, NMCC advocated for these timeframes to be shorter than two business days during the rule development process and commend CAQH CORE efforts to drive consensus, as other organizations pursued much longer timeframes.

The requirements in the proposed CAQH CORE Prior Authorization and Connectivity Operating Rules represent true compromise among many diverse stakeholders committed to driving greater prior authorization automation, improving interoperability, and ultimately enabling patients to receive more timely care.

NMCC supports NCVHS efforts to reduce administrative burden and encourages NCVHS to demonstrate their commitment to this topic by recommending the proposed operating rules to HHS

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NMCC
New Mexico Cancer Center
New Mexico Oncology Hematology Consultants, Ltd.

for federal mandate.

Thank you for the opportunity to provide comment. Please reach out to me with any questions.

Sincerely,

Barbara L. McAneny MD, CEO
New Mexico Cancer Center
Immediate Past President of the American Medical Association

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July 27, 2020

Alexandra (Alix) Goss, Co-chair, Subcommittee on Standards
Richard Landen, Co-chair, Subcommittee on Standards
National Committee on Vital and Health Statistics

Dear Ms. Goss and Mr. Landen,

The National Uniform Claim Committee (NUCC) is pleased to offer our comments on the request by the CAQH Committee on Operating Rules for Information Exchange (CORE) for the adoption of the Prior Authorization (278) Data Content Rule vPA.1.0, Prior Authorization (278) Infrastructure Rule vPA.2.0, and Connectivity Rule vC3.1.0 under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. In general, we support the adoption of electronic standards and operating rules, with the goal of reducing administrative burdens imposed by disparate requirements by stakeholders throughout the industry.

As you are aware, the NUCC is both a Data Content Committee and advisor to the Secretary of Health and Human Services (HHS) for the adoption of new and modified standards under HIPAA. We have a diverse membership of health care providers, health plans, designated standards maintenance organizations, public health organizations, and vendors. Many of our member organizations will be providing testimony to the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards at its August 25-26 hearing, and as such, the NUCC did not wish to duplicate their efforts. We do have the following overarching comments.

<u>Proposed Operating Rules</u>

The NUCC supports CORE's effort to increase the efficiency and standardization of the prior authorization process through these operating rules. Unfortunately, there is a lack of consensus among the NUCC members as to whether the requirements of the operating rules will achieve the intended goal. Specifically, there are differing opinions on the maximum two-day response requirement, role of CORE in clarifying data content requirements of the standard, and the appropriate connectivity requirements. We recommend that NCVHS further explore the requirements of each operating rule and the various organizations' expert analyses during its hearing.

<u>Document Attachments</u>

These operating rules acknowledge the frequent need for providers to submit additional documentation to the health plan to support prior authorization requests and the heavy reliance on manual processes to accomplish this. While outside the scope of these operating rules, the industry is in dire need of an

attachments standard to bring much needed efficiency, decreased cost, and standardization to the electronic exchange of additional documentation. The prior authorization standard transaction and operating rules, if mandated, will struggle to gain significant adoption without an attachments standard.

The NUCC appreciates the opportunity to comment on CAQH CORE's request to have these operating rules adopted under HIPAA. If you have any questions, please contact me at (312) 330-2953 or nancy.spector@ama-assn.org

Sincerely,

/s/

Nancy Spector
Chair, National Uniform Claim Committee

July 24, 2020

William W. Stead, MD
Chair
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: CAQH CORE Operating Rules Proposed to NCVHS for Federal Adoption

Dear Dr. Stead,

Thank you for the opportunity to provide feedback on the CAQH Committee on Operating Rules for Information Exchange (CORE) Prior Authorization and Connectivity Operating Rules proposed to the National Committee on Vital and Health Statistics (NCVHS). OhioHealth fully supports the proposal and recommends the operating rules to NCVHS and the Department of Health and Human Services (HHS) for federal adoption under HIPAA.

OhioHealth is a nationally recognized, not-for-profit, charitable, healthcare outreach of the United Methodist Church. We are a family of 35,000 associates, physicians and volunteers, and a network of 12 hospitals, 200+ ambulatory sites, hospice, home health, medical equipment, and other health services spanning 47 Ohio counties.

It is estimated that over 20,000 OhioHealth patients are impacted by prior authorization denials annually, even more patients experience care delays due to the inherent process inefficiencies. The improvements resulting from the CAQH CORE operating rules support the OhioHealth mission "to improve the health of those we serve". Simply reducing prior authorization turnaround times from 15 days to two days is a significant step to improve patient care.

The healthcare industry has lamented for many years that the prior authorization process is overly burdensome and unnecessarily costly. OhioHealth employs approximately 70 staff to submit prior authorization information via web portals, phones, faxes, etc., resulting in approximately $3M in annual FTE costs. OhioHealth spends another $5M on appeals and $2M in net write-offs due to lost appeals. Altogether, OhioHealth spends approximately $10M per year to manage an ineffective and inefficient prior authorization process.

The operating rule package proposed by CAQH CORE will drive greater automation, increase efficiencies, improve access to timely patient care, enhance health plan and provider data exchange, and significantly reduce OhioHealth's overall spend on prior authorization processes. The proposed rules represent meaningful steps that healthcare stakeholders can take now to support the move toward automation of prior authorization.

OhioHealth applauds NCVHS efforts to accelerate the adoption of standards and operating rules to achieve the purposes of security, automation, efficiency and interoperability of health data and systems. We encourage NCVHS to promote industry progress by supporting and advancing industry-driven efforts like CAQH CORE. Detailed feedback on each of the 11 questions posed by NCVHS on the proposed CAQH CORE Operating Rules is included below.

Thank you for the opportunity to provide comment. Please do not hesitate to reach out with questions.

Sincerely,

Margaret Schuler
System Vice President, Revenue Cycle
OhioHealth (Provider)
margaret.schuler@ohiohealth.com

1. **Participation in Development of the Rules: If your organization participated in identification and development of the proposed operating rules for prior authorization and/or connectivity, describe the skill set of the individuals involved (business or technical) and in what way they participated in the process.**

More than 125 unique CAQH CORE Participating Organizations collectively contributed to the development of the proposed operating rules. These entities represented a range of stakeholders including providers, health plans, vendors, clearinghouses, associations, standards development organizations, and government agencies. Individuals participating in operating rule development had a range of job titles, representing business, clinical, and technical functions as well as leadership. CAQH CORE rule development is a collaborative, consensus-based iterative process.

Each of the three proposed rules received at least 80 percent support in the CAQH CORE Participant Vote per the CAQH CORE Voting Process.

Randy Gabel, Senior Director of Revenue Cycle, and LeAnne Stratton, Manager of Patient Access, participated directly in the CAQH CORE operating rule development process on behalf of OhioHealth. The table below details the level of effort.

CAQH CORE Operating Rule Development	OhioHealth Engagement
1. CAQH CORE Connectivity Rule vC3.1.0	*N/A: OhioHealth joined as a CAQH CORE Participating Organization in 2018, after this operating rule was approved by the CAQH CORE Participants.*
2. CAQH CORE Prior Authorization & Referrals Data Content Rule	**Randy Gabel** actively participated in the CAQH CORE Rules Work Group to review/vet the draft rule and the Certification & Testing Subgroup to develop the associated certification test suite.
3. CAQH CORE Prior Authorization & Referrals Infrastructure Rule	*NOTE: This rule was initially developed prior to OhioHealth joining CAQH CORE, however OhioHealth actively supported the 2019 rule update process.* **Randy Gabel** Co-Chaired the CAQH CORE Task Group that updated the response timeframe requirements. **LeAnne Stratton** also participated in this Task Group.

2. **Workflow (prior authorization rules): In what way(s) will the proposed operating rules for prior authorization improve workflow for your organization's industry sector? Discuss the prior authorization data content and infrastructure rules and describe how the proposed requirements from each will impact your workflow, reduce burden (if relevant) and better support patient care.**

OhioHealth employs approximately 70 staff to submit prior authorization information via web portals, phone, etc., resulting in approximately $3M in annual FTE costs. OhioHealth spends another $5M on appeals and $2M in net write-offs due lost appeals. Altogether, OhioHealth spends approximately $10M per year to manage ineffective and inefficient prior authorization processes. The operating rule package proposed by CAQH CORE will drive greater automation, increase efficiencies, enhance health plan and provider data exchange, and potentially reduce OhioHealth's overall spend on prior authorization processes by $5M.

