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Richard Landen
Denise Love
Co-Chairs
National Committee on Vital and Health Statistics
Subcommittee on Standards
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

July 30, 2021

Re: Request for Public Comment on Healthcare Standards Development, Adoption, and Implementation

Dear Mr. Landen and Ms. Love,

Thank you for the opportunity to provide feedback on the National Committee on Vital and Health Statistics' (NCVHS) Request for Public Comment – "Healthcare Standards Development, Adoption, and Implementation." We appreciate your efforts to create a strategy for standards that will enable progress in the way the healthcare industry exchanges information.

The Committee on Operating Rules for Information Exchange (CORE), an initiative of CAQH, is a leading nonprofit, 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.

The healthcare industry is moving towards a more interoperable ecosystem that includes the convergence of clinical and administrative data. X12 transactions remain the backbone of administrative data exchange, while momentum for application programming interfaces (APIs) continues to build. However, within this continuum of technology industry stakeholders are at varying levels of maturity – early adopters are already testing new API-based use cases while others have limited resources for innovation. This lack of alignment will quickly become an impediment to the industry's long-term vision of interoperability if not addressed.

Operating rules, 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,"[1] can help bridge the gap between current and emerging standards to ensure ongoing interoperability between all stakeholders. The CAQH CORE Board is in the process of developing a longer-term strategy to support industry interoperability as technology continually advances. It is with this lens that we submit the following responses to your questions:

Question 1: How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?

Opportunities abound for enhancing data exchange between healthcare stakeholders as business needs and technology continually advance at a faster and faster pace. Greater industry alignment and collaboration, broad engagement and testing, and a standards-agnostic approach to transitions using the flexibilities within HIPAA are needed to drive improvements.

1. **Need for Alignment and Collaboration:** Given the current environment for healthcare standards, operating rules, and code sets, no one organization or government entity can solve the interoperability challenge. Feedback from CAQH CORE Participants has indicated the need for greater intra-industry alignment, collaboration, and leadership on a common vision for achieving true interoperability. CAQH CORE encourages NCVHS and HHS to promote industry alignment and collaboration to support the goals of interoperability through an ongoing, routine, and aligned process to establish expectations within the industry for annual transitional improvements. An aligned approach across government entities, standard development organizations, operating rule development, and code set maintenance would enable more purposeful industry progress and reduce confusion over priorities. One key aspect of this approach should include streamlining and simplification of the multiple industry committees, review processes, and use of regulatory authorities across HHS to demonstrate leadership, clarify priorities, improve communication, ensure broad industry applicability, and promote a more efficient and predictable process for continuous improvement.

   Additionally, NCVHS and HHS should consider the impact of their recommendations on innovation, pace of adoption, and return on investment (ROI). CAQH CORE Participants invest significant resources in the operating rule development processes during which criteria such as ROI, a strong business case, and cost to implement are used to evaluate potential requirements. A rule can only be approved via the CAQH CORE process if more than two-thirds of Participating Organizations support it. Similar criteria should be the key drivers for any successful collaborative efforts.

2. **Broad Engagement and Testing to Support Implementation:** Improving the adoption and updating of current standards, operating rules, and code sets is as important as developing new standards. To date, a lack of consolidated data related to adoption of HL7 FHIR-based technologies across the industry makes progress difficult to measure and muddles lessons

[1] Affordable Care Act.

learned. There is a need for research on the real-world adoption of new technologies, ROI, and best practices. In 2020, the annual CAQH Index started tracking industry readiness/use of HL7 FHIR. As industry gathers this data, it is critical that current standards continue to be updated (through newer versions or operating rules) to meet evolving industry needs and that clear roadmaps exist for transitions to new technologies supported by ROI research and best practices.

CAQH CORE has observed the importance of engaging all impacted stakeholders in this process. While technical experts can define the technical specifications, input is also needed from business, clinical, and operational staff who have greater insight into actual workflows and real-world challenges. Connectathons can only test the efficacy of new standards in an ideal environment but cannot unearth challenges that arise from issues like imperfect data, workflow disruptions, etc. For example, CAQH CORE has been engaged with the Cleveland Clinic and PriorAuthNow to study the impact of prior authorization standardization on the workflow resulting in practical, real world findings.

Clinical, business, operational, and technical expert engagement in the development and testing of new standards will mitigate implementation barriers and identify areas where operating rules are needed to further streamline the business use of technical standards, specifications, and options.

