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.