- Reduce staffing requirements by half

- Reduce initial denial appeal cost by half
- Reduce net write-offs due to lost appeal by half

The CAQH CORE Prior Authorization Data Content and Infrastructure Operating Rules will create national expectations for the exchange of electronic prior authorization rather than each state having its own regulations. One administrative burden expressed by the industry is the need to comply with varying state laws regarding prior authorization. Based on a recent review of state requirements by CAQH CORE, 30 states have prior authorization response time requirements that vary from 24 hours to 15 business days with differences in definitions and applicability from state to state. At OhioHealth, current health plan response time to prior authorization requests can take up to 15 days. Shorter turnaround times will incentivize provider to adopt the X12 278 transaction resulting in better, faster patient care.

The operating rules will create efficiencies in the OhioHealth workflow and labor costs promoting the use of electronic transactions versus the manual entry of data into a portal, phone call or faxing. Today, staff attempt to get prior authorization via entry into a health plan portal, phone call, or fax. If the procedures occur before formal authorization is received, it can result in denials that then are worked by OhioHealth and its vendor partners to overturn.

The CAQH CORE Prior Authorization (278) Data Content Rule enhances and further standardizes the data shared between plans and providers. Among other requirements, it targets one of the most significant problem areas in the prior authorization process: pended requests for medical services due to missing or incomplete information, generally medical necessity information. The rule will reduce the unnecessary back and forth between OhioHealth and health plans that often occurs when confirming medical necessity, enabling shorter adjudication timeframes and less manual follow-up.
OhioHealth has identified the following specific benefits of the data content rule requirements:

- Addition of PWK segment with document specific codes will help OhioHealth determine the requested supporting document without ambiguity. This will minimize delays in the approval process.
- Mandating HCSDRC to provide a reason for the authorization decision will provide clarity on the decision and help determine appropriate response.
- AAA segment helps OhioHealth segregate content errors vs. security errors to route it to the right support queue for quick resolution.

The CAQH CORE Prior Authorization (278) Infrastructure Rule specifies prior authorization requirements for system availability, acknowledgements, companion guides, and response timeframes. Rule requirements align with other federally mandated infrastructure rules. In 2019, OhioHealth co-chaired an effort to update the rule to include three new response time requirements ensuring progressive system enhancements to further advance the prior authorization process along the automation spectrum.

OhioHealth has identified the following specific benefits of the infrastructure rule requirements:

- Standardized SLAs across health plans and states with predefined response times will help with efficient scheduling and minimized rescheduling.
- Connectivity requirements will further strengthen security as OhioHealth plans payer integrations.
- Improving the patient experience by reducing wait times for procedures requiring prior authorizations.

3. **Transaction exchange (connectivity rule**): **In what way(s) will the proposed operating rule for connectivity improve the processing of transactions, message payload, connectivity, security, etc. if adopted by HHS? What are the anticipated benefits that this operating rule offers vs. the current state (please provide examples if possible)?**

Updating the federally mandated connectivity requirements from vC1.1.0 and vC2.2.0 for eligibility, claims status, and electronic remittance advice to vC3.1.0 and requiring vC3.1.0 for prior authorization has the following benefits for OhioHealth:

- It will further strengthen security as OhioHealth integrates with health plans.
- It will enable OhioHealth to extend existing connections that are used with other integrations to EDI transactions (eligibility, claim, electronic remittance advice, prior authorization).
- A consistent CAQH CORE Connectivity safe harbor across the EDI transactions will drive efficiencies and reduce onboarding costs (reduce vendor cost, reduce labor cost, reduce cost to support, etc.).

Compared to the current state (vC2.2.0), the CAQH CORE Connectivity Rule vC3.1.0:

- **Promotes a Single Standard:** Reduces complexity and simplifies interoperability by requiring a single SOAP + WSDL envelope standard vs two envelope standards and establishes more robust and uniform support for handling transaction payload by requiring MTOM for SOAP for both real time and batch processing modes.
- **Improves Security:** By requiring use of X.509 Client Certificate-based authentication and removing the security vulnerable username + password, implementors benefit from a more robust and industry standard security. Additionally, provides support for FIPS 140-2 compliance for entities requiring such compliance, in terms of transport security and message envelope security.
- **Enables Safe Harbor:** The CAQH CORE Connectivity safe harbor specifies that application vendors, clearinghouses, providers, and health plans can be assured CAQH CORE Connectivity will be supported by any HIPAA covered entity and/or a CORE-certified entity, meaning that the entity is capable and ready at the time of the request by a trading partner to exchange data using the CAQH CORE Connectivity Rule. The rule does not require entities to remove existing connections. For example, 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).
- **Enhances Messaging and Error Reporting:** Improves the communication of errors with updated error codes.

4. Improving use of transactions and/or adoption of standards (all proposed operating rules): Describe how adopting the proposed operating rules will or could increase in the use of any of the adopted HIPAA transaction standards.

OhioHealth is confident that the requirements in the proposed rule package greatly enhance the value of the X12 278 transaction by specifying and standardizing the transaction infrastructure and the data shared between providers and health plans. With more information available via the X12 278, OhioHealth is encouraged to consider its adoption into various workflows given:

- The data content requirements help a provider accurately request member-specific information needed for a prior authorization and enable a health plan to clearly communicate next steps in the prior authorization process, including what additional documentation is needed.
- The availability of enhanced data content helps overcome the hurdle of missing or inconsistent data and streamlines the review of prior authorization requests, facilitates faster response times, and provides for an automated adjudication of a final determination.
- Infrastructure rules ensure common expectations and SLAs across health plans for consistent data exchange and automation.
- The timeframe requirements in the infrastructure rule incentivizes adoption among providers as they can be assured of a maximum response time when utilizing the X12 278 transaction. A federal mandate would also reduce the need for health plans to comply with varying state requirements.

Although there is strong industry support for the operating rules as demonstrated by the high approval rates across CAQH CORE Participating Organizations and early adopters, federal mandates accelerate industry adoption by raising awareness and making investment dollars available for federal compliance. CAQH CORE surveys indicate the most frequent reason cited for lagging adoption is the lack of a federal mandate to support prioritization and allocation of resources. Timely, federal adoption of these operating rules could raise industry awareness, particularly among providers, and encourage vendor development of prior authorization solutions that have significantly lagged development of solutions for other administrative transactions.

5. **Connectivity rule implementation for your organization or industry wide (please specify):**
    a. **What are the implications, costs and benefits of implementing the new connectivity rule requirements for the prior authorization, eligibility & benefits, claim status and electronic remittance advice transactions? Providing generalized or high-level information will be helpful to the Committee.**

There will be effort and minimal cost involved as OhioHealth ensures all components of the integration workflow meet the mandated security protocols. Given the requirements align with standard security protocols, OhioHealth foresees significant alignment with current initiatives. As a company that relies on vendor provided software for 278 transactions, there will be some internal overhead (effort/cost) to develop documentation and provide web-based connectivity.

The benefits for our patients related to faster turnaround of authorization, eligibility & benefits, claim status, and electronic remittance advice via electronic transactions outweighs the current cost of manual requests and follow-up on these same requests. A consistent CAQH CORE Connectivity safe harbor across the EDI transactions will drive efficiencies and reduce onboarding costs (reduce vendor cost, reduce labor cost, reduce cost to support, etc.).

    b. **Can you provide general types of costs and benefits of meeting the processing mode requirements for both real time and batch submissions?**

The only new processing mode requirements proposed by CAQH CORE are in the CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule. This rule requires that a health plan or its agent implement server requirements for either real time or batch processing mode for the 5010X217 278 Request and Response transactions. Optionally, a plan can implement both. OhioHealth could incur potential costs associated with enhancing our platform to provide high availability to handle real-time requests and monitoring to enable zero down time if real time is pursued.

Building off existing infrastructure in place for eligibility, claim status and electronic remittance advice can greatly reduce costs to implement when leveraging these existing EDI efforts.