3. **Standard Agnostic Approaches:** Regardless of the standard used, industry needs consistency in the data content, infrastructure, and code sets supporting X12, HL7 FHIR, and other existing and emerging standards to support interoperability. Aligning data and infrastructure expectations across standards for the same business process via "standard agnostic" operating rules has the potential to accelerate interoperability by capitalizing on existing value built in backend systems, facilitating ease of technology transition, and supporting smaller entities with fewer resources. Whether a prior authorization is conducted using the X12 278 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 therefore enabling common expectations regardless of the standard will keep backend data consistent and enable a more successful glidepath.

   Current prior authorization standards and operating rules provide an early example of how industry can align data across standards and exchange mechanisms. The CAQH CORE Prior Authorization Web Portal Operating Rule requires health plans use the 5010X217 278 Request / Response TR3 Implementation Names for web portal data field labels, which supports the HIPAA-mandated standard transaction. Additionally, if a web portal operator maps the data collected from the web form to an X12 278, it must conform with the CAQH CORE Prior Authorization & Referrals Data Content Rule. This ensures that regardless of the method of exchange, the same data elements are used across portals and EDI transactions, easing the burden of data collection for providers.

   Additionally, the new CAQH CORE Connectivity Rule vC4.0.0 has been updated to support protocols including REpresentational State Transfer (REST) and APIs for use with all existing

CAQH CORE Operating Rules for HIPAA transactions. This operating rule thus facilitates the use of X12 standards with new connectivity methods. X12 and the DaVinci Project are in the process of mapping the X12 278 to HL7 FHIR to support consistent prior authorization data exchange using HL7 FHIR APIs. The data content and infrastructure requirements in the CAQH CORE 278 Prior Authorization Operating Rules can be applied in a standard agnostic approach to help bridge and align industry use of other prior authorization exchange mechanisms like HL7 FHIR.

Beyond data content, there is value to ensuring a consistent set of exchange expectations, or infrastructure, for healthcare business processes. Regardless of the standard, common response times, system availability, error handling, acknowledgements, companion guide formats, etc. will improve interoperability.

CAQH CORE recommends that NCVHS and HHS consider the vital role that operating rules can play in continually improving interoperability through the integration and transition between standards and technology.

4. **Utilize Flexibility in HIPAA:** 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 HHS 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 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) <u>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.</u>*

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. Given the growing connection and need for clinical information in administrative and financial processes, the use of HIPAA provides the opportunity to create the necessary integrations between these information sources in a more holistic way to support end to end workflows. 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.

HIPAA also provides the framework to maintain consistent support for standards and code sets that are working extremely well in our current healthcare ecosystem. More effectively using the authorities in HIPAA in a routine, annual process to update, change, create new standards and operating rules, or reaffirm well-functioning standards and code sets, would help the industry continually improve interoperability and proactively plan for resources and transitions.

5. **More Timely and Flexible Updates to Standards Based on Business Need:** Industry has been clamoring for more timely, incremental updates to standards and operating rules when there is a strong business case to support them, as NCVHS is aware from its work on the Predictability Roadmap. The Centers for Medicare and Medicaid Services has multiple ways of communicating and implementing policy changes at regular intervals, such as the annual payment rule notices and regular transmittals of guidance and policy updates. We encourage HHS to build on the success of these existing mechanisms to support transition and change management.

   In addition, CAQH CORE recommends NCVHS and HHS determine clear overarching benchmarks that must be met to justify advancing to a new standard, set of operating rules, or code set based on the extent of the change. This will provide transparency and certify a strong business case before a major change is required given the investment of significant resources to implement large system updates, while also providing a timelier mechanism for smaller changes to facilitate ongoing transitions.

Question 2: Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

CAQH CORE has tackled a number of industry challenges over the past year via operating rule development, leading industry efforts to drive efficient data exchange and automation. In our role as the HHS-designated operating rule authoring entity, CAQH CORE anticipates recommending a number of recently approved and upcoming operating rules to NCVHS and HHS for federal mandate in the Spring of 2022. The updated CAQH CORE Connectivity Rule and the new CAQH CORE Attachment Operating Rules serve as a bridge between existing and emerging standards. Additionally, the updated CAQH CORE Eligibility Data Content Rule, new Patient Attribution Operating Rules, and general Infrastructure Rules update will modernize current industry standards and support new business needs that have emerged since v5010 of the X12 standards was developed.

