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March 13, 2023

Centers For Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0057-P
P.O. Box 8013
Baltimore, MD 21244-8013
Washington, DC 20201

Submitted via the Federal Regulations Web Portal, http://www.regulations.gov

RE: CMS-0057-P; RIN 0938-AU87

Dear Administrator Brooks-LaSure,

Thank you for the opportunity to provide feedback on the *Advancing Interoperability and Improving Prior Authorization Processes* proposed rule (CMS-0057 P) to improve the electronic exchange of healthcare data and streamline processes related to prior authorization to drive interoperability in the healthcare market.

As a non-profit alliance working in concert with a wide range of healthcare stakeholders, CAQH develops and implements shared, industry-wide initiatives to reduce administrative burden. CAQH regularly engages with ~2.5 million providers and payers representing over 265 million covered lives to reduce the burden of data exchange and help the industry operate more efficiently.

The CAQH Committee on Operating Rules for Information Exchange (CORE), an initiative of CAQH, is a non-profit, national multistakeholder 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 multistakeholder, consensus-based process.

The comments submitted by CAQH on this proposed rule are informed by our experience working with payers and providers across markets, lines of business, and provider types to reduce the administrative burden associated with data exchange, promote interoperability and support automation of the prior authorization process.

Detailed responses to the proposed rule are included in the Appendix of this document. In addition to these detailed responses, we have the following overarching comments regarding rule impacts, scope/authority in adoption of new or modified standards for HIPAA covered entities and the utilization, value-add and prioritization of the proposed requirements.

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

While CAQH appreciates the expansion of impacted payers from the previous electronic prior authorization proposed rule (CMS-9123-P), we remain concerned that the new proposed rule does not apply to all payer organizations, including commercial insurers, as CMS is using its authority over public programs to advance these requirements. Specifically, as proposed, the rule would only apply to Medicare Advantage (MA) organizations, state Medicaid Fee-for-Service (FFS) programs, state Children's Health Insurance Program (CHIP) FFS programs, Medicaid Managed Care Plans, CHIP Managed Care Entities, and Qualified Health Plan issuers on the Federally-facilitated Exchanges (FFEs). Moving forward with only a subset of payers will create a fragmented system where requirements apply to certain market segments and not others, creating unintended barriers to standardization and interoperability for payers and providers.

CAQH sees 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), rather than a bifurcated approach, to consistently drive industry-wide adoption of new and modified standards, including prior authorization, and 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.

Utilization, Value-Add, and Return on Investment related to APIs and RFIs

CAQH appreciates the focus of CMS to finding effective and efficient ways to improve the electronic exchange of healthcare data and streamline processes related to interoperability, APIs and prior authorization in the healthcare market. However, it is critical that CMS ensure that as finalized, the rule is not only applicable across all market segments (both government programs and commercial lines of business), but appropriately mandates stakeholders to participate, adequately incentivizes utilization so as to assure return on investment and that implementation is prioritized given competing priorities.

Thank you for considering our comments and recommendations. We look forward to continued engagement with CMS to support industry-wide improvements to reduce administrative burden for payers and providers and support consumers. Should you have any questions, please contact me at atodd@caqh.org .

Sincerely,

April Todd
Chief Policy & Research Officer, CAQH

CC:
Robin Thomashauer, CEO, CAQH
CAQH Board Members
CORE Board Members

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Appendix

Below are detailed comments regarding prior authorization, patient, provider, and payer-to-payer application programming interface (APIs) provisions and the request for information (RFI) specific to social determinants of health risk data.

Prior Authorization

CAQH CORE comments in response to Section D: Improving Prior Authorization Processes in the proposed rule are based on our history of working with stakeholders across the healthcare industry to promote interoperability and reduce administrative burden from a business, operational, and technical perspective. Over the past six years, CORE Participating Organizations worked collaboratively to develop and approve operating rules to drive prior authorization automation. The CAQH CORE Prior Authorization Operating Rules are strongly recommended by the National Committee on Vital and Health Statistics (NCVHS) for voluntary implementation and the CAQH CORE Attachments Prior Authorization Operating Rules are currently under review by NCVHS for recommendation to HHS for federal mandate.

