June 8, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Administrative Standards and the Standards Development Process

Dear Secretary Becerra,

The undersigned organizations write today to offer our perspectives and recommendations in response to the National Committee on Vital and Health Statistics (NCVHS) March 30, 2022, letter with the subject "Recommendations to Modernize Aspects of HIPAA and Other HIT Standards to Improve Patient Care and Achieve Burden Reduction."

As the organizations supporting the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Affordable Care Act of 2010 (ACA) to develop and facilitate implementation of administrative standards and operating rules for the health care industry, we strongly support the work of the NCVHS and share their commitment to deploying standards and when necessary, operating rules that improve the efficiency of data exchange, lower administrative costs for all stakeholders, and improve the care delivery process for patients.

In response to the NCVHS recommendations to the Department of Health and Human Services (HHS), our organizations came together to collaborate on common recommendations and context to share with HHS given our unique leadership roles within this industry space. Our comments fall into three main categories:

1. Support for expedited issuance of regulation establishing a standardized approach to electronic attachments
2. Prioritization of a predictable federal process and guidelines for demonstrating value of adoption
3. Opportunities to streamline HIPAA process for ease of implementation and effectiveness of standards

Additional detail and recommendations are included below based on our common experiences and observations as drivers of standards and operating rules development and industry conveners.

1. Support for expedited issuance of regulation establishing a standardized approach to electronic attachments

Today, most providers are using fax, mail, and proprietary websites to exchange the clinical data necessary to respond to health plan requests for additional information. Electronic attachments can significantly reduce administrative burden and improve patient care by supporting claim submissions, prior authorizations, referrals, transitions of care, care coordination documentation requirements, as well as simplifying other patient data communication requests.

Both standards and operating rules to support the electronic exchange of attachments are ready for industry adoption. Yet according to the 2021 CAQH Index only 21 percent of attachments are exchanged electronically in the medical industry. In its recommendations, NCVHS urged HHS to adopt standards for electronic standards "as soon as possible to meet today's business needs." Currently, many organizations are hesitant to invest in the infrastructure needed to support electronic attachments because they are waiting on specific federal regulations. HHS has indicated for several years via the Unified Agenda of Regulatory Actions that a regulation is imminent, but the Department has not yet released a proposed rule. **As a leadership group, we strongly urge HHS to expedite issuance of a regulation establishing a standardized approach to electronic attachments.**

2. Prioritization of a predictable federal process and guidelines for demonstrating value of adoption

In its recommendations, NCVHS urges HHS to "streamline the process for adopting HIPAA transaction standards so that it is reliable, efficient, and timely." We concur with this sentiment. Industry has long clamored for more timely, incremental updates to standards and operating rules when there is a strong business case to support them, as NCVHS observed in its Predictability Roadmap efforts. Our organizations have made significant strides in recent years to improve our processes and increase the pace of standards and operating rule development. However, the current regulatory approval process has hindered industry adoption. NCVHS correctly observes that the industry needs "an updated and streamlined standards update and/or rule promulgation process that produces a more nimble and responsive approach to standards adoption to better support federal policy objectives, industry business requirements and emerging technologies." **As HHS considers how best to execute on this recommendation, we encourage prioritization of a predictable federal process and guidelines for demonstrating value of adoption**. **We pledge to work with you in development of this more nimble and responsive approach to standards adoption.**

Need for Predictability from HHS

The pathway to a federal mandate is overly lengthy and cumbersome for industry. Stakeholders first provide direct input into the ANSI-accredited standards development and approval processes. They may also engage in operating rule development and related processes. Advancement of standards and operating rules is followed in some instances by the Designated Standards Maintenance Organizations (DSMO) review for new and updated standards. Next is the NCVHS review process and then, if recommended to HHS and adopted, the lengthy regulatory process begins. In some instances, such as with electronic attachments, years have passed after NCVHS has made a recommendation to HHS without response or action. **We urge that regulations be issued without undue delay for those standards and operating rules with widespread industry support. As well, the regulatory release process itself lacks a predictable cadence, with industry stakeholders who are left in the dark regarding when to expect, plan, and budget for standards and operating rules implementation. We recommend HHS work with the industry to develop a standardized release date for new and/or modified standards and operating rules.**

More recently, given the convergence of clinical and administrative standards, the process has become even more convoluted as HIPAA is not always the regulatory authority under which HHS is promulgating standards through the Centers for Medicare & Medicaid Services (CMS), resulting in further industry confusion. For example, administrative simplification and standardization efforts are underway at the Office of the National Coordinator for Health Information Technology (ONC) as they seek to implement

interoperability and burden reduction provisions of the 21st Century Cures Act. At the same time, CMS is undertaking efforts to promulgate patient access, interoperability, and prior authorization regulations. **With this fragmentation potentially resulting in a patchwork approach to administrative standards and interoperability, we recommend HHS ensure that close cooperation and collaboration exists between CMS and ONC.**

Our organizations recommend HHS address the burden of multiple industry committees, inconsistent review processes, and use of varying regulatory authorities across HHS and encourage broad adoption via a streamlined approach under HIPAA. HHS should also establish a more regular cadence for standards and, when necessary, operating rules adoption similar to how CMS communicates and implements policy changes at regular intervals for 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 and consider new approaches to support transition and change management.**

Clear Expectations and Support for Determining Value of Adoption

Considering lessons learned from past implementations (e.g., v5010, ICD-10, etc.), several opportunities exist for HHS to develop consistent and clear expectations regarding the necessary impact data to justify new or updated standards and operating rules. This data can then be used to determine the appropriate timing for