New Operating Rules Under Development/Newly Approved:

1. **CAQH CORE Connectivity Rule vC4.0.0:** Regardless of the standard, industry needs common methods of connectivity to drive interoperability. The CAQH CORE Connectivity

Rule establishes a national standard and safe harbor for how healthcare entities exchange data — a fundamental part of healthcare interoperability. The latest version, CAQH CORE Connectivity Rule vC4.0.0, has been updated to support protocols including REST and APIs. Like CAQH CORE Connectivity vC2.2.0 (which is federally mandated), the CAQH CORE Connectivity Rule vC4.0.0 is a Safe Harbor connectivity method and supports two connectivity standards; transitioning from SOAP/MIME in versions 2 and 3 to SOAP/REST in version 4. As such, payers and intermediaries must implement capability to support SOAP **and** REST in the CAQH CORE Connectivity Rule vC4.0.0 requirements. Providers must implement capability to support either SOAP **or** REST in the vC4.0.0 requirements. This version can be applied to all transactions addressed by existing CAQH CORE Operating Rules and other payload types, aligning with the CMS and ONC Interoperability Rules to move the industry closer to a single, uniform approach for administrative and clinical data exchange. This approach applied to connectivity is an important component of any change or update in technology or standards as it will create a transition with common expectations for organizations that may be at different stages of maturity. *Status: Rule approved for industry implementation.*

2. **Draft CAQH CORE Attachments Operating Rules:** Attachments are the bridge between clinical and administrative data. However, the current attachments workflow is primarily manual and a source of significant administrative burden. The goal of drafting CAQH CORE Attachment Rules is to develop a set of common specifications to support the exchange of attachments/additional documentation using the X12 transaction and/or other transaction types such as HL7 C-CDA, HL7 FHIR, .pdf, etc. CAQH CORE is currently refining and finalizing requirements for the CAQH CORE Attachments Infrastructure Rules and CAQH CORE Attachments Data Content Rules for Prior Authorization and Claims use cases. The Draft CAQH CORE Attachments Infrastructure Rules specify minimum system availability, maximum response times for acknowledgements, minimum supported file sizes, connectivity, electronic policy access requirements, and use of common Companion Guide formats. The Draft CAQH CORE Attachments Data Content Rules specify codes to reassociate X12 275 attachments to prior authorization requests or claim submissions, establish common reference data to connect X12 and non-X12 attachments, and require health plans to use appropriate codes to request the most specific additional information. *Status: Rules drafted and expected to be finalized in early 2022.*

3. **Draft CAQH CORE Eligibility Operating Rule Update:** CAQH CORE is currently working with an Eligibility & Benefits Task Group to draft updated and new requirements for the CAQH CORE Eligibility & Benefits Data Content Rule (which is federally mandated). These draft requirements support the following opportunity areas: telemedicine, expansion of required service type codes (STCs), remaining coverage benefits, tiered benefits, procedure codes, and authorization/certification. The delivery of robust and comprehensive eligibility and benefit information is supported by the CAQH CORE Connectivity Rule vC4.0.0 allowing essential coverage information to be exchanged quickly and securely over RESTful APIs. *Status: Rule update drafted and expected to be finalized in early 2022.*

4. **CAQH CORE Value-based Payment Attribution Rules:** In late 2020, the CAQH CORE Participants and Board approved a set of patient attribution rules developed to reduce the burden associated with the exchange of attribution information between plans and providers. Currently this data is shared via a range of formats outside the provider's workflow (spreadsheets, FTP files, etc.), using inconsistent data elements, at varying intervals (weekly, monthly, quarterly, etc.). The CAQH CORE Eligibility & Benefits (270/271) Single Patient Attribution Data Rule is the latest addition to the Eligibility Operating Rule Set to enable provider notification of an attributed patient under a value-based care contract within the eligibility workflow. The rule requires health plans to return the patient attribution status (yes/no/partial) and effective dates of attribution in the X12 271 transaction.

   The Attributed Patient Roster Operating Rules support the electronic exchange of attributed patient rosters between health plans and providers via data content and infrastructure requirements using the X12 00510X318 834 transaction. The data content rule standardizes the minimum data elements a health plan must return to identify patients within the value-based population, including a contract name and effective dates of attribution. The infrastructure rule standardizes expectations for exchange and requires health plans to send providers an updated attributed patient roster (including updated dates of effective attribution) at least once per month. *Status: Rules approved for industry implementation.*

   Both attribution rule sets are supported by the CAQH CORE Connectivity Rule vC4.0.0 allowing information to be exchanged quickly and securely over RESTful APIs.

5. **General Infrastructure Rules Update:** In the Fall of 2021, CAQH CORE plans to launch a process to conduct a global update of the CAQH CORE Infrastructure Operating Rules, of which three are federally mandated. The purpose of this update is to modernize the rule requirements to align industry expectations across transactions and business processes for data exchange and drive continual progress. *Status: Rules update launching later in 2021 and expected to be finalized in early 2022.*

Question 3: How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

Healthcare is a complex industry to be sure, but lessons from operating rule implementation in financial services are applicable to healthcare and have been used as a model by CAQH CORE since our founding. Almost 50 years ago, the banking industry hit a turning point with the introduction of the ATM. The ATM's automated cash withdrawals and integrated global banking systems provided increased financial accessibility and streamlined everyday transactions between banks and customers. Today, the ATM is the backbone of online and mobile banking systems that enable customers to communicate with banks 24 hours a day.

