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January 4, 2021

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications – CMS-9123-P

Dear Administrator Verma,

Thank you for the opportunity to provide feedback on proposed rule CMS-9123-P to improve healthcare data exchange and streamline prior authorization processes in alignment with CMS efforts to reduce overall payer and provider burden and improve patient access to health information. We appreciate your efforts to improve interoperability across payers, providers, and patients.

The CAQH Committee on Operating Rules for Information Exchange (CORE), an initiative of CAQH, is a non-profit, national multi-stakeholder collaborative that drives the creation and adoption of healthcare operating rules that support standards, accelerate interoperability, and align administrative and clinical activities among providers, payers, and consumers. CAQH CORE Participating Organizations represent more than 75 percent of insured Americans, including health plans, providers, electronic health record (EHR) and other vendors/clearinghouses, state and federal government entities, associations, and standards development organizations. CAQH CORE is designated by the Secretary of the Department of Health and Human Services (HHS) as the author of federal operating rules for the HIPAA administrative healthcare transactions. Operating rules are developed by CAQH CORE Participants via a multi-stakeholder, consensus-based process.

Proposed rule CMS-9123-P cites both CAQH CORE and the CAQH Index, an annual publication that tracks adoption by the healthcare industry (medical and dental) of electronic business transactions and associated volume and costs.

CAQH CORE comments on proposed rule CMS-9123-P are based on our history of working with stakeholders across the healthcare industry to promote interoperability and reduce administrative burden, including prior authorization. Our comments fall under the following overarching themes:

- Rule Program Impacts
- Authority to Adopt New and Modified Standards for All HIPAA-covered Entities

- Clarity of Rule Requirements
- Prior Authorization Timeframes

Rule Program Impacts

The proposed rule CMS-9123-P only applies to a subset of the healthcare industry, specifically to Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies, CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges. CAQH CORE is concerned that the narrow scope of the proposed rule that does not include Medicare Advantage and commercial lines of business more broadly will create a fragmented system where requirements apply to certain market segments and not others, creating unintended barriers to standardization and interoperability. As CAQH CORE has learned from its CORE Certification program, many payers have multiple backend systems supporting different lines of business. The proposed rule states that payers with multiple lines of business may choose to implement these polices for Medicare Advantage to support better internal alignment and create more efficiencies and transparency for their patients. However, it is not clear what the incentive would be for a payer to make this type of costly and complex investment across disparate backend systems without a federal requirement.

Additionally, many providers rely on vendors and clearinghouses to support healthcare data exchange. These third-party stakeholders may be reluctant to invest in the system upgrades required by the proposed rule without broader industry application or may do so at a significant enhancement cost to providers. As a result, a provider practice with few Medicaid patients may choose to stop taking those patients to avoid compliance with these rule requirements.

Finally, Medicaid programs have fewer resources generally and may struggle to implement the proposed rule. This rule may be especially challenging for Medicaid programs to focus on at this time given the COVID-19 pandemic which has resulted in increased Medicaid enrollments and increased demand on Medicaid resources and state budgets.

Authority to Adopt New and Modified Standards for All HIPAA-covered Entities

At CAQH CORE we see firsthand the critical importance of applying uniform standards and operating rules across the entire healthcare industry to enable consistent automation and interoperability, rather than a piecemeal approach by market segment. We encourage CMS to use its existing authority under the Administrative Simplification provisions in the Health Insurance Portability and Accountability Act (HIPAA) and expanded under the Affordable Care Act (ACA) to drive industry-wide adoption of new and modified standards, including prior authorization to avoid fragmented industry adoption. Specifically, Section 1172 of the Social Security Act states:

> *The Secretary shall adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for--(A) the financial and administrative transactions described in paragraph (2); and (B) other financial and administrative transactions determined appropriate by the Secretary, consistent with the goals of improving the operation of the health care system and reducing administrative costs.*

Additionally, language specified in Sections 1172 through 1176 of the Social Security Act permits the Secretary to establish different standards, new standards, and modified standards in consultation with public and private organizations. This language specified under HIPAA also provides a tested and predictable timeframe for adoption by all HIPAA-covered entities and authorities to enforce compliance. The process is open to the

public, includes an appeals process, can be enforced by CMS, and, most importantly, moves the entire industry forward together.