CAQH CORE is very supportive of federal efforts to automate and simplify prior authorization. The process to conduct prior authorization is labor intensive and has become a significant source of administrative burden for healthcare providers and payers. Our comments reflect insights and lessons learned from our work with the industry on prior authorization and fall under two overarching themes:

- Critical importance of requirements versus recommendations and optionality in implementation guides
- Prior authorization timeframe considerations

Critical Importance of Requirements versus Recommendations and Optionality in Implementation Guides

According to the 2022 CAQH Index, the percentage of prior authorization transactions conducted electronically using the HIPAA-mandated X12 278 transactions in 2021 was 28 percent. While the industry has made incremental progress, adoption of electronic prior authorization processes lag other transactions adopted under HIPAA. In 2019, CAQH CORE published a white paper titled Moving Forward: Building Momentum for End-to-End Automation of the Prior Authorization Process. The report identified numerous barriers that prevented or slowed the adoption of electronic prior authorization. These barriers encompassed the nature of the transaction itself, the lack of operating rules to support use of the electronic transaction standard, a lack of infrastructure supporting electronic submission of supporting clinical documentation, vendor readiness, the ubiquity of web portals, and a myriad of state laws. In addition, some components of the prior authorization workflow occur outside the scope of the HIPAA-mandated standard.

The FHIR and Prior Authorization Requirements, Documentation and Decision (PARDD) API requirements present a promising solution to current prior authorization processes. The scope of the PARDD API encompasses the end-to-end prior authorization workflow, with the exception of the electronic exchange of additional documentation. Although FHIR enables direct access to structured data within the electronic health record (EHR) limiting the need for manual intervention to gather supporting information, CAQH CORE is concerned that without addressing the challenges

industry faced with implementation of the X12 278, the industry will continue to have interoperability challenges due to a lack of uniformity across trading partners.

For example, our 2019 white paper highlighted that a lack of requirements for specific data elements within the X12 278 limited the value of the transaction and ultimately impacted adoption. Specifically, inconsistency and optionality in how codes were used to communicate status, errors, and next steps, including the need for clinical documentation to prove medical necessity, all lead to manual processes. In a landscape where requirements for prior authorizations differ across (and within) payers and benefit packages, providers lack an efficient way to identify what critical information to submit in the request. Lack of uniformity in code use and the use of overly generic codes do not provide clear direction and next steps. This inconsistency and variability in prior authorization responses leads to implementation challenges, proprietary approaches, and gaps in interoperability. Implementation of just the base requirements, although not ideal, is often the approach taken by industry stakeholders when needed data elements are optional instead of required.

To address these inconsistencies, the CAQH CORE Prior Authorization Operating Rules and the CAQH CORE Attachments Prior Authorization Operating Rules require payers to respond to the provider with specific data requirements needed to support the prior authorization request and for the provider to submit the additional documentation in a mode that meets the provider where they are at – either through their practice management system (PMS) or EHR. Ensuring uniform and consistent data content meets interoperability goals.

The proposed rule recognizes the need for a common approach to data content and infrastructure requirements for prior authorization by recommending three Da Vinci Implementation Guides to support the PARDD API requirements – specifically the HL7 FHIR Da Vinci Coverage Requirements Discovery (CRD) Implementation Guide (IG), Documentation Templates and Rules (DTR) IG, and Prior Authorization Support (PAS) IG. CAQH CORE notes the importance of the term "recommendation" versus a "requirement." CAQH CORE is concerned that without explicitly requiring specific IGs and data content, the industry may end up with varied implementations that negatively impact interoperability. As CMS states in the proposed rule, "There are several pilots underway to test the PARDD API, as well as other tools. The results are all positive for the policies that are being tested and showcased in demonstrations at conferences. However, no quantitative data have yet been shared with CMS to include with this proposed rule, but is anticipated in the near future." While Connectathons can effectively test the technology behind a given IG, they cannot account for workflow and business challenges that arise in the real-world. Given the very limited adoption of the Da Vinci IGs to date, CAQH CORE understands the desire of CMS to enable flexibility to allow the IGs to evolve; however, an unintended consequence may be interoperability barriers and industry confusion. We encourage broader, production-level testing of the IGs across multiple types of services before widespread adoption.

