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Honorable Xavier Becerra
Secretary, U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building
330 C Street S.W.
Washington, D.C. 20201

RE: Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria (RIN 0955-AA04)

Dear Secretary Becerra,

Thank you for the opportunity to provide feedback on the Office of the National Coordinator's (ONC) Request for Information (RFI) – Electronic Prior Authorization Standards, Implementation Specifications, and Criteria. We appreciate your consideration as to how the ONC Health IT Certification Program can address electronic prior authorization for items and services beyond medications to advance adoption and enable consistent exchange of clinical and administrative information.

The 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 Health Insurance Portability and Accountability Act (HIPAA) administrative healthcare transactions. Operating rules are defined as "the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications." Operating rules are developed by CAQH CORE Participants via a multi-stakeholder, consensus-based process. The CORE Certification program is the industry gold standard for demonstrating conformance with the CAQH CORE Operating Rules; more than 400 certifications have been awarded to date.
Though electronic adoption of the HIPAA-mandated X12 278 prior authorization transaction continues to lag other administrative transactions, adoption has increased significantly from 8% to 26% of all prior authorizations over the past five years.[1] CAQH CORE has experienced firsthand that adoption of electronic transactions is often incremental, growing with industry education, real

[1] https://www.caqh.org/sites/default/files/explorations/index/2021-caqh-index.pdf

world experience in operational settings, identification of gaps, and ongoing refinement of technical implementation specifications and operating rules. Simply requiring a technical standard may not result in timely adoption that satisfies industry business needs.

One of the primary barriers to improving the prior authorization workflow and increasing electronic adoption has been the absence of a standard for electronic attachments. In addition, adoption has historically lagged due to a lack of detail and consistency in the use of data content in the prior authorization transaction. CAQH CORE operating rules were released in 2020 that address this barrier and specify requirements for response times. Other barriers to adoption span an array of factors including vendor readiness, industry awareness of a HIPAA standard, the ubiquity of proprietary solutions, a lack of integration between clinical and administrative systems, and a multitude of state laws.

CAQH CORE recently finalized Attachments Prior Authorization Operating Rules that build on the existing CAQH CORE Prior Authorization & Referrals Operating Rules and include operating rules to support the X12 275 transaction, the HL7-CDA, and emerging standards including HL7 FHIR. Our comments delineate the benefits of a phased approach and the role of standard agnostic operating rules while also addressing the opportunity for HHS to leverage its existing authority under HIPAA to facilitate industry-wide adoption.

CAQH CORE comments in response to the ONC RFI are based on our history of working with stakeholders across the healthcare industry to promote interoperability and reduce administrative burden from both an operational and technical perspective. The development of the CAQH CORE Prior Authorization and Attachments Operating Rules, and operational testing of requirements and standards via the CAQH CORE Pilot and Measurement Initiative and CORE Certification Program are particularly relevant to our remarks, which address the following areas ONC is seeking comment:

- How to address alignment between standards adopted for HIPAA and standards adopted under the ONC Certification Program
- Methods to facilitate ONC adoption of the proposed certification criterion for the prior authorization workflow, while accounting for a fully HIPAA compliant exchange
- Potential intersection with other administrative operating processes that should be considered when exploring options for the exchange of attachments and how to harmonize efforts
- Feasible timeline for use of proposed implementation guides given limited testing of the specifications to date
- Risks to advancing implementation of the certification criteria if the proposed implementation guides are not yet ready for adoption, with consideration towards the potential to delay adoption of the implementation specifications

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

CAQH CORE encourages HHS to leverage its existing authority under the Administrative Simplification provisions in the Health Insurance Portability and Accountability Act (HIPAA) and expanded under the Affordable Care Act (45 CFR § 162.910-930) to drive industry-wide adoption of standards and operating rules to support prior authorization and the exchange of associated clinical and administrative information. HHS authority can be used to modify existing standards (45 CFR § 162.910) and/or advance new and emerging standards for additional administrative functions per Section 1173 of the Social Security Act that 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.*

Use of the authority under HIPAA ensures that the entire industry moves forward together without different requirements for the commercial vs government sectors. Different rules for different segments of the industry would complicate adoption and create more administrative burden for payers and providers. Furthermore, having different requirements for prior authorization and attachments under ONC authorities and HIPAA is likely to confuse the industry and thus stall adoption. Additionally, the use of authority under HIPAA ensures that administrative transactions with clinical components can be used alongside other associated administrative transactions to facilitate a seamless end to end workflow. This includes common applicability of other components under HIPAA such as the Privacy Rule that facilitates the exchange of data between covered entities for purposes of treatment, payment, and operations.