Clarity of Rule Requirements

While CAQH CORE agrees that significant industry attention is needed to improve prior authorization processes and reduce provider and patient burden, the new requirements proposed in this rule have not been tested to demonstrate a return on investment to encourage industry adoption and it is unclear how these requirements will specifically interact with the required prior authorization standard under HIPAA. To further specify the interaction between these proposed requirements and the required HIPAA prior authorization standard, and gather evidence to support a return on investment, CAQH CORE encourages CMS to test and pilot these requirements and interactions as permitted under HIPAA (45 C.F.R. § 162.940) prior to requiring industry adoption.

As referenced on page 85 of the preamble of the proposed rule, CAQH CORE has identified that one of the primary barriers to adoption of the prior authorization standard required under HIPAA is the inconsistent use of data content in the transaction. To address this barrier, in February 2020 CAQH CORE proposed operating rules for federal mandate to enhance the data content for the prior authorization standard to create more clarity and consistency in the information shared between providers and payers. Specifically, the CAQH CORE Prior Authorization & Referrals (278) Data Content Rule includes data content requirements related to patient identification and verification, return of error and action codes, and use of codes to specify needed documentation and inform on status and next steps. These rule requirements would specifically address the requirement to provide a reason for a denial on page 94 of the proposed rule, in addition to requiring additional data content to provide needed clarity in the prior authorization process.

The CAQH CORE Prior Authorization & Referrals (278) Data Content Rule was approved by nearly 90 percent of CAQH CORE Participating Organizations representing over 75% of covered lives in the US. At the August 2020 National Committee on Vital and Health Statistics (NCVHS) hearing on the proposed CAQH CORE prior authorization operating rules, initial results from the CAQH CORE Prior Authorization Pilot & Measurement Initiative with Cleveland Clinic and PriorAuthNow found an 80% reduction in staff time through use of the operating rules in comparison to the use of web portals. Specifically, the pilot included the use of the X12 278, CAQH CORE prior authorization operating rules, and intersection with the EMR workflow.

Prior Authorization Timeframes

CAQH CORE also has concerns related to the timeframes for prior authorization included in the proposed rule. CMS-9123-P requires impacted payers (not including QHP issuers on the FFEs) to send prior authorization decisions within 72 hours for urgent requests and seven calendar days for standard requests. These broad timeframes may have the unintended effect of increasing the number of denials as they do not account for the conversational nature of the prior authorization process. Providers and payers often have multiple exchanges of information back and forth, including the sharing of medical documentation or need to retrieve specific information from the patient, prior to a final determination. A blanket timeline does not account for these intermediate steps. Additionally, applying timeframes only to a subset of market segments only adds to the burden of adjudicating prior authorizations in light of the already inconsistent hodgepodge of state and federal prior authorization and claim denial requirements.

In 2019, CAQH CORE Participants conducted extensive research and provided significant feedback on prior authorization timeframes when updating the CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule. At that time, approximately 30 states had prior authorization response time requirements that varied from 24 hours to 15 business days with differences in definitions and applicability from state to state. Although

some CAQH CORE Participants support shorter response time requirements and others support longer response time requirements, 80 percent of CAQH CORE Participating Organizations reached a compromise to establish national expectations for prior authorization response times via operating rules. Specifically, the CAQH CORE Prior Authorization & Referral (X12 278) Infrastructure Rule includes three requirements that result in faster prior authorization adjudication while also addressing the conversational nature of the exchange:

- **Two-Day Additional Information Request:** A health plan, payer, or its agent has two business days to review a prior authorization request from a provider and respond with additional documentation needed to complete the request or respond with a final determination if no additional documentation is needed.
- **Two-Day Final Determination:** Once all requested information has been received from a provider, the health plan, payer, or its agent has two business days to send a response containing a final determination.
- **Optional Close Out:** A health plan, payer, or its agent may choose to close out a prior authorization request if the additional information needed to make a final determination is not received from the provider within 15 business days of communicating what additional information is needed.

The industry has been clamoring for predictability and consistency related to the standards adoption process to advance interoperability. NCVHS and other federal advisory committees have also highlighted the need to test and pilot the use of new standards prior to a federal mandate to ensure return on investment. While we appreciate the desire of CMS to address the challenges posed by the prior authorization process and enhance interoperability via the proposed rule, the scope is currently too limited to have broad impact and may result in further market fragmentation. New and modified standards will continue to be needed by the healthcare industry over time to address emerging business needs. CAQH CORE encourages HHS and CMS to use its authority under HIPAA to drive full market adoption rather than by individual market segments.

Thank you for considering our comments to proposed rule CMS-9123-P and our previous request to extend the comment period by at least 60 days to facilitate sufficient industry review and feedback. Should you have questions, please contact me at atodd@caqh.org.

Sincerely,

April Todd
Senior Vice President, CAQH CORE & Explorations

CC:
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