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December 20, 2018

Subcommittee on Standards
National Committee on Vital and Health Statistics
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: Request for Comment on Draft Predictability Roadmap Recommendations

Dear NCVHS Members,

Thank you for the opportunity to provide input on the Draft NCVHS Recommendations for the Predictability Roadmap. CAQH CORE appreciates the time and effort NCVHS has invested to understand industry challenges and opportunities.

CAQH 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, clearinghouses, vendors, government agencies, associations, and standards development organizations (SDOs). CAQH CORE has been 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.

CAQH CORE is pleased to see alignment between many of the Draft NCVHS Predictability Roadmap Recommendations and CAQH CORE priorities. Key areas of overlap include:

- Expedited development of operating rules
- Importance of broad industry collaboration
- Support for greater adoption of operating rules
- Focus on cost-benefit analyses to drive industry adoption

As NCVHS finalizes these recommendations, CAQH CORE encourages consideration of the following:

- How HHS can use existing statutes and regulations to enable greater predictability and innovation rather than additional rule making, which could be time consuming and slow industry innovation.
- How to ensure development of new/updated standards and operating rules is driven by industry need, backed by strong business cases, rather than arbitrary timelines set by HHS.

Below are detailed comments from CAQH CORE regarding the Draft Predictability Roadmap Recommendations and Calls to Action that are most pertinent to CAQH CORE and our participating organizations. To inform our comments, CAQH CORE held a virtual meeting with our participants on the draft recommendations on November 5, 2018 and conducted a follow-up survey. Our comments are inclusive of this feedback. CAQH CORE looks forward to working with NCVHS to finalize the recommendations to the Secretary and ultimately drive more predictability and innovation across the industry.

Re: Draft Recommendations #3, #4 and #5, Call to Action G, and Measurement 2.

Feedback on the draft recommendations from CAQH CORE participating organizations communicated the need for greater intra-industry collaboration across the SDOs and CAQH CORE. To support this request and the desire for more predictable and accelerated innovation, CAQH CORE encourages NCVHS to promote coordination through the Review Committee outlined in Section 1104(j) of the Affordable Care Act (ACA), rather than create another entity or recreate the Designated Standards Maintenance Organization (DSMO).

Replacing the DSMO with a new entity (or “modernizing” the existing DSMO) adds another layer to the process and may impede the NCVHS goal of enabling timely adoption, testing, and implementation of updated or new standards and operating rules. As these recommendations are further refined, NCVHS should consider the unintended consequences a new or modernized entity could have on innovation and the pace of adoption. Additionally, the point at which the DSMO review currently occurs is too late in the process to ensure industry alignment and assess return on investment (ROI). The industry invests 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. These criteria should drive requirement development.

Operating rules have been successfully reviewed and recommended to HHS by NCVHS without the DSMO for many years. By not participating in the DSMO, CAQH CORE is able to more rapidly bring new operating rules to NCVHS for review and consideration. CAQH CORE encourages NCVHS to consider how this model could be expanded to the SDOs and the role NCVHS plays in facilitating coordination across the SDOs and CAQH CORE throughout the process. To ensure new/updated standards and operating rules are fully vetted, NCVHS should consider developing a list of supporting information that must be submitted along with the new/updated standards and operating rules for NCVHS consideration.

Should NCVHS decide to move forward with recommending a new entity, CAQH CORE recommends the entity be granted a limited coordinating function -- rather than an oversight function -- to align standard and operating rule requirements and metrics across the industry. If NCVHS proceeds with the existing recommendations, CAQH CORE requests greater clarity on the recommendations including:

- Whether it is expected that CAQH CORE would be included in the development and membership of the new entity
- How the new entity would be substantively different than the current DSMO (and if rule making is really needed to create this differentiation)
- What the intended relationship of the new entity would be with NCVHS
- Whether the intent of Recommendation #5 is to give authority to the new entity to “review and approve maintenance and modifications to adopted (or proposed)

standards” in lieu of the need for federal rule making or as a step to enable federal rule making

Re: Draft Recommendations #6, #8, and #10.

CAQH CORE supports more timely, incremental updates to the standards and operating rules on a frequency not greater than two years when there is a strong business case to support the updates. Organizations invest significant resources into system updates and thus expect a ROI. The industry should drive the need for updates within the existing statutory framework that specifies a 90-day, expedited interim final rule by HHS per Section 1104(i)(3) of the ACA, versus arbitrary timelines set by HHS. Requiring updates simply to meet pre-determined timeframe requirements will only result in industry fatigue and frustration. NCVHS should encourage HHS to leverage existing statutes to both encourage the industry to bring forth timely updates for consideration and adopt those updates within an accelerated timeframe.