Facilitating Interoperability Across the Technology Spectrum with Industry-Approved Guardrails

A Standard Agnostic Approach to Prior Authorization Attachments

Establishing a standard approach for the exchange of clinical information/attachments to support prior authorization with consistent applicability of infrastructure and data content, regardless of the standard used, would ease the transition to emerging technology, decrease burden faced throughout the industry, and address the proliferation of proprietary solutions. Attachments are the bridge between clinical and administrative data; however, the attachments workflow remains primarily manual. The 2021 CAQH Index found that only 21% of attachments are sent electronically using defined standards, the lowest of all measured transactions. Often, the primary pain point cited among industry stakeholders is the lack of an established attachments standard, which in turn fuels a sense of uncertainty about the value of organizational investments in various electronic prior authorization solutions and further deters uniform vendor support for use of the X12 278 electronic transaction. This has resulted in numerous manual workarounds and proprietary approaches that providers are required to support.

To begin to address some of these challenges, CAQH CORE launched an Attachments Initiative with the goal of establishing a set of common specifications to support the exchange of attachments and additional documentation using existing standards such as the X12 275 transaction and HL7-CDA, and emerging standards including HL7 FHIR. Throughout the rule

development process consideration was given to the fact that the healthcare industry is in the process of a transformation – augmenting traditional EDI-based standards and infrastructure with application programming interfaces (APIs). Given the disparity in technology maturity across the industry, the recently published Attachments Operating Rules are scoped to apply when:

- Attachments are sent using the X12 275 transaction to support an X12 278 Prior Authorization Request, and
- Additional documentation is sent without using the X12 275 transaction (i.e., using CORE Connectivity vC4.0.0 to exchange any non-X12 payload including, HL7 FHIR Resources, HL7 C-CDA, .PDF, etc.) to support an X12 278 Prior Authorization Request

This concept can serve as a foundation for how alignment between standards adopted for HIPAA (e.g., X12 278 prior authorization transaction and X12 837 health care claim transaction) and other standards, such as the proposed Da Vinci specifications, can be adopted in harmony – moving the industry forward, while still capitalizing on existing value built into backend systems and supporting smaller entities with fewer resources. We encourage ONC and HHS to consider this approach when addressing the alignment between standards adopted for HIPAA and standards proposed for inclusion under the ONC Certification Program until further operational testing of the new standards is conducted.

Application to Additional Attachments Use Cases

CAQH CORE also recognizes that the attachments workflow could be applied to use cases beyond prior authorization, including attachments sent to support health care claim submissions. Research conducted throughout the CAQH CORE attachments rule development process found that there is considerable alignment in best practices to address many of the data variability and workflow issues associated with attachments, whether the attachment was sent to support a prior authorization request or a health care claim submission.

For example, the CAQH CORE Attachments Prior Authorization Operating Rules establish data elements that should be included with the attachment sent by the provider to assist the health plan with linking the attachment to the original prior authorization request received. The pain point experienced by health plans of reassociating or linking the attachment to the original prior authorization request is mirrored in the health care claims workflow. Many of the data elements that assist with reassociation for prior authorization overlap with data elements that assist with reassociation for claims transactions.

CAQH CORE urges ONC to conduct further research into the alignment of standards and implementation approaches across the administrative use cases when developing certification criteria as it will ultimately support efficiency across administrative and clinical systems. Additionally, we encourage HL7 and the Da Vinci Project to conduct operational workflow testing to understand the capability of the proposed Da Vinci specifications to be generalizable to the health care claims use case and other administrative transactions to avoid disparate workflows across administrative and clinical systems.

The Role for Standard Agnostic Operating Rules

Whether an attachment sent to support a prior authorization is conducted using the X12 275 or via HL7 FHIR, it is critical the data and infrastructure of the transaction remain consistent. Industry cannot shift from a current to an emerging standard overnight and enabling common expectations regardless of the standard will keep backend data consistent and enable a more successful glidepath for organizations transitioning to emerging standards.

Regardless of the standard used, the industry needs consistent expectations for the data content, infrastructure, and connectivity used to prevent entities from implementing the same standard in different ways. Historically, CAQH CORE operating rules have addressed these gaps, aligning exchange expectations across standards for the same business process. Standard agnostic CAQH CORE operating rules, like the new CAQH CORE Attachments Operating Rules, include built in flexibility to update requirements as the industry evolves, providing structure for providers to interoperate, regardless of where they are on the technology adoption spectrum.

The most recent version of the CAQH CORE Connectivity Rule vC4.0.0 includes requirements for the exchange of information using both SOAP and REST technologies for use with all CAQH CORE operating rules, including requirements for attachments, prior authorization, and health care claim transactions. This creates a standard agnostic approach to exchanging these transactions in a uniform manner, regardless of the standard used. For example, entities may:

- Use CORE Connectivity vC4.0.0 to exchange an X12 275 attachment transaction sent to support an X12 278 prior authorization request or an X12 837 claim submission
- Use CORE Connectivity vC4.0.0 to exchange the HL7 FHIR standard to support a prior authorization request or claim submission via a REST API

CORE Connectivity vC4.0.0 thus facilitates the use of X12 standards such as the X12 278 with new exchange methods including HL7 FHIR. With this version of CORE Connectivity, the data content and infrastructure requirements in the CAQH CORE Prior Authorization Operating Rules and CAQH CORE Attachments Operating Rules can be applied in a standard agnostic manner to align industry use of other prior authorization and attachments exchange mechanisms like HL7 FHIR.