As we have learned from implementations of the HIPAA-mandated transactions, the healthcare industry often adopts the bare minimum of what is required. For example, when the eligibility and benefits transaction (X12 270/271) was first mandated, organizations only implemented the required data elements within the standard and very few, if any, of the situational data elements that added immense value to the transaction and supported greater automation. Ultimately the HIPAA-mandated CAQH CORE Eligibility & Benefits Operating Rules drove industry adoption of these situational data elements, including detailed coverage information and patient financial responsibility, and led to a more than 25 percentage point increase in electronic eligibility verification over a ten-year period.

The recent updates to the CAQH CORE Eligibility & Benefits Operating Rules allow providers to inquire on benefits at the procedure code level and require payers to indicate whether the procedure requires prior authorization or not, which is another example of a situational data element that when required can significantly improve automation and interoperability. Furthermore, the eligibility transaction also requires data elements that facilitate the level of detail needed in the commercial market to determine whether a prior authorization is needed at a specific patient, provider, location, and health benefit plan level.

CAQH CORE notes similar concerns with the concept of required versus situational data elements in the current versions of the recommended Da Vinci IGs. The CRD, DTR, and PAS IGs have several data elements and processes that are optional for use despite their ability to drive automation and reduce manual interactions. For example, the CRD IG does not require the return of a DTR so the provider would be required to initiate a separate transaction to determine the requirements for a prior authorization. Additionally, the CRD IG allows for hyperlinks to be returned to the provider. This means that a valid response to a CRD can be a hyperlink to a third-party prior authorization vendor where the provider would have to initiate a prior authorization request through a provider portal and drop to a manual process outside of their EHR and PMS.

As noted, CMS has also expressed its desire for health plans to voluntarily adopt the PARDD APIs to support additional lines of business not included the proposed rule including the commercial and Administrative Services Only (ASO) markets. CAQH CORE is concerned that the recommended Da Vinci IGs do not consider many of the complexities of commercial insurance benefits and coverage for these types of markets and products. Government-based prior authorization requirements are usually a benefit verification; however, commercial and ASO prior authorization requirements, for example require the adjudication of data related to the provider (including provider location, service location, provider contract, etc.) and member benefit information – often to the procedure code level. The effort to digitize these extremely detailed and specific benefit and coverage policies into a rules engine as referenced in the CRD IG and DTR IG is significant, and the level of input detail varies by plan. For example, when a provider queries the CRD they may be told a prior authorization for a procedure is not needed, when in fact the patient is in an ASO plan and their employer requires a prior authorization for the requested service (for certain providers, at certain locations) but that employer-level policy requirement is not built into the rules engine as the health plan has built to the minimum requirements of the IG.

Prior Authorization Timeframe Considerations

CAQH CORE appreciates CMS efforts to improve patient care outcomes and ensure patients have timely access to services by aligning prior authorization decision timeframes across impacted payers. The proposed rule requires impacted payers to send prior authorization decisions within 72 hours for urgent requests and seven calendar days for standard requests. The response can include that the authorization request has been approved (and for how long), denied (with a reason for the denial), or request for more information from the provider to support the prior authorization request (often identified as a "pend").

While the PARDD API aims to streamline the prior authorization process and improve access to documentation requirements more quickly, providers and health plans will still have multiple exchanges of information back and forth, including additional medical documentation and patient-specific information, prior to a final determination. The proposed decision timeframes do not account for these situations, and these requirements in combination with a lack of required data content could unintentionally increase the number of denials.

In 2019, CORE Participants conducted extensive research and provided significant feedback on prior authorization timeframes when updating the CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule. Although some CORE Participants support shorter response time requirements and others support longer response time requirements, 80 percent of 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.

