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Donald W. Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
330 C Street, S.W.
Floor 7
Washington, DC 20201

Re: Office of the National Coordinator for Health Information Technology (ONC) Request for Public Comment on Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs

Dear Dr. Rucker,

Thank you for the opportunity to provide feedback on the Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs (ONC Draft Strategy). CAQH CORE values and supports the goals of this effort to reduce the sources of provider burden, enhance the provider-patient experience, and ultimately improve patient care.

The CAQH Committee on Operating Rules for Information Exchange (CORE) is a non-profit, national multi-stakeholder collaborative that streamlines electronic healthcare administrative data exchange and improves health plan-provider interoperability through an integrated model of operating rule development, adoption, and maintenance. [CAQH CORE Participating Organizations](#) represent more than 130 healthcare providers, health plans, electronic health record (EHR) and other vendors/clearinghouses, 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 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.” Commonly used in other industries including financial services and telecommunications, operating rules support technology solutions by providing uniform business requirements to enhance the exchange of healthcare information. The rules go beyond reference or implementation guides by enabling business to consistently use technology and standards to generate value and reduce administrative burden.

Below are detailed comments from CAQH CORE regarding the ONC Draft Strategy Recommendations based on our history of working with stakeholders across the healthcare industry on topics including greater automation of prior authorization, attachments, and value-based payment. Our recommendations fall under three overarching themes:

- Healthcare operating rules support standards and technical requirements to ensure common industry expectations across electronic transactions. Addressing the business aspects of these transactions is critical to long-term industry-wide adoption and return on investment.
- Stakeholders are working together to streamline administrative transactions for prior authorization and clinical documentation to reduce provider burden and ultimately ensure better care for patients through CAQH CORE. HHS can support these industry efforts through timely adoption of attachment standards.
- As healthcare transitions from fee-for-service to value-based payment, there is a need for clinical and administrative operations to work in synch; operating rules can help facilitate this convergence.

Thank you for considering these recommendations and comments. Should you have questions for CAQH CORE, please contact me at atodd@caqh.org or 202-664-5674.

Sincerely,



April Todd
Senior Vice President, CAQH CORE & Explorations

cc:

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CAQH CORE Comments on ONC Draft Strategy Recommendations

Clinical Documentation, Strategy 3: Leverage health IT to standardize data and processes around ordering services and related prior authorization processes.

- **Recommendation 1: Evaluate and address other process and clinical workflow factors contributing to burden associated with prior authorization.**
- **Recommendation 2: Support automation of ordering and prior authorization processes for medical services and equipment through adoption of standardized templates, data elements, and real-time standards-based electronic transactions between providers, suppliers, and payers.**

CAQH CORE agrees with the ONC Draft Strategy findings regarding the challenge of the current prior authorization process and the importance of HHS engaging with stakeholders to come up with effective solutions. Each step of the prior authorization process is labor-intensive and generates time-consuming and costly administrative burden for providers, as well as payers, and can delay patient care. According to the newly released [2018 CAQH Index](#), 51 percent of prior authorizations are submitted manually, 36 percent are submitted via web portal or interactive voice response and 12 percent are submitted via the 5010X217 278 Request.

To date, CAQH CORE Participants have developed three prior authorization operating rules which address the following challenges in the prior authorization process:

- Lack of consistency in the infrastructure supporting the 5010X217 278 Request and Response.
- 5010X217 278 Requests for medical services and equipment that are pended due to missing or incomplete information.
- Inconsistencies in web portal uniformity.

The [Phase IV CAQH CORE 452 Health Care Services Review – Request for Review and Response \(278\) Infrastructure Rule](#) establishes foundational requirements that build consistency with other operating rules for the Health Insurance Portability and Accountability Act (HIPAA) transactions, including receipt acknowledgement, common connectivity methods (i.e., a “safe harbor”), required response times, minimum system availability, and a common companion guide format.