Recommendations to support more timely standards, operating rules, and associated updates are well aligned with CAQH CORE priorities to increase the pace of rule development, while maintaining the quality and impact of the rules. Current CAQH CORE rule development processes take, on average, one and a half to two years from launch of an Advisory Group and environmental scan to completion of the formal [CAQH CORE voting process](#). Processes under development include:

- Tightening the timeline and scope of Advisory Groups
- Applying agile/lean methodologies to the rule development process to increase pace and output
- Addressing more contentious topics with smaller groups of stakeholders committed to piloting solutions
- Measuring ROI through collaboration with the [CAQH Index](#), which can be used to encourage broader industry adoption

As NCVHS considers the detail of these recommendations, it is meaningful to highlight how operating rules differ from standards. Generally, operating rules are developed in phases, with each phase building off previous requirements, rather than discontinuing the entirety of a previous version and publishing a new version with new requirements. This incremental approach allows for industry progress towards greater automation as new operating rule requirements complement or assist in transitioning from existing ones.

In addition to timelier regulatory processes, enabling flexibility within regulations to allow the industry to maintain aspects of standards and operating rules outside the regulatory process is critical. CAQH CORE supports greater adoption of processes over specific requirements, such as the CORE Code Combinations maintenance process for the Phase III CAQH CORE Uniform Use of CARCs and RARCs. The CORE Code Combinations are maintained as a separate document from the rule to enable more rapid updates to meet industry need and prevent delays via the regulatory process. The Centers for Medicare and Medicaid Services (CMS) recognized this process in a [Notice to the Industry](#).

Furthermore, by mandating specific versions of standards (e.g. v4010 or v5010 of the X12 standards) and operating rules, the industry is often unable to launch pilots, promote innovation, or move the industry forward to the next version without further federal mandates. This does not ensure that the industry has fully vetted the latest version through piloting, testing, and ROI studies to promote adoption.

CAQH CORE urges HHS to consider how to adopt regulations that reference standards and operating rules recommended by NCVHS versus detailing the specific requirements in regulation. HHS should also consider publishing an annual notice referencing the most current set of standards and operating rules recommended by NCVHS that would be mandated for the industry and the date required for adoption.

Re: Draft Recommendation #7.

CAQH CORE supports HHS providing industry guidance on where to find information on the appropriate use of the standards and operating rules from the authors -- rather than directly providing implementation guidance -- to minimize industry confusion.

CAQH CORE offers extensive resources and guidance to support efficient planning and implementation of the operating rules. This includes free access to the operating rules on our website, free implementation tools (such as the Analysis and Planning Guide to help entities prepare for implementation), hundreds of FAQs on technical rule requirements, industry-driven education webinars (available for download on our website for free), and our CORE Certification program.

Re: Draft Recommendations #11 and #12.

One of the CAQH CORE guiding principles states that “operating rules will not be based on the least common denominator but rather will encourage feasible progress” with an underlying assumption that the rules are a floor, not a ceiling. This encourages CORE-certified entities to go beyond the operating rule requirements.

The concept of a floor versus a ceiling supports the phased approach of both data content and infrastructure operating rules but may need to be applied differently for standards. For example, organizations can go above and beyond the 20-second real-time response requirements in the operating rules and conduct three-second responses. Additionally, entities can go above and beyond data content requirements by including more situational data elements in their transactions. In a CAQH CORE participant webinar poll, more than 60 percent of respondents indicated their organizations were going above and beyond operating rule requirements.

CAQH CORE recommends that NCVHS conduct additional research and provide common guidance regarding the recommendation for adoption of a floor versus a ceiling approach. Specifically, NCVHS should highlight that an agreement is needed between willing trading partners to go above and beyond mandated requirements to ensure stakeholders are not forced to support multiple implementations.

CAQH CORE also recommends that NCVHS explore the concept of a safe harbor and how it could support this recommendation. For example, the CAQH CORE Connectivity Safe Harbor specifies connectivity and security methods that application vendors, providers, and health plans can be assured are supported by any HIPAA-covered entity and/or a CORE-certified entity. This means that the entity is capable and ready, at the time of the request by a trading partner, to exchange data using the CAQH CORE Connectivity Rule. The rule does not require entities to remove connections that do not match the rule, nor does it require that all covered entities use a specific method for all new connections.