6. **Implementation time frame for each proposed rule:**
    a. **What is the anticipated lead time needed by your organization to develop, test and implement the proposed operating rules? What are the dependencies that impact the timeline, e.g., vendors, trading partners and business associates? If possible, please provide an estimate of the amount of time your vendors would require to develop their component of the solution?**

OhioHealth is dependent on vendor systems (EHR, Health Plan systems, etc.) to implement the proposed operating rules. It would take an estimated 9 – 12 months of lead time to implement. OhioHealth is already working with their EMR vendor to initiate 278 implementation.

- Content Rule – Updates to existing 278 EDI file generation process to include new data elements. Potential updates to EMR platform to have a place holder for these new attributes.
- Infrastructure Rule – Putting processes and alerts in place to meet the new SLAs.

- Connectivity Rule – Revisiting all existing X12 integrations and validating and or upgrading them to meet minimum security/data transfer method protocols.

b. Should considerations be given to size or organization type for the proposed implementation timeframe? Please discuss for each of the proposed operating rules (Prior authorization content, prior authorization infrastructure and connectivity).

Given there is a one to many relationship between provider and health plans, it can be assumed that the larger the number of health plans the more time will be required to test and implement. There may also be enhancements made to the X12 278 that would require modifications to the integration between providers and health plans. These types of changes can lead to delays in adoption and use standards.

The size of the health plan or provider institution can impact its ability to fund vendor solutions to implement the X12 278. Smaller systems may not be able to afford or will require more dependency on vendors to implement (e.g., physician practices, small localized health plans, community hospital, etc.).

7. Costs (Prior Authorization rules): Is your organization able to provide an estimate of the implementation cost for the requirements of the two prior authorization operating rules for data content and infrastructure? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting these rules?

The benefits of the proposed CAQH CORE operating rules will outweigh implementation costs over time for both OhioHealth and industry. Federal adoption of the proposed prior authorization operating rules facilitates automation, faster response times, and reduce administrative costs associated with the costliest and most time-consuming manual transaction tracked by the CAQH Index. According to the 2019 CAQH Index, the industry could save $12.31 per prior authorization transaction by moving from manual processing to use of the HIPAA-mandated 5010X217278 Request and Response.

The healthcare industry has lamented for many years that the prior authorization process is overly burdensome and unnecessarily costly. OhioHealth employs approximately 70 staff to submit prior authorization information via web portals, phone, fax, etc., resulting in approximately $3M in annual FTE costs. OhioHealth spends another $5M on appeals and $2M in net write-offs due to lost appeals. Altogether, OhioHealth spends approximately $10M per year to manage ineffective and inefficient prior authorization processes.

The operating rule package proposed by CAQH CORE will reduce OhioHealth's overall spend on prior authorization processes through efficiencies gains and standardization. There will be implementation costs (man-hours) for both OhioHealth and the health plans. Both groups will be dependent on technical teams to build, connect and test electronic transactions. Estimating only OhioHealth efforts, it would take an estimated 9 – 12 months of lead time to implement.

The savings for OhioHealth through a reduction in staff, denial appeals, and net write-offs could be at least $5M. This represents approximately half of what OhioHealth spends per year to manage ineffective and inefficient prior authorization processes.

8. Costs (Connectivity rule): Is your organization able to provide an estimate of the implementation cost for the requirements of the connectivity operating rule? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting this rule and its requirements?

Many HIPAA-covered entities have already implemented the CAQH CORE Connectivity Rule vC2.2.0, given it is federally mandated for eligibility, claim status, and electronic remittance advice. Therefore, these entities will not

be required to fully implement all the CAQH CORE Connectivity Rule vC3.1.0 requirements due to commonalities in transport, envelope, authentication standards, and metadata. Implementation costs may be reduced due to only needing to support one submitter authentication standard. Most contemporary web-based traffic now uses digital certification technology and the largest certificate authorities provide free digital certifications. Therefore, the costs may be lower than continued support of username/password (less administrative support, better network authentication, and greater security).

OhioHealth estimates infrastructure and connectivity one-time costs to be no more than $50,000. It is dependent on security and connectivity vendor costs. These costs include:

- Internal overhead (effort/cost) to develop documentation and provide web based connectivity.
- Electronic Medical Records vendor costs for the 278 will be $16K for the base license with $250 monthly maintenance.
- OhioHealth expects nominal fees with its clearing house partner.

9. Additional comments: Given that the Connectivity Rule is highly technical, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?

Updating the currently mandated CAQH CORE Connectivity requirements for eligibility, claim status, and ERA transactions will ensure a modern and secure connectivity method is available for industry and reduce the need for continued industry support for multiple authentication standards. Additionally, a single connectivity rule across all transactions is easier to update, reduces confusion, and promotes industry alignment on best practices.

It is critical for providers and health plans to work together on the connectivity and testing of the standard transactions. Often, implementations fail because of misunderstanding or lack of communication. Standard transactions make it easier to update and support for all groups. Partnering with each groups' vendors is also key to a successful implementation. A next logical step is sharing patient information (demographic, clinical, and other supporting data) to support patient information requests between health plans and providers (e.g. X12 275 transaction type).

10. Additional comments: For the Prior Authorization operating rules, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?

Prior authorization directly impacts patient care. Patients need solutions to lengthy prior authorization processes now. The CAQH CORE Connectivity and Prior Authorization Operating Rules address a pressing industry need to automate prior authorization adjudication. The benefits and savings of having a uniform way of communicating between providers and health plans will provide savings to both groups in time, FTEs, and patient/consumer satisfaction. Additionally, speeding up the authorization process allows for more timely care for OhioHealth patients. These rules can align with and help bridge the gap to new and emerging standards over time.

11. General: For each rule, please provide the rationale for your support or opposition to its adoption to inform the Committee's deliberations.

OhioHealth fully supports the proposal and recommends the three CAQH CORE Prior Authorization and Connectivity Operating Rules to NCVHS and the Department of Health and Human Services (HHS) for federal adoption under HIPAA. Specifically:

- The prior authorization operating rules address a pressing need to improve automation and timeliness of the prior authorization process, reducing costs and improving access to timely patient care.
- The connectivity operating rule enhances security and promotes uniform interoperability requirements across administrative transactions.
- These operating rules set the stage for future operating rules to further enable the critical convergence of administrative and clinical data and support the use of new technologies with existing standards.

From: Mona Reimers
To: NCVHS Mail (CDC)
Subject: Comments: CAQH CORE Operating Rules for prior authorization and connectivity
Date: Friday, July 24, 2020 4:05:54 PM

July 24, 2020

Re: Request for Public Comment on CAQH CORE Operating Rules
Dear Committee Members,

As a medical practice administrator with decades of experience dealing with prior authorizations, I am submitting my comments below on the proposed CAQH CORE Operating Rules for prior authorization and connectivity.

These comments are also on behalf of Orthopaedics NorthEast, PC (ONE), my current employer. ONE is a nearly sixty-year-old orthopedic, anesthesia and pain management practice with an average of 650 patient encounters per day in the office and surgery settings, treated by over 70 providers in NorthEast Indiana. Like many medical practices, ONE struggles with prior authorization and spends significant financial resources to obtain authorizations for office and surgical services as well as prescription medication, durable medical equipment, physical therapy, and other services. To complete this work timely and closely align the timing requirements of the various medical needs and payer expectations of us, we employ over 18 full time staff who work exclusively in the prior authorization department. For these reasons, ONE enthusiastically supports the proposed CAQH CORE Prior Authorization and Connectivity Operating Rules.

The need for greater standardization of the prior authorization processes through an electronic exchange of data is long overdue, even with existing HIPAA mandates. Because this issue has not yet been addressed, the problems have increased, and the medical industry has experienced a drastic increase in expense due to the lack of swift and trusted technologic workflows. Instead the industry relies on old-fashioned faxing, hundreds of web portals, encrypted emails, and millions of phone calls nationwide. The wasted overhead expense has ultimately been borne by the patients, insurers' providers and American businesses. And every human interaction with a provider's office where the insurer turns over a previous denial (for any reason) or the provider had other information needed (and not included) the first time, the insurer has wasted operational cost. These costs add nothing to the quality of medical care ultimately provided.

More importantly there is significant delay in receiving care, which reduces America's workforce's productivity, and at times limits the workforces' financial contribution to their economy when care is delayed or are unnecessarily denied and the worker is not able to work until they receive care.