The draft Phase V CAQH CORE Prior Authorization Operating Rules, expected to be finalized in spring 2019, address needed data content within the prior authorization transaction and enable greater consistency across other modes of prior authorization submissions. Specifically, the [draft Phase V CAQH CORE Prior Authorization \(278\) Request / Response Data Content Rule](#) requirements target one of the most significant problem areas in the prior authorization process: requests for medical services that are pended due to missing or incomplete information, primarily medical necessity information. The Data Content Rule reduces the back and forth between providers and health plans, and enables shorter electronic adjudication timeframes by:

- Strengthening the data submitted by the provider on the prior authorization request and the communication of consistent codes by the health plan to indicate errors, documentation needed, and next steps for the provider on the response.
- Specifying the required data content for provider and patient identification on a prior authorization request to reduce common errors and associated health plan denials.

- Easing the burden of interpretation on the provider by standardizing code use (i.e. diagnosis, procedure, revenue, etc. codes) and requiring display of code descriptions.

The [draft Phase V CAQH CORE Prior Authorization Web Portal Rule](#) addresses consistency in prior authorization web portals. As evidenced by the 2018 CAQH Index, provider-facing web portals are one of the most common methods for prior authorization submission, and many such portal-based requests are mapped to the 5010X217 278 Request and Response transaction. However, the lack of data field uniformity and consistency across portals consumes a significant amount of provider staff time. For each health plan with which the provider contracts, provider staff must log into a different portal, keying information into the system manually.

The standard 5010X217 278 Request and Response transaction is not a viable option if the provider does not have the system to support it. This is common given only 12 percent of vendor solutions support the 5010X217 278 Request and Response transaction according to the [2017 CAQH Index](#). Low vendor support is partially due to the lack of a federal attachment standard to support communication of clinical documentation.

The Phase V CAQH CORE Prior Authorization Web Portal Rule builds a bridge toward overall consistency for referral and prior authorization requests and responses by addressing fundamental uniformity for data field labels, ensuring confirmation of the receipt of a request, and providing for system availability. The rule reduces administrative burden and encourages pathways to automation by:

- Requiring use of the 5010X217 278 Request and Response TR3 implementation names for the web portal data field labels for prior authorizations and referrals, which supports the HIPAA-mandated standard transaction.
- Adhering to the requirements outlined in the Phase V CAQH CORE Prior Authorization Request / Response Data Content Rule when the portal operator maps the collected data from the web portal to the 5010X217 278 Request and Response transaction.
- Reducing variation in data element names to ease submission burden and encourage technology solutions to minimize the need for providers to submit information to multiple web portals.

CAQH CORE will continue to consider additional operating rules in 2019 to address prior authorization across the technology and standards spectrum. Examples of topics under consideration include timeframe requirements for final determination and support for providers to determine whether a prior authorization is needed from a health plan.

- **Recommendation 3: Incentivize adoption of technology which can generate and exchange standardized data supporting documentation needs for ordering and prior authorization processes.**

CAQH CORE agrees with the recommendation to provide incentives or other benefits to encourage health IT solution developers to follow standard practices to allow for interoperability and reduce burden to providers. That said, requiring technology is only a first step toward automation and streamlined workflows. We urge ONC to consider the vital role of business operating rules to govern the processes that support technical specifications. Common expectations for when, what, and how data is shared is critical for true interoperability.

CAQH CORE drives adoption of operating rules through our [CORE Certification](#) program. CORE Certification provides an incentive to implementers to demonstrate their conformance with the CAQH CORE Operating Rules and underlying standards. Numerous IT vendors pursue CORE

Certification to attract health plan and provider clients. Currently, more than 350 CORE Certifications have been awarded to health plans, providers, and IT vendors since the inception of the program. CAQH CORE Participating Organizations work together to develop the CORE Certification test framework, a third-party testing vendor hosts a testing site, and CAQH CORE serves as the program administrator. CORE-certified health plans represent over 65 percent of all covered lives in the United States.