The operating rules developed by Nacha, the Electronic Payments Association, and the Federal Reserve, act as the foundation of every automated clearinghouse (ACH) transaction. These

operating rules enable customers to authorize their banks to send bills or payments electronically — allowing huge amounts of data to be exchanged immediately and accurately. Although participation is voluntary, Nacha represents approximately 91 percent of all U.S. financial institutions, including the Federal Reserve. In 2018, Nacha convened the Afinis Interoperability Standards to advance API standardization and other financial services standards that enhance the efficiency and security of today's modern financial industry. We recommend HHS and NCVHS engage with Nacha to learn more detail about the testing, implementation, and certification components of this successful initiative.

Question 4: What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

Short-term Opportunities – Focus on Incremental Progress: NCVHS mentions a wide range of opportunity areas for industry in Question #2 and CAQH CORE encourages consideration of industry resources and a phased approach to enable success. It is important to learn from past successes and avoid trying to upend processes that are already working with a strong base of adoption for the industry such as claims, eligibility, and codes sets including the Current Procedural Terminology (CPT®) code set. HHS should prioritize the most pressing opportunities – those processes not currently working – and consider what incremental steps are needed to ensure all stakeholders, regardless of where they sit on the technology spectrum, can successfully exchange critical data electronically. For example, the draft CAQH CORE Attachment Operating Rules, expected to be finalized in early 2022, are a short-term opportunity for NCVHS and HHS to address a long-term industry challenge to support electronic exchange of medical documentation. Additionally, updating outdated requirements, such as updating federal operating rule mandates with the most recent versions of those operating rules, including the updated CAQH CORE Connectivity Rule that supports both SOAP and REST, will put the industry on a strong trajectory for success. In the short term, NCVHS and HHS should take the opportunity to make incremental progress while starting to lay out a roadmap to help the industry transition and prioritize resources.

Mid-term Opportunities – Provide a Roadmap and Drive Industry Alignment: CAQH CORE hears from industry stakeholders that feel they are in a holding pattern without clear direction from HHS on its plans for future standards and operating rules. The result is "implementation paralysis" whereby organizations focus on minimal compliance with little resources left for piloting and testing new opportunities. This lack of real-world implementation beyond simple connectathons means there is little supporting evidence to drive adoption of updated and emerging standards and operating rules. Transitioning the industry to updated and emerging standards cannot happen overnight. A future roadmap with expectations for transitions is needed to help organizations prioritize investments. In establishing this roadmap, it is important to note that technology is only one step toward automation and streamlined workflows. HHS should define its interoperability goals from both a technical and business perspective. Common expectations for when, what, and how data is shared is critical for true interoperability.

Once HHS sets industry expectations and priorities for transitions and common interoperability goals, it will be critical that standards development organizations, code maintenance groups, and

CAQH CORE be aligned in their efforts to optimize industry resources. CAQH CORE can lead as a trusted, standards-agnostic convenor to bridge existing and emerging standards working with standard development organizations and provide measurement support. The CAQH Index also measures industry use of both X12 and HL7 transactions.

Long-term Opportunities – Establish a Transparent and Predictable Annual Process to Make Continual Progress: Over the longer term, CAQH CORE recommends that HHS establish and maintain a transparent and predictable annual process with appropriate resources to make continuous improvements in interoperability. The pace of change will only increase over time and the industry will need clarity and alignment to continually adapt to support interoperability. A routine and timely process aligned across HHS initiatives to evaluate changes to standards and technology and communicate expectations for transitions is needed for effective change management and broad adoption across the industry. In addition to using the authorities in HIPAA, there are existing annual processes employed by HHS such as the annual payment notices for Medicare that are highly anticipated and followed by industry participants that should be used as models for routine industry communication.

The primary goal of interoperability should be to support the health of all patients regardless of their healthcare coverage in a way that is timely, accurate, complete, and straightforward for a patient and their caregivers. To achieve this goal, the industry needs to be aligned around routine, predictable processes that establish reasonable expectations for transitions to make continuous improvements in interoperability.

Thank you for considering our feedback to your information request. Should you have questions, please contact me at atodd@caqh.org.

Sincerely,

April Todd
Senior Vice President, CAQH CORE & Explorations

CC: Robin Thomashauer, President
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