Under the timeframe requirements in the proposed rule, there is no requirement on the health plans to respond with a final determination if additional documentation is requested and then submitted from the provider. Additionally, there is no clear guidance for situations when the provider does not submit requested documentation in a timely manner. While CAQH CORE understands that the PARDD API automates much of this exchange, it is our experience that circumstances will continue to arise that may delay or prevent automated exchange, including when a health plan returns a hyperlink in response to a CRD inquiry to a third-party prior authorization vendor. This situation forces the provider outside of the PARDD API workflow. CAQH CORE encourages CMS to consider adding industry guidance or requirements into the prior authorization decision timeframes aligned with the CAQH CORE requirements to account for the conversational nature of the prior authorization process and require a final determination (approval or denial) to increase overall effectiveness of the proposed rule.

Application Programming Interfaces (APIs) – Patient, Provider, Payer-to-Payer (proposed January 1, 2026 effective date)

The comments submitted by CAQH regarding the APIs are informed by our experience working with both payers and providers across markets, lines of business, and provider types to reduce administrative burden.

CAQH appreciates the steps CMS is taking overall as it relates to the APIs and notes the following comments related to implementation of the APIs:

- **Patient Access API:** CMS noted the importance of maintaining the privacy and security of patient information as one of the most important aspects of making health data accessible. A key component of that is the ability to have robust privacy and security information on application developers, in addition to education and resources that are provided to enrollees. While plans are unable to deny app vendors due to privacy/security assessments, as recommended by CMS in prior

interoperability rules, CAQH currently maintains an Endpoint Directory for which we collect privacy/security information from app vendors that is available for health plans to share in a standardized way with their members. This information includes questions related to privacy policies, data security, data use and user content, and certification/accreditations of app vendors that is made available to plans to share with members in a standardized way to help members make informed decisions about sharing their health information with app vendors.

- **Provider Access API**: CAQH is supportive of this API being opt-out by patients given the data would support treatment, payment and operations under HIPAA. CAQH recommends that this should be a bi-directional API and could be used to effectively support use cases such as prior authorization.
- **Payer-to-Payer API:** CMS is proposing that payers develop and maintain a process to identify a patient's previous and/or concurrent payer(s) and to allow enrollees to opt ***into*** payer-to-payer data exchange prior to the start of coverage. CAQH understands payers are considering the use of the enrollment form/process for opting IN noting this would likely be the most efficient means of collecting this consent. However, this API would be more beneficial for the industry if members are required to opt ***OUT*** given that the information and data exchange can be very valuable for payers to support treatment and operations (i.e. support prior authorization, reduce unnecessary testing, assist with provider quality measurement, reduce duplicative questions of providers, etc.). If there is concern with data being covered under HIPAA for treatment, payment and operations CAQH recommends that CMS reduce the scope of data exchange to allow for member opt out. Absent this API being opt out, the use of this API is likely to be low at a similar volume to that experienced for the Patient Access API, resulting in a high implementation cost in comparison to the value from volume of use.

Requests for Information

Accelerating the Adoption of Standards Related to Social Risk Factor Data

The collection of Social Determinants of Health (SDOH), Sexual Orientation and Gender Identity (SOGI) and Race, Ethnicity and Language (REL) data by key stakeholders across the health care industry (namely payers and providers) is a key component in the ability to achieve health equity. However, key to this data collection being able to move the needle and achieve health equity is the need to standardize the data being collected, who is collecting what data and how the data is used. The standardization of data collected and exchanged about patients and providers will enable consistency at the federal and state level, reduce burden that is emerging across state and federal requirements/programs and most importantly facilitate aggregation and analysis to help reduce disparities and advance health equity.

Generally, CAQH supports the exploration of new technologies and standards that advance interoperability, data standardization, and automation. Several of the proposals from this NPRM show promise in advancing the collection and exchange of social risk data between patients, payers, and providers. CAQH cautions CMS that new technologies and standards should have their value demonstrated through comprehensive and complete real-world testing to ensure they can be widely applied across the industry and to initiatives targeting the standardization of social risk data. Where appropriate, CMS should explore the applicability of well-implemented solutions, such as X12N transactions, in their ability to support the standardized exchange of social risk data.

Below are comments regarding Member and Provider Data Collections:

Member Data

SDOH, SOGI and REL information is captured and stored in a variety of locations and formats. CAQH is aware of both structured and unstructured data in EHRs, relatively rare inclusions of ICD-10 Z-codes on health care claim submissions, and a growing vendor market specializing in the analysis and presentation of data.