Lastly, CAQH CORE encourages NCVHS to consider regulatory adoption of processes, such as the CORE Code Combinations versus specific requirements to enable flexibility and future innovation. Consider how existing statutory flexibility can support voluntary use of new or

updated standards and operating rules so this recommendation can be achieved earlier than the 2021-2024 draft timeframe.

Re: Draft Call to Action C.

More than 350 CORE Certifications have been awarded to organizations that have demonstrated adoption of the CAQH CORE Operating Rules since its inception. The CAQH CORE participants develop the CORE Certification test scripts, 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. CAQH CORE strongly encourages NCVHS to ensure that any recommendations to HHS related to certification do not duplicate existing initiatives, such as CORE Certification. This redundancy can create waste and stifle industry innovation. On the recent CAQH CORE Participant survey, 75 percent of respondents supported maintaining CORE Certification when asked about this Call to Action.

CAQH CORE also encourages NCVHS to provide more clarity around to this Call to Action. Specifically, CAQH CORE requests clarity around the intent and how the Call to Action drives greater predictability. If the intent is to increase certifications, NCVHS should consider recommending that HHS and WEDI collaborate to educate the industry on existing certification programs. If the intent is to drive adoption of standards and operating rules through mandated certification, HHS should consider using existing authority under Section 1104 (h)(4) of the ACA and work in collaboration with existing certification programs.

Re: Draft Call to Action D.

CAQH CORE strongly agrees with the NCVHS call to action for greater cost benefit analysis to measure industry ROI of standards and operating rules. This is a key priority for CAQH CORE over the next three years.

To measure industry progress and value, CAQH CORE encourages NCVHS to recommend that HHS leverage existing initiatives, such as the CAQH Index which tracks industry adoption of administrative transactions. HHS can coordinate with CAQH to support and expand the work of the CAQH Index and CAQH CORE for cost benefit analyses and ROI studies via additional resource, funding, and recruitment support.

Re: Draft Call to Actions E and F.

CAQH CORE agrees with NCVHS that broad industry participation and collaboration on standards and operating rule development is essential. More than 130 organizations representing provider organizations, health plans, vendors, government entities, associations, and SDOs participate in CAQH CORE and engagement is high. A typical subgroup or work group includes 40 to 100 organizations working collaboratively to develop and refine operating rule requirements. More than 350 CORE Certifications have been awarded to date representing over 65 percent of all covered lives in the United States.

Re: Draft Call to Action H.

CAQH CORE supports and regularly provides feedback on the Office of the National Coordinator (ONC) Interoperability Standards Advisory (ISA) and was encouraged by the addition of administrative standards and operating rules in 2018. CAQH CORE has observed in past comments to ONC that by only including federally mandated administrative standards and

operating rules, the ISA is not fully encouraging industry innovation. Voluntary operating rules (e.g., the Phase IV CAQH CORE Operating Rules) should be added to the ISA given other voluntary standards are included in the publication.

Re: Draft Narrative Report.

CAQH CORE requests that the description of CAQH CORE be updated on page 9 of the draft narrative report, *Improving Health Care System Efficiency by Accelerating the Update, Adoption, and Use of Administrative Standards and Operating Rules: A Brief History and Draft Recommendations*, to read:

CAQH 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. Since 2005, CAQH CORE has developed and issued multiple sets of operating rules that support standards, accelerate interoperability and align fee-for-service administrative activities among providers, payers and consumers. Several sets of CAQH CORE Operating Rules are federally mandated under HIPAA. In 2015, the CAQH CORE scope expanded to include administrative exchange needs for value-based payment.

Concluding Thoughts

As expressed throughout this letter, there is significant overlap between the Draft NCVHS Predictability Roadmap Recommendations and the 2019 CAQH CORE goals. The pace of change in healthcare technology is accelerating. CAQH CORE is evolving processes to be more nimble and responsive to industry needs, while remaining cognizant of the need for predictability and ROI.

As NCVHS finalizes the recommendations, CAQH CORE would highlight four considerations:

1. Consider how to use the flexibility in existing statutes and regulations rather than new rule making to achieve the goal of predictability. Many of the recommendations included in the Draft Predictability Roadmap can be achieved by taking full advantage of existing law.
2. 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.
3. At the [NCVHS Appreciative Inquiry Workshop](#) a key theme identified was to ensure third-party vendors integrate standards and operating rules into their software and systems. Consider additional recommendations to ensure full and timely adoption of standards and operating rules by third-party vendors.
4. 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.

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,



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