The CAQH CORE Prior Authorization and Connectivity Operating Rules for the X12 278 transaction address several concerns and problems experienced in current prior authorization workflows while providing stability and reliability. Building on the success of the electronic claims submission, payment posting and eligibility rules, healthcare stakeholders trust the CAQH CORE consensus-based process to develop reliable and uniform technology requirements to support standards that are

easily adopted nationwide. The specific problems these operating rules will almost fully eradicate include:

1.) Proof of delivery. Today, many providers and insurers use fax, web portals and telephone banks with call recording to maintain records of submission of the request for prior authorization. Generally a follow up call to get an insurer to verify receipt and status of an authorization request is 3-7 days after submission.
    a. A file submitted electronically through a clearinghouse would allow proof the request was made, much like the 837 standardization. The standard proof of delivery would be within 20 seconds of the submission and the clearinghouses would store this information. This will save valuable time and significantly reduce wasted staff time. Less phone calls from providers to insurers "checking" the status of their request – which is really meant to verify receipt.
    b. It is also essential if the insurer loses that information to get a fast-tracked decision to avoid "starting over."

2.) Proof of follow up. Under the proposed rules insurers would communicate with providers (using the X12 278) if they need further information to process the prior authorization within two business days of request receipt. (Currently many insurers require a minimum of 7 – 14 days before a provider can even check the status of any non-emergent prior authorization request).

3.) The provider can then follow up with the necessary documentation. The attachment could be returned electronically by the provider and decrease the chance of it being misrouted or lost. Lost, misplaced or misunderstood documentation. Under the proposed rules, the communications between providers and health plans will be automated using the X12 278 and "additional documentation" needed to make decisions can be more easily identified and returned to the health plan for review.

4.) Timely final determination. Once all necessary documentation is received, t can take up to 15 – 30 days to get a final prior authorization determination from an insurer. The proposed operating rules require health plans to send a final determination within two business days of receiving all information needed to make a decision. Shortening the timeframe to final determination will enable patients to receive needed care more quickly with less administrative burden.

In addition to the incredible value added via the timeframe requirements for prior authorization, the proposed operating rules have a number of additional benefits that will result in a reduction in staffing, denial appeals, and write-offs due to lost appeals for ONE. Specifically:

- The Prior Authorization Data Content Rule includes requirements for use of codes that will help providers like ONE understand what supporting documentation is needed and provide clarity on decisions to determine next steps.
- The Prior Authorization Infrastructure Rule will improve patient care by reducing wait times. Uniform SLAs across insurers will help standardize data exchange.
- The Connectivity Rule vC3.1.0 with offer a common connectivity safe harbor across

administrative transactions simplifying the onboarding process with new insurers.

The nationwide adoption of this type of system and the technology already available via the health plan – clearinghouse-provider infrastructure would be a monumental improvement to America's healthcare system.

Please feel free to contact me if I can provide any assistance to you or answer any questions about the current day prior authorizations for Orthopaedics Northeast. Thank you for your attention to this very important matter.

Sincerely,

Mona Reimers | Director of Administrative Operations
Ortho NorthEast ("ONE")
mreimers@orthone.com | direct tel: (260) 408-2331
main tel: (260) 484-8551
5050 N. Clinton St | Fort Wayne, Indiana 46825

RadNet
Leading Radiology Forward

July 24, 2020

William W. Stead, MD
Chair, National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: RadNet's Comments on CAQH CORE Operating Rules

Dear Dr. Stead:

RadNet appreciates the opportunity to comment on the proposed Prior-Authorization and Connectivity Operating Rules for federal adoption from the Committee on Operating Rules for Information Exchange (CORE) Board of the Council for Affordable Quality Healthcare (CAQH). The current prior-authorization ecosystem is challenging for clinicians, frustrating for patients, and increasingly burdensome and costly. RadNet is supportive of efforts to make prior-authorization more efficient, less burdensome, and costly through automation and the promulgation of standards supported by the federal government. However, in order to achieve widespread adoption by providers, the automated prior-authorization process has to be superior in terms of speed and information conveyed to alternative methods (portals, phone calls) which often are quicker and easier than electronic means.

About RadNet

RadNet, Inc. is the leading national provider of freestanding, fixed-site diagnostic imaging services in the United States based on the number of locations and annual imaging revenue. Our goal is to deliver high-quality, conveniently accessible care in the most cost-effective manner possible -- all of which makes us the alternative to the higher-priced hospital and health system-based or owned imaging provider. RadNet has a network of more than 340 owned and/or operated outpatient imaging centers. RadNet's markets include California, Maryland, Florida, Delaware, New Jersey, and New York. Our over 340 imaging centers, nearly 800 radiologists, and approximately 8,500 employees perform an estimated eight million imaging procedures annually. In addition, RadNet provides radiology information technology solutions, teleradiology professional services, and other related products and services to customers in the diagnostic imaging industry.

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I. General Comments

A. Prior-Authorization

Prior-authorization is a significant problem. In its current mostly manual form, prior-authorization leads to delays in patient care, added burden on providers, financial hardships, and higher costs. Patient care is delayed while the requested imaging study awaits approval from the payor or benefits manager which can take several days.

RadNet has significant first-hand experience with prior-authorization. We perform over eight million procedures annually; approximately 20 percent (or 1.6 million) are advanced diagnostic imaging modalities (e.g., CT, MRI) which typically require prior-authorization. A significant percentage of our denials are related to prior-authorization or justification for the exam. RadNet has had to invest substantially in additional staff resources to work these denials in an attempt to collect from payors. It has been a source of frustration that we continue to absorb the risk, burden, and expense of this process while seeing no benefit in return.

B. Prior-Authorization from a Rendering Provider's Perspective

The proposed operating rules summarize many of the issues associated with prior-authorization. To these, we add the following challenges from the perspective of a rendering provider:

- Inconsistent Application of Prior-Authorization

  Patients will present to schedule their imaging studies without the necessary prior approval. Then, either the study will be postponed; thus delaying care until the approval has been received, or; the study will proceed and we bear the risk of claim denials and non-payment. Conversely, patients will present to schedule imaging with prior-authorizations having been performed; only to determine that the authorization was not required. This wastes time, money, and pulls resources from patient care.

- Clinically Inflexible

  We strive to provide the right imaging exam to answer the patient's clinical question based on indications and conditions. This may necessitate changing the study ordered and authorized. For example, a MRI of the brain without contrast could be ordered, but the radiologist recommends that a MRI of the brain with and without contrast is the more appropriate examination. Contrast reactions, either suspected or documented, are another reason for changing an examination. An authorization for a specific procedure limits the flexibility of radiologists and ordering physicians to select the right imaging exam for their patients. Instead, an authorization should designate a family of related services which would provide the needed flexibility to tailor the examination to the patient without having to re-start the prior-authorization process and incurring additional delays.

- Lack of Coordination

  Greater use of electronic notifications or automated messaging would improve authorization coordination between the payor and care team. Information regarding the rendering provider typically is part of the prior-authorization request. The proposed operating rules envision payors automatically notifying the ordering physician of a prior-authorization decision. But, payors and benefits managers do not automatically notify the rendering provider who requires the authorization to perform the procedure and to be paid. In the absence of automated notifications, the ordering provider has to transfer prior-authorization approval information to

the scrip manually or the rendering provider has to hunt-down authorizations from a web-portal. Either way, the authorization information may not reach the rendering provider in a timely manner which delays care and may result in a patient being rescheduled if the authorization has not been approved yet.

- Verification of Medical Necessity

  Upon receiving a compliant order and authorization, radiology and other referral-based specialties should be able to rely that the determination of medical necessity has been made and the exam can proceed and will be appropriately reimbursed. Payors frequently ask us for additional documentation supporting the medical necessity for a procedure in question as a condition for payment. Not only does this delay payment, but unfairly puts the onus on us to do work that should have happened before the exam was ordered.

II. CAQH CORE Proposed Operating Rules

A. NCVHS Questions for Public Comments

The Committee requests public comments to aid in its deliberations regarding the benefits of adopting these rules. Specific questions were developed to ensure that the comments addressed various key issues under consideration by the Committee. Comments should be organized according to the corresponding operating rule. Our comments follow these guidelines.