For example, the CAQH CORE Prior Authorization Infrastructure Rule specifies requirements for response times, setting time limits for health plans to request supporting clinical information from providers, and make a final decision on a prior authorization request. While the rule is scoped to apply to the X12 278, the response time specifications serve as an example of a standard agnostic requirement that could be applied to other standards to ensure invariable and timely exchange of information to support the adjudication of a prior authorization request. We urge ONC and HHS to explore a standard agnostic approach to infrastructure and data content requirements that establishes consistent expectations for data exchange throughout the industry, despite the standard used.

Value of a Phased Approach and ROI Measurement to Incrementally Move Industry Forward

Real World Implementation to Inform Feasibility

We encourage ONC and HHS to consider a phased approach to addressing electronic prior authorization standards that includes operational testing and piloting to understand the feasibility and potential limitations of the proposed standards prior to adoption under the ONC Certification

Program. A phase-based approach facilitates ease of technology transition and supports smaller health plans and providers with fewer resources and ability to implement, while moving the industry forward to a more fully automated prior authorization workflow. Given the need for operational workflow testing of the specifications, we recommend ONC initially delay adoption of the proposed implementation specifications until the Da Vinci implementation guides are tested within an operational workflow. HHS has multiple ways of communicating and implementing policy changes at regular intervals and we urge ONC and HHS to apply these existing mechanisms to support a phased approach.

Initial results from the CAQH CORE Prior Authorization Pilot and Measurement Initiative partnership with Cleveland Clinic and PriorAuthNow demonstrate the value of incremental prior authorization workflow automation in an operational setting. Leveraging the CAQH CORE prior authorization requirements, HIPAA-mandated X12 278 standard, and APIs, overall time to conduct an end-to-end prior authorization decreased from an average of 45 minutes without automation to 4 minutes with automation. The results, taken in tandem with 2021 CAQH Index data that estimates health plans can save $3.47 and providers $7.52 per transaction if prior authorizations were conducted fully electronically, indicate that automation using standards and operating rules, even without the inclusion of consistent expectations around the exchange of attachments, represents significant improvements to provider and health plan time, cost, and patient care.

Implementation of real world pilot and testing initiatives is imperative to the successful inclusion of the proposed implementation specifications, particularly given the Da Vinci implementation guides have largely not been tested in an operational setting. We recommend ONC and HHS conduct similar operational real world testing using the proposed standards to measure the feasibility of implementation, and impact on workflow efficiency metrics prior to adoption under the ONC Certification Program.

CAQH CORE Certification for the Prior Authorization Workflow

Through the CORE Certification Program, CAQH CORE certifies entities that create, transmit or use the healthcare administrative and financial transactions addressed by the CAQH CORE operating rules. As such, CAQH CORE understands that the time needed to build, implement, alpha/beta test, and successfully certify organizations is often 18 months or more from initial build to certification. Given the limited testing of the proposed specifications to date, and the recommended piloting of the specifications prior to adoption under ONC's Certification Program, a minimum of 24 months is needed for the use of the proposed specifications in production for prior authorization transactions.

The results of the CAQH CORE pilot study with Cleveland Clinic and PriorAuthNow, and data obtained from early CORE Certifiers of the CAQH CORE Prior Authorization Operating Rules have clearly demonstrated that incremental automation of the prior authorization workflow is beneficial, with improvements to cost savings, administrative burden, and patient care, even without addressing the exchange of additional information. Thus, adopting certification criteria that only accounts for a portion of the prior authorization workflow can promote increased adoption of electronic prior authorizations, but ONC and HHS also should establish a clear roadmap to help the industry transition to a fully automated prior authorization workflow that includes attachments.

Next Steps

There is a need for an overarching strategy to consider how standards established for the electronic prior authorization workflow, including attachments, can be tested in an operational setting, implemented, and harmonized across the administrative transactions to reduce unnecessary burden. Phased implementation that couples a standard agnostic approach with extensive testing and piloting could help ensure adoption of a standardized electronic prior authorization workflow that moves the industry forward without creating additional burden.

CAQH CORE looks forward to supporting this work and encourages the agencies to continue to consider industry feedback to develop standardized approaches and appropriate timelines for implementation that reduce the burden of this process and ensure lasting value for patients. Thank you for considering our comments in response to the Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria Request for Information. Should you have any questions, please contact me at atodd@caqh.org.

Sincerely,

April Todd
Senior Vice President, CAQH CORE & Explorations

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