The Gravity Project has taken essential steps to standardize the recording and exchange of SDOH data. Their work has identified standard pathways between common screening tool elements and structured documentation in the medical record. While their work is envisioned as a method to bolster the API-driven exchange of information, the standardization it provides also provides holistic benefits to a complete and accurate medical record.

The Gravity Project is further working to expand the scope and utility of ICD-10 Z-codes by recommending new codes that cover a greater number of social risks. Recently new codes proposed by the Gravity Project covering the housing, food, and education domains were approved for implementation. Routine maintenance and additions to the ICD-10 code list may directly combat provider perceptions that Z-codes do not provide a full picture of all the social risks they encounter in practice.

However, the use of ICD-10 Z-codes is persistently limited, despite their recognized advantages. Some stakeholders argue that the Z-codes are not comprehensive enough to capture all social risks, limiting their use in practice. Others highlight that providers are ill-equipped to address harmful social risks in practice, leading to less overall discovery and a greater reluctance to codify when they are revealed. Lastly, limited space on claim submission forms leads providers to prioritize medical diagnoses that are perceived to be more closely tied to a patient's clinical presentation. Standardizing claim submission mechanisms to accommodate the SDOH data could stimulate greater uptake across the industry by minimizing the need for providers to weigh the relative importance of diagnosis codes.

Payers can support the standardization and exchange of data using a variety of methods. For one, health plans can unify around common data sets used to collect demographic information at the point of enrollment. Health plans often employ different data collection tools for socio-demographic variables, such as race and ethnicity. This limits interoperability and leads to a reduction in the quality of information that could have otherwise been used to enhance downstream efforts addressing health disparities.

In addition, health plans can promote documentation and, by extension, the exchange of data by minimizing the need for providers to "choose" whether a social risk diagnosis is included on a claim. This could be achieved by expanding the number of diagnoses that can be submitted per claim. Without a mechanism to support standardized collection of this information, providers may over-prioritize diagnoses they feel are more relevant to a patient's clinical presentation, potentially neglecting to record the impact of social risks.

To encourage documentation and use of social risk data, health plans and payers can incentivize the documentation of Z-codes through add-on payments or as part of methodologies used in alternative payment models. Already, CPT coding guidance allows providers to bill more resource-intensive evaluation and management codes when social risks influence care. This leads to higher rates of

reimbursement and a more complete listing of social diagnoses that support the higher resourced CPT.

There is promise in leveraging existing HIPAA-mandated transactions to support the capture and documentation of social risk data. For example, the widely used X12N 837 Health Care Claim transaction is an accepted mechanism for the submission of ICD-10 diagnosis codes supporting provider reimbursement. Further, the X12N 834 for Health Plan Enrollment/Disenrollment could serve as a method to standardize the capture of socio-demographic information. Where appropriate, CMS should explore the adoption of new standards that fulfill the uniform capture and exchange of SDOH, SOGI and REL data but CAQH recommends that any such proposals should only be made once adequate real-world testing has been undertaken.

Finally, CMS should consider the impact of mandating the USCDI Core Data Set. This data set has been continually improved in the years since it was first implemented, and now features a robust set of variables to capture and assess social determinants of health data.

Provider Data

There are several considerations regarding the collection and reporting of demographic data (namely SOGI and REL) and related information regarding providers and practice locations. State requirements in this area are relatively new, however, there is already variability in the definitions of terms and questions asked across states that may lead to increased administrative burden, confusion, and inaccuracy for providers and payers. There is a need for standardization of these data elements to support the goals of advancing health equity and reducing administrative burden.

Another consideration regarding provider data is that although this information can assist a consumer in finding a provider they are most comfortable with, this information should only be requested voluntarily of providers and only made publicly available with their permission. Some providers are concerned that public release of this information could result in discrimination or harassment, so they may only consent to its use for network adequacy evaluation and patient referrals. Collection of this data could alternatively be requested at an aggregate practice versus provider specific level to encourage provider response.