One of the questions from the Committee was whether or not the commenter participated in the development of the proposed operating rules. RadNet was <u>not</u> involved in the authoring of any of the proposed operating rules. However, we have extensive clinical, technical, and business "know how" from being a major national provider of healthcare services, whose services (imaging) are frequently subjected to prior-authorization.

B. <u>Prior Authorization (278) Data Content Rule v5.0.0</u>

1. About the Data Content Rule:

   The Data Content Rule is intended to give health plans a more robust electronic means of communicating with providers about missing clinical information and documentation.

2. Workflow: *In what way(s) will the proposed operating rules for prior authorization improve workflow for your organization's industry sector? Discuss the prior authorization data content rule and describe how the proposed requirements from each will impact your workflow, reduce burden (if relevant) and better support patient care.*

   The pending of prior-authorization requests because of missing or incomplete information is a significant problem with the current prior-authorization process. Through the standardization of required information and more useful and timelier feedback on prior-authorization requests, the proposed Data Content Rule is intended to reduce the unnecessary back and forth between

providers and payors, shorten adjudication time, and reduce staff resources spent on manual follow-up.

Automating the X12 278 prior-authorization request/response/pending processes is a major improvement. But, its impact on provider workflows will be limited and the goals of administrative simplification and burden reduction not achieved if the new X12 278 transaction experience is not equal to or superior, in terms of speed and information, than alternative means of prior-authorization (portals, phone calls). Providers and their patients expect prior-authorization determinations as quickly as possible.

Second, the proposed Data Content Rule does not address the problem of the ordering provider knowing whether or not prior-authorization is required. Thus, patients may present for their studies without the necessary authorization or with an authorization when not necessary which leads to delayed care in former and wasted resources and frustration in the latter.

Finally, while the immediate X12 278 receipt acknowledgement is helpful, any information available about the adjudication of the prior-authorization request should be returned immediately and not be subject to a two-day delay. Our experience is that almost half of our prior-authorization requests are approved immediately. If the X12 278-exchange process delays care for the other half of our patients requiring prior authorization then it will be difficult to invest in the use of the X12 278 exchange.

3. Improving use of transactions and/or adoption of standards: *Describe how adopting the proposed operating rules will or could increase in the use of any of the adopted HIPAA transaction standards.*

   A goal of this rule is to assure that electronic prior-authorization transactions contain standardized, consistent, and accurate information. A problem we encounter regularly is the fields may be in common between payors, but the definitions and criteria may differ. The establishment of rules and standards for transactions is a positive step towards more reliable and consistent transactions.

   As for increased use of transaction standards by providers that will depend largely on whether the new rules for electronic X12 278 transactions for prior-authorizations offer a real improvement in terms of timeliness and information than phone calls or portals. If providers view the new rules as codifying existing practice rather than being transformative, then uptake by providers will be limited.

4. Implementation time frame: *a. What is the anticipated lead time needed by your organization to develop, test and implement the proposed operating rules? What are the dependencies that impact the timeline, e.g., vendors, trading partners and business associates? If possible, please provide an estimate of the amount of time your vendors would require to develop their component of the solution? b. Should considerations be given to size or organization type for the proposed implementation timeframe? Please discuss for each of the proposed operating rules (Prior authorization content, prior authorization infrastructure and connectivity).*

   Healthcare providers and insurers have 25 months to adopt and implement new operating rules once mandated by HHS via an interim final rule with a 60-day comment period. This should be sufficient time for providers and their third-party vendors (e.g., billing companies, clearinghouses) to adopt and test the new standards. However, small physician practices that perform services in-house may need more time to implement the requirements.

5. Costs: *Is your organization able to provide an estimate of the implementation cost for the requirements of the two prior authorization operating rules for data content and infrastructure? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting these rules?*

   In order to adopt these rules, RadNet and other providers will incur costs related to: (1) technology and (2) personnel/human resources. Technology costs include new or updated software or systems, implementation, and support by the provider themselves and/or their third-party vendors (e.g., billing, revenue cycle management, clearinghouse). There will be expenses associated with modifying existing workflows. Finally, personnel/human resource expenses cover management and training of staff to the new rules and workflows.

   Providers will see a positive return on their investment in the new operating rules if automated prior-authorization transactions are faster and less expensive than what can be achieve through alternative means (phone calls, portals). For example, real-time X12 270/271 transactions have permitted us to skip portals and manual look-ups in determining a patient's out-of-pocket costs. We have been able to lower our costs while providing patients with more timely estimates of their cost-share, if applicable.

6. Additional Comments: *For the Prior Authorization operating rules, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?*

   No further comments.

7. General Comments: *For each rule, please provide the rationale for your support or opposition to its adoption to inform the Committee's deliberations*

   No further comments.

C. Prior Authorization (278) Infrastructure Rule v4.1.0

1. About the Infrastructure Rule:

   The Prior Authorization (278) Infrastructure Operating Rule includes proposed requirements for system availability, acknowledgements, companion guides, and response times (batch and real-time) for the X12 278 Request and Response.

2. Workflow: *In what way(s) will the proposed operating rules for prior authorization improve workflow for your organization's industry sector? Discuss the prior authorization infrastructure rule and describe how the proposed requirements from each will impact your workflow, reduce burden (if relevant) and better support patient care.*

   RadNet generally is supportive of the establishment of performance metrics (e.g., time requirements, up-time minimums) because the added predictability brought to the prior-authorization process has the potential to lower burden and costs and promote timelier patient care.

   We have several concerns with the rule's time requirements. First, providers will have no incentive to use X12 278 transactions if they have to wait two days to receive a decision when they can get a response faster via a phone call or portal particularly with a patient on hold trying to schedule a study. With many healthcare providers and facilities offering services on weekends, health plans and their agents should adjust their prior-authorization procedures in keeping with the care needs of their beneficiaries. Thus, prior-authorization transactions should be measured in seconds and not days. Second, the Infrastructure Rule leaves the discretion of the actual calendar day(s) constituting business day(s) to the health plan or its agent. Business days can lead to long wait times for a decision, particularly if they span a weekend. Also, the discretion between calendar days and business days introduces variability and uncertainty in the prior-authorization process which is counter to the goal of standardization. Finally, we question what impact this has on states that require prior-authorization responses less than the proposed two-day standard. In these instances, the shorter, more stringent requirement should apply.

   The Infrastructure Rule requires that HIPAA-covered health plans or their agents support either real-time or batch X12 278 Request and Response transaction processing. (Health plans or their agents may implement both real-time and batch processing.)[1] Batch processing slows prior-authorizations and gets in the way of patients and their care. Therefore, all health plans and their agents should be required to support real-time X12 278 processing.

[1] Infrastructure Operating rule, footnote 14, page 11

3. Improving use of transactions and/or adoption of standards: *Describe how adopting the proposed operating rules will or could increase in the use of any of the adopted HIPAA transaction standards.*

   The establishment of performance metrics should make the X12 278 transaction process more predictable which, in turn, should encourage greater use. Providers will not fully embrace X12 278 transactions until they offer greater speed and information than alternatives.

4. Implementation time frame: *a. What is the anticipated lead time needed by your organization to develop, test and implement the proposed operating rules? What are the dependencies that impact the timeline, e.g., vendors, trading partners and business associates? If possible, please provide an estimate of the amount of time your vendors would require to develop their component of the solution? b. Should considerations be given to size or organization type for the proposed implementation timeframe? Please discuss for each of the proposed operating rules (Prior authorization content, prior authorization infrastructure and connectivity).*

   See our comments on implementation time frame under Data Content Rule.

5. Costs: *Is your organization able to provide an estimate of the implementation cost for the requirements of the two prior authorization operating rules for data content and infrastructure? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting these rules?*

   See our comments on costs under Data Content Rule.

6. Additional Comments: *For the Prior Authorization operating rules, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?*

   No further comments.

7. General Comments: *For each rule, please provide the rationale for your support or opposition to its adoption to inform the Committee's deliberations*

   No further comments.

D. Connectivity Rule 4.0.0

1. About the Connectivity Rule:

   The CAQH CORE Connectivity Rule v4.0.0 is intended to improve security and simplify interoperability across administrative transactions.