- **Recommendation 4: Work with payers and other intermediary entities to support pilots for standardized electronic ordering of services.**

The recommendation to support pilots to drive wider adoption of standardized electronic ordering of services is in alignment with CAQH CORE priorities to conduct more piloting and testing of operating rule requirements. In 2019, CAQH CORE is launching several initiatives to streamline and speed up the pace of our work to keep up with changing demands and technological advancements. These include:

- Applying agile/lean methodologies to the rule development process to increase pace and output without sacrificing quality and industry value.
- Working with Participating Organizations to develop a pilot model strategy to build into the operating rule development process more robust feasibility testing and value assessments.
- Testing our concepts before they are released for implementation, including conducting an impact analysis, to inform whether to move forward with a particular requirement.
- Measuring ROI through collaboration with the CAQH Index, which can be used to encourage broader industry adoption.

As ONC considers the detail of this recommendation, CAQH CORE would be pleased to collaborate to further develop criteria and best practices for launching pilots to ensure successful adoption and ROI.

- **Recommendation 5: Coordinate efforts to advance new standard approaches supporting prior authorization.**

CAQH CORE agrees with the principles contained in this recommendation to advance standardized approaches for prior authorization. We also agree that current efforts, such as the DaVinci Project and the P2FHIR Task Force, are making meaningful progress to address some of the challenges in the prior authorization workflow. However, as previously mentioned, there is a critical need for business operating rules to support standards and technical requirements to drive the industry forward. Business operating rules support a transaction regardless of the underlying standard or technology and ensure common expectations for data exchange. The challenges addressed in this recommendation and the overall ONC Draft Strategy will require multiple points of collaboration to have a measurable impact. It will be critical to test feasibility with all types of stakeholders, not just the most innovative, for standards and operating rules to support the entire industry.

The financial services industry provides an example of how industry standards and operating rules can lift a whole industry and have a positive impact on consumers. Almost 50 years ago, the banking industry introduced ATMs which increased financial accessibility and streamlined everyday transactions between banks and customers. The banking industry's ability to digitize and automate day-to-day transactions and work flows reduced bank operating costs by up to 25 percent, while allowing customers to pay bills on-demand and check balances in real time¹. This

¹ <https://www.nacha.org/system/files/resources/Healthcare-EFT-Standard-A-Quick-Reference-Guide.pdf>.

was possible because of public and private sector collaboration. Operating rules developed by NACHA, the Electronic Payments Association, and the Federal Reserve, act as the foundation of every automated clearinghouse (ACH) transaction. In other words, operating rules support the transfer of \$40 trillion worth of electronic payments or deposits to and from a customer's checking or savings account each year. Although participation is voluntary, NACHA represents approximately 91 percent of all U.S. financial institutions, including the Federal Reserve. The banking industry's adoption of digital innovation would not be where it is today without a standardized set of business operating rules to follow. Healthcare is a complex industry, but lessons from operating rule implementation in financial services are applicable to healthcare. In fact, CAQH CORE collaborated with NACHA to develop the [Phase III CAQH CORE EFT & ERA Operating Rules](#) which support the ACH transaction for healthcare.

CAQH CORE Participating Organizations have tackled some of the most difficult healthcare administrative tasks with a shared goal of aligning administrative and clinical activities among providers, payers, and consumers. CAQH CORE encourages ONC to consider the role of operating rules and multi-stakeholder organizations such as CAQH CORE in the recommendations to address the challenges contained in the ONC Draft Strategy.

Finally, CAQH CORE supports the recommendation to use the National Committee on Vital and Health Statistics (NCVHS) to pursue consensus for prior authorization standards. Operating rules have been reviewed and recommended to HHS by NCVHS for several years. In a recent [comment letter](#) to NCVHS regarding their [draft Recommendations for the Predictability Roadmap](#), CAQH CORE emphasized two key points which are applicable to the ONC Draft Strategy as well:

- Be aware of the potential for unintended consequences of using regulation to encourage innovation, as regulation can be stifling. Many organizations report that they choose to wait for the next regulation before they update their systems. Industry should be encouraged to collaboratively innovate and adopt new/updated standards and operating rules with strong ROI, regardless of regulatory timeframes.
- Predictability related to new/updated standards and operating rules will benefit the industry, but the ultimate goal should be new/updated standards and operating rules that offer a compelling business case for implementers. Adopting standards or requiring system updates to meet arbitrary timelines will not add value.