2. Transaction Exchange: *In what way(s) will the proposed operating rule for connectivity improve the processing of transactions, message payload, connectivity, security, etc. if adopted by HHS? What are the anticipated benefits that this operating rule offers vs. the current state (please provide examples if possible)?*

   See our previous comments on the need for real-time prior-authorization.

3. Improving use of transactions and/or adoption of standards: *Describe how adopting the proposed operating rules will or could increase in the use of any of the adopted HIPAA transaction standards.*

   See our previous comments on the need for real-time prior-authorization.

4. Connectivity rule implementation for your organization or industry wide (please specify): *a. What are the implications, costs and benefits of implementing the new connectivity rule requirements (Rule 4.0.0) for the claims, prior authorization, premium payment and enrollment/disenrollment transactions? Providing generalized or high level information will be helpful to the Committee. b. Can you provide general types of costs and benefits of meeting the processing mode requirements for both real time and batch submissions?*

   No comments.

5. Implementation time frame: *a. What is the anticipated lead time needed by your organization to develop, test and implement the proposed operating rules? What are the dependencies that impact the timeline, e.g., vendors, trading partners and business associates? If possible, please provide an estimate of the amount of time your vendors would require to develop their component of the solution? b. Should considerations be given to size or organization type for the proposed implementation timeframe? Please discuss for each of the proposed operating rules (Prior authorization content, prior authorization infrastructure and connectivity).*

   See our comments on implementation time frame under Data Content Rule.

6. Costs: *Is your organization able to provide an estimate of the implementation cost for the requirements of the connectivity operating rule? If not, how would you advise NCVHS and HHS to make a cost benefit determination about adopting this rule and its requirements?*

   See our comments on costs under Data Content Rule

7. Additional Comments: *Given that the Connectivity Rule is highly technical, from an overall implementation and value perspective, do you have additional comments for the Committee's consideration?*

   No further comments.

8. General Comments: *For each rule, please provide the rationale for your support or opposition to its adoption to inform the Committee's deliberations*

   No further comments.

III. Future Development

Automating healthcare transactions can improve care, reduce burden, and lower cost. The prior-authorization process is ripe for improvement and the proposed operating rules are a step in the right direction. Other opportunities for automation and process improvement are presented below. RadNet would welcome the opportunity to explore these further.

- Electronic Ordering

  Many of our referring physicians work in independent, non-hospital practices. It is our experience that a significant percentage of orders for imaging studies involve some form of paper and manual processing (e.g., fax, paper scrips, phone calls). Encouraging the adoption of electronic ordering promotes greater interoperability. Electronic ordering also lessens imaging non-compliance issues (e.g., lost scrips, patient no-shows), permits follow-up and re-orders as needed, and eases data collection and reporting in support of process and care improvement. This is good for the imaging provider too because it avoids the manual entry of order information (e.g., patient name, study, referring clinician, reason for exam) and patient adherence to imaging appointments will improve.

- Real-Time Claim Adjudication

  The next step in the automation of healthcare transactions is real-time claims adjudication (processing). With real-time adjudication, the claim for medical services is submitted by the provider to the insurer and settled within moments at the patient's point of care. Real-time claims adjudication can reduce the expenses associated with claims processing significantly and provide patients with more timely estimates of their out-of-pocket costs.

- Prior-Authorization Coordination Between Providers

  Our comments described the challenges associated with the lack of prior-authorization coordination. The automation of prior-authorization has the potential to improve coordination between ordering clinician, rendering provider, and payor if the ordering clinician and the rendering receive the X12 278 final determinations. The X12 278 Request includes the rendering provider. Currently, the clinician who submits the X12 278 Request receives the final response. If approved, the authorization information has to be transferred (usually manually) to the order to the rendering provider. This is inefficient, introduces the potential for error, and patients may present for studies without the required approval. Alternatively, if rendering providers also received the X12 278 approval determinations, patient scheduling would be facilitated and patients could be followed and missed studies reduced.

IV. Summary

The current prior-authorization ecosystem is challenging for clinicians, frustrating for patients, and increasingly burdensome and costly. Ideally, medical necessity determinations should be a seamless automated transaction involving ordering clinicians, payors, and rendering providers covering the continuum of care from order through payment. Optimizing electronic workflows, advancing new standards, and automating prior-authorization processes have the potential for reducing burden, costs, and delays in patient care. CAQH CORE's proposed operating rules are steps in the right direction, but only go so far. The X12 278 transaction process needs to outperform alternatives in terms of speed and information before it is embraced fully by providers.

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RadNet appreciates the opportunity to provide the NCVHS with our comments on the proposed operating rules from CAQH CORE. If you have any questions or need additional information, please contact Michael Mabry, RadNet's Director of Public Policy and Economic Analysis at 443.810.4798 or Michael.Mabry@RadNet.com.

Respectfully submitted,

Susan Hollabaugh
Vice President, Regulatory Analysis and Conformance
RadNet

cc: Ranjan Jayanathan, RadNet
Michael Mabry, RadNet

UNITEDHEALTH GROUP®

Tim Kaja
COO, UnitedHealth Networks
UnitedHealthcare
9900 Bren Road East | MN008-T904
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August 14, 2020

William W. Stead, MD
Chair
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: Three CAQH CORE Operating Rules Proposed to NCVHS for Federal Adoption

Dear Dr. Stead,

Thank you for the opportunity to comment on the three CAQH CORE Prior Authorization and Connectivity Operating Rules proposed for federal adoption. As a health plan, UnitedHealth Group (UHG) strives to minimize administrative burdens across the healthcare industry through innovative and interoperable approaches, including for prior authorization. It is for this reason that UHG supports the proposed operating rules and encourages the National Committee on Vital and Health Statistics (NCVHS) to recommend the rules for federal adoption to the Secretary of the U.S. Department of Health and Human Services (HHS).

UHG is dedicated to helping people live healthier lives and making the health care system work better for everyone by simplifying the health care experience, meeting consumer health and wellness needs, and sustaining trusted relationships with care providers. In the United States, UHG contracts directly with more than 1.2 million physicians and care professionals, and 6,500 hospitals and other care facilities nationwide. We serve people within many of the country's most respected employers, in Medicare serving nearly one in five seniors nationwide, and in Medicaid supporting underserved communities in 31 States and the District of Columbia.

As a founding participant in CAQH CORE, UHG enthusiastically supports the collaborative, consensus-based process to develop operating rules that streamline the business of healthcare. We have achieved three CORE Certifications to date and experienced firsthand the cost-savings and efficiencies associated with operating rule implementation. The proposed prior authorization and connectivity operating rules will bring much needed infrastructure, interoperability, and consistent data exchange to the prior authorization process. The rules enable greater automation, reducing the need for manual interventions, and improving turnaround times.

Since inception, NCVHS has delivered sound guidance to HHS on data policy decision-making. UHG appreciates the work of the committee to accelerate the adoption of standards and operating rules.

Thank you for the opportunity to provide comment. Please do not hesitate to reach out with questions.

Sincerely,

Tim Kaja
COO, UnitedHealth Networks
UnitedHealthcare

August 25, 2020

NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS

Subcommittee on Standards
Review Committee

PROPOSED OPERATING RULES on PRIOR AUTHORIZATIONS

Comments regarding
Department of Veterans Affairs
as Health Care Provider

Given the current lack of uniformity and usage of the Prior Authorization transaction, the recommendation is that the proposed Operating Rules should be adopted.

As the largest integrated healthcare system in the US, VA sent and received over 80 million healthcare transactions in 2019, and is committed to implementing HIPAA mandated electronic transactions to ensure the benefits of administrative simplification are met across the healthcare industry. These benefits are then passed on to our Nation's Veterans.

These remarks address the questions posed by NCVHS for Operating Rules on Prior Authorizations and are organized in two following categories:

1. **VA's past successes and challenges with the Operating Rules**
2. **VA's view on moving forward with the proposed Operating Rules**

VA's past successes and challenges with the Operating Rules

VA's experience with implementing electronic transactions under HIPAA shows VA is proactive in developing internal software solutions to meet electronic standards, so until the standard is mandated and ultimately enforced, VA's success is limited.

VA's internal Prior Authorization software was developed and ready to test in 2016. But developing software solutions before a final operating rule is in place, and a wide range of payers utilizing the transaction, is difficult. VA began by first developing a

template based upon the initial X12 transaction information, which hopefully would fit with further clarification of the operating rule. This template was designed to streamline information provided to payers from Utilization Review (UR) nursing staff.

Over the past four years, the biggest challenge VA has found is uncovering healthcare payers with which to test. There are only a limited number of payers who offer the 278 transaction to providers. Of nearly 700 payers with which VA exchanges electronic transactions, only four payers offer the X12 278 transaction through the clearinghouse. VA could be ready to send and accept 278 transactions, but with so few payers to exchange the transactions with, the efficiency is limited. It also places an administrative burden on UR staff, requiring them to determine which payers accept electronic authorizations and which require manual processes. Even for the payers who accept electronic prior authorizations, UR staff must continue manual follow-up in order to receive prior authorization approval, which negates potential benefits as implemented thus far.

VA's view on moving forward with the proposed Operating Rules

The intent and purpose of the X12 278 Prior Authorization transaction and associated operating rules is to reduce administrative burden and provide better and faster care for patients. Currently, with the limited use of the transaction, it is difficult to gauge if implementation of these operating rules will positively impact the efficiency of the workflow. However, VA is optimistic that with clear guidelines, increased adoption of the transaction and associated processes, the intended benefits can be realized, as they have been with the other HIPAA EDI transactions.

An area of concern that will prevent VA from being successful in utilizing the 278 is stated in the Data Content Rule. As written, it says it is not required for a HIPAA covered entity or its agent to conduct, use or process the X12 278 if it does not currently do so. This qualifier precludes industry adoption and stunts the opportunities to realize benefits for patients. Currently, of the few payers who do offer the 278 transaction, several have delegated authorization for certain specialty services to Utilization Management Organizations (UMOs). In these circumstances, VA must first exchange a 278 with the payer only to receive a rejection message, referring to the UMO for clarification. However, because the UMO does not utilize

the 278 transaction, UR staff must complete this follow-up through manual processes. With this rule, if the UMO isn't using the 278 now, there's no mandate to have them to use the X12 transaction moving forward. If the rule isn't modified to mandate UMOs to utilize the 278 transaction, the prior authorization process will continue to be disjointed and a combination of manual and electronic processes, which does not align with the intent of HIPAA.

VA remains committed to the benefits of HIPAA's electronic transactions and will continue to support the prior authorization electronic transaction and associated operating rules. Any further adoption of this transaction across the industry is recommended and supported, hoping to bring an end to the multiple processes to secure prior authorizations for payment for services delivered to Veterans.

July 24, 2020

Alexandra (Alix) Goss, Co-chair, Subcommittee on Standards
Richard Landen, Co-chair, Subcommittee on Standards
National Committee on Vital and Health Statistics
Subcommittee on Standards
3311 Toledo Road
Hyattsville, MD 20782–2002

Dear Ms. Goss and Mr. Landen

WEDI is pleased to provide our comments as requested by the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards on the new operating rules proposed by the CAQH Committee on Operating Rules for Information Exchange (CORE). These proposed rules seek to adopt the Prior Authorization & Referrals (278) Data Content Rule vPA.1.0, Prior Authorization & Referral (278) Infrastructure Rule vPA.2.0, and Connectivity Rule vC3.1.0 under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. We appreciate this opportunity and consider it part of our role as an advisor to the Secretary of the Department of Health and Human Services (HHS) to respond to requests from NCVHS.

WEDI convened a virtual Policy Advisory Group (PAG), which is our formal process for developing official recommendations on matters pertinent to the health care industry. The purpose of this PAG was to obtain wide-ranging input from a diverse array of stakeholders. The PAG was held on July 16, 2020 for 90 minutes. There were 95 participants representing 61 WEDI members and 62 organizations in total.

Overall Comments on the PAG

The PAG provided an important opportunity to obtain information and perspectives from many WEDI members and other stakeholders. The participants were well versed in the details of the three CAQH CORE operating rules and contributed eagerly to the discussion. Time constraints of the PAG prevented exploring and capturing the nuances of all participants' viewpoints and did not result in clear agreement on the questions and issues posed by NCVHS. Even so, several key themes emerged from the discussion that are further described below.

Key Themes

Overall Costs and Benefits

There were differences of opinion about the potential benefits of the CAQH CORE operating rules. While some acknowledged that provisions of the operating rules would help improve the prior authorization process and improve care for patients, they also suggested that the operating rules should do more to reduce response times and clarify information requirements. Some suggested that even if the operating rules resulted in an improved prior authorization process, they may have little impact on patient care.

Some health plans raised concerns with the proposed two-day response requirement and related costs for implementing the operating rules. Of interest was the information shared by one payer stating that current automated prior authorization processes would need to be modified to meet the proposed response time requirements, which would likely result in fewer finalized prior authorizations due to the complexity of the processes.

A few PAG participants questioned whether the CAQH CORE operating rules offered the best solution for the prior authorization process at this time. It was noted that other alternatives are being developed and it may be beneficial to wait until these standards, capabilities, and products are also available.

Role of Operating Rules for Data Content

There was no agreement by participants that a data content operating rule is necessary. Some PAG participants expressed views that data content should be addressed through the standards development organizations (SDOs) structure and process, rather than through operating rules. They noted that creating data content requirements via operating rules can lead to confusion and disparities in how data content requirements are applied and implemented. Others noted that the process to adopt new standards is not timely enough to meet the industry's need for data content changes, and operating rules provide an important opportunity to fill gaps where data content clarification and changes are necessary.

Timing Issues

A key objective of the Prior Authorization & Referral (278) Infrastructure Rule vPA.2.0 is to provide requirements and clarification for response times for providers and health plans responding to prior authorization requests. Still, concerns were raised about distinguishing between "calendar" and "business" days and the impact of weekends and holidays. Further clarification is needed to fully evaluate the response time requirements.

One participant noted that its organization had reduced its prior authorization requirements to only a limited number of services and products requiring detailed manual review and shared others' concerns for the two-day decision requirement. They added a concern about the proposed fifteen-day documentation response period allowed to the submitter following a request from the payer, as it may result in requiring a re-review, which duplicates their work.

Other Concerns

- Retrospective Prior Authorization for Laboratory Services

  One participant noted that laboratories were excluded from the Prior Authorization (278) Infrastructure Rule vPA.2.0 and therefore laboratory retrospective prior authorizations were excluded from the requirements. The participant stated laboratories account for 3% of health care spending, but they influence 70% of medical decisions, which means that delays in laboratory results due to prior authorization can have a significant impact on patient care.

- Need for Federally Adopted Attachments Standard

  The PAG discussed how attachments are integral to the prior authorization process as they provide the delivery method for the documentation necessary to adjudicate the prior authorization request. An understanding of the role and interplay of attachments as part of the proposed operating rules is key to discussing and evaluating the proposed rules. Because there is no federally mandated attachment standard, the scope of the CAQH CORE operating rules did not extend to attachments. Without this important context, it is challenging to fully evaluate and respond to the operating rules.

  Several PAG participants expressed views that the intended benefits and impacts of the CAQH CORE operating rules would not be achieved, or would be suboptimal, unless and until an attachment standard was adopted.

We appreciate the opportunity to offer our comments on behalf of the WEDI PAG members who offered their viewpoints and expertise on the CAQH CORE operating rules. We offer these comments in the spirit of adding commentary to supplement the panel of presenters appearing before your August Subcommittee on Standards hearing. Please contact Charles Stellar, President and CEO of WEDI, if you have questions or need additional information pertaining to WEDI's comments.

Sincerely,

/s/

Jay Eisenstock
Chair, WEDI

cc: WEDI Board of Directors

About WEDI

WEDI is a national, multi-stakeholder organization leading improvement in health information exchange to enhance quality and reduce costs to the health care system.

For nearly 30 years, WEDI has been an instrumental force in establishing and later enhancing standards for electronic administrative transactions, data privacy and data security; driving down the costs associated with manual, paper-based transactions and increasing the confidentiality of patient information.