NCVHS serves as a forum for interaction between HHS and interested private sector groups on a range of health data issues. This mechanism could be used to advance the ONC Draft Strategy recommendations on prior authorization as well as other administrative and regulatory inefficiencies that are causing provider burden.

Health IT Usability and the User Experience, Strategy 1: Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation tools.

- **Recommendation 1: Better align EHR system design with real-world clinical workflow.**

EHR design should incorporate the real-world experience of providers. Use of an EHR should not require a provider to add or change how they conduct their routine work to treat their patients. CAQH CORE has taken this into consideration in its development of operating rules for prior authorization and as it tackles the administrative challenges inherent in the transition to value-based payment.

In a [study](#) of value-based payment, CAQH CORE found that to address the administrative challenges associated with value-based payment, industry solutions need to support a provider's workflow rather than adding administrative burdens that further limit a provider's time spent with a patient. CAQH CORE research also found that the while revenue cycle processes are generally consistent across the spectrum of fee-for-service to value-based payment, that providers and health plans need more data delivered earlier in the workflow to successfully execute on value-based payment arrangements.

For example, at the time of a patient encounter, a provider often does not know whether a patient is attributed to their value-based payment population. As such, the provider is not aware of metric reporting requirements or other critical information associated with this population. This requires providers to spend valuable time at the end of the reporting year going back through EHRs and clinician notes to send reporting information, instead of at the time of service. Streamlining the adoption of value-based payments will require better data quality, collected and delivered earlier in the workflow if providers are to best manage their patient's care. These are the types of challenges the CAQH CORE value-based payment initiative intends to address.

- **Recommendation 3: Improve clinical documentation functionality.**

There is a lack of functionality in the industry to support clinical documentation, as well as a lack of functionality to electronically communicate this information between providers and health plans. According to the 2017 CAQH Index, only six percent of healthcare attachments containing clinical documentation to support a prior authorization or claim payment are submitted electronically. Most health plans report that 100% of attachments are submitted manually.

Industry implementation of electronic attachments to communicate clinical documentation should ease the healthcare system workflow. However, no federal standard has yet been adopted for attachments. In October 2018, CAQH CORE held a Townhall and asked audience members to identify their biggest barrier or reason for delay in implementing electronic attachments. Only 11 percent of the audience had implemented an electronic method of exchanging clinical documentation. Over 44 percent said that their organization was waiting for federal regulatory direction, followed by 22 percent waiting for industry direction. While various standards for attachments have been available for many years, adoption has been stymied by the lack of a mandated federal standard and associated business rules to support implementation.

Through its HHS designation as the Operating Rule Author for all HIPAA-covered transactions, the goal of CAQH CORE is to accelerate the adoption of the forthcoming federal attachment standard and streamline the electronic communication of clinical documentation through the development of operating rules. In anticipation of a federal attachment standard, CAQH CORE has engaged in a variety of work efforts to educate and promote industry adoption of electronic attachments and survey industry utilization and barriers to identify opportunities for the development of operating rules. These work efforts include:

- **Research:** CAQH CORE surveyed attachments initiatives occurring across the industry including pilot projects, work groups, conferences, publications, and regulatory activities.
- **Environmental Scan:** CAQH CORE interviewed 40+ stakeholders and collected data to understand processes, barriers, and best practices across manual and electronic attachment exchanges. Research found that operating rule opportunities for attachments are similar to prior authorization. The industry needs uniform rules and codes to define what is required for additional documentation and confirmation of receipt.
- **Education:** CAQH CORE hosted a series of attachment webinars to provide education to the industry on various attachment topics including: fundamentals, standards, technical

topics, implementations, and use cases. Further, CAQH CORE has presented its attachment insights at a number of industry conferences.

- **Phase V Prior Authorization Operating Rules:** CAQH CORE has pushed the industry a step forward by building rules that aid to automate attachment workflows. The [draft Phase V CAQH CORE Prior Authorization Request / Response Data Content Rule](#) requires health plans to use appropriate LOINC and/or PWK01 Attachment Report Type Codes when clinical documentation is needed from a provider to move a pended prior authorization request forward.

In early 2019, CAQH CORE plans to publish detailed findings from its environmental scan and launch an Advisory Group to identify potential operating rule requirements.