WEDI was formed in 1991 by then-Secretary of the U.S. Department of Health and Human Service (HHS) Dr. Louis Sullivan. Named in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) legislation as an advisor to the Secretary of HHS, we have worked closely with every Administration. In addition, we have productive working relationships with the Centers for Medicare & Medicaid Services (CMS), Office for Civil Rights (OCR), and Office of the National Coordinator for Health Information Technology (ONC).

WEDI's membership represents ambulatory providers, hospitals, health systems, health plans, health information technology standards organizations, health information technology vendors and government entities. We are a voluntary public-private collaborative in which our members lead and foster partnerships among diverse organizations to solve practical, real-world health information exchange challenges. Our topical workgroups create and disseminate a range of educational materials to accelerate the industry's best use of 21st century technology to achieve better health at lower cost and burden.

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July 24, 2020

Alexandra (Alix) Goss and
Richard W. Landen
Chairs
Subcommittee on Standards
National Committee on Vital and Health Statistics
Email: NCVHSmail@cdc.gov

Greetings,

I would like to thank the Subcommittee on Standards for allowing X12 to provide written and verbal testimony regarding CAQH CORE's proposed operating rules.

X12 has operated as an ANSI-accredited standards developing organization (SDO) for more than 40 years. As a consensus-based SDO, we focus on the development, implementation, and ongoing use of interoperable electronic data interchange standards that drive business processes globally. X12 is supported by a strong and diverse membership that includes business leaders, process experts, and technologists, encompassing health care, insurance, transportation, finance, government, supply chain, and other industries.

As you are aware, the majority of the administrative transactions adopted under the Health Insurance Portability and Accountability Act (HIPAA) were developed and are maintained by X12. Specifically, the Prior Authorization (278) Data Content Rule v5.0.0 proposed by CAQH CORE for federal adoption is intended to support and enhance X12's 005010X217 Health Care Services Review – Request for Review and Response (278) implementation guide.

X12's written testimony is included below. Please contact me at csheppard@x12.org if you need further information or have any questions.

Sincerely,

Cathy Sheppard
X12 Executive Director

X12's Written Testimony on Proposed CAQH CORE Operating Rules

The Patient Protection and Affordable Care Act (ACA), Section 1104 established requirements to improve the utility of the existing HIPAA administrative transactions and reduce administrative costs. ACA Section 1104 requires the Secretary of the Department of Health and Human Services (HHS) to adopt and regularly update standards, implementation specifications, and operating rules for the electronic exchange and use of health information for financial and administrative transactions. 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."

X12 and CAQH CORE have developed and continue to maintain a successful working relationship focused on providing value to and easing burdens on the health care industry at large. Our cooperative and collaborative projects are dynamic, with ongoing fine-tuning to our current activities and regular exploration of new opportunities to work together. The organizations strive to produce complimentary work products and to present them to the industry so that they are easily cross-referenced, conveniently available, and well-communicated. X12 whole-heartedly supports and endorses CAQH CORE's efforts related to industry assessment, surveys, and analysis.

Proposed Prior Authorization (278) Data Content Rule

Regarding data content operating rules, X12 supports and encourages the development of data content operating rules that align with an underlying mandated X12 standard or its implementation instructions and do not contradict or countermand those instructions. This type of operating rule serves as a pilot or proof-of-concept for revisions which, if proven advantageous, are then considered for inclusion in the next version of the standard or implementation instruction. This proposed data content operating rule applies to X12's 005010X217 Health Care Services Review – Request for Review and Response (278) implementation guide, hereafter referenced as 005010X217.

X12 members and others within the health care industry have approached X12 leaders about concerns related to the requirements noted in *4.1.1 Patient Identification* of the proposed operating rule. Specifically, the concern is that this operating rule countermands the instructions defined in X12's associated implementation specification regarding the transmission of subscriber and patient birth dates. X12 notes that the implementation guide instruction defines the condition when the birth date is to be transmitted and prohibits its transmission except under those conditions. The proposed operating rule requires the birth date to be transmitted in all cases. X12 acknowledges this operating rule arguably overreaches in that it directly countermands the implementation guide. However, based on the fact that Section 1.12.2 of 005010X217 specifically permits a UMO to require the birth date if necessary and the fact that the X12 group responsible for updated versions of the X217 implementation guide is already considering making the birth date required in a future

version, X12 does not object to this requirement and looks forward to assessing the industry's reaction to the requirement and to evaluating any increases in 278 utilization that can be concretely attributed to requiring the subscriber and patient birth dates.

Related to *4.2.2 Consistent and Uniform Use of AAA Error and Action Codes* in the proposed operating rule, X12 has no objection to the requirement that the most specific applicable reject reason code must be returned; however, we note that there are no general or all-purpose reject reason codes included in the AAA segments of the loops named in this portion of the rule, except for a very limited number of codes that are already restricted to situations when no specific reject reason code applies. Because this is the case, X12 does not expect this requirement to significantly impact the information that is being returned today, nor do we anticipate improvements in efficiency, consistency, or automation will be realized based on the requirement.

Regarding the requirements of *4.2.3.1 Patient Event Level* in the proposed operating rule, X12 has reservations about the instructions for categorizing the listed types of events. As described, this categorization occurs when the request transaction includes one or more diagnosis codes. However, diagnosis codes are not required in the request transaction as that information is not always available at the time of the request. Also, the phrase "that can be categorized" leaves open the possibility that the health plan or its agent may not be able to categorize based on the diagnosis information and since there is no documented general agreement within the industry as to what diagnosis codes fall under each of these categories, the categorization requirement may result in additional inconsistencies instead of increasing consistency between health plans. However, since *3.9 Assumptions* of the proposed operating rule specifically states that any entity is free to offer more than what is required in this operating rule, X12 does not object to the limited set of events noted in *4.2.3.1 Patient Event Level* as health plans who wish to provide attachment report information in the PWK segment or LOINC codes in the HI segment will be free to do so based on the X12 implementation instructions. Parenthetically, X12 notes that the first two categories on the list described as types of service represent place-of-service breakdowns instead of type-of-service breakdowns.

X12 fully supports the requirement in *4.2.3.1 Patient Event Level* that a health plan and its agent must return specific HCR segment information and either PWK or HI information when the review outcome is pended for additional medical information and notes that these instructions are consistent with the 005010X217 implementation instructions.

Regarding the requirements of *4.2.3.2 Service Level* in the proposed operating rule, X12 has reservations related to this section that are similar to those noted for *4.2.3.1 Patient Event Level* above. Similarly, we do not offer an objection to the proposed requirements of *4.2.3.2 Service Level*.

Related to *4.2.4 Using Health Care Service Decision Reason Codes (HCSDRC)*, X12 has no objection to these recommendations. However, we note that the suggestive "should" wording does not carry the weight of a "must" requirement and is not significantly different from the 005010X217's implementation instruction that the sender may choose to provide one or more HCSDRC codes at their discretion. As proposed, this operating rule may not significantly increase the number of instances where the health plan provides the most comprehensive information back to the provider.

Unfortunately, CORE's findings related to these data content improvements were not presented directly to X12 for consideration concurrently to their being developed as separate operating rules. X12 only recently finalized its latest version of the X217 implementation guide and some of these revisions might have been incorporated directly into the implementation guide itself instead of being propagated as a second set of requirements that the health care industry will have to understand, manage, and implement. However, over the coming weeks, the proposed data content recommendations will be funneled into X12's maintenance process so they can be considered for inclusion in the next version of the X217 implementation guide. In the future, X12 and CORE will integrate their efforts more closely to ensure that data content enhancements and modifications that may serve to improve patient care, provider workflow, automation, efficiency, or consistency or to increase the use of electronic prior authorizations are applied directly into the implementation instructions as soon as possible, simplifying transitions, implementation, and ongoing use for the health care industry implementers.

Should the proposed data content operating rule move forward as a federal mandate, X12 looks forward to working closely with CAQH CORE as they assess and evaluate any statistical improvements in patient care, provider workflow, automation, efficiency, or consistency, any increases in the use of electronic prior authorizations, or any cost reductions based on the implementation of this data content operating rule.

Proposed Prior Authorization (278) Infrastructure Rule

Regarding the proposed infrastructure rule, X12 is neutral and offers no comment.

Proposed Connectivity Rule

Regarding the proposed connectivity rule, X12 is neutral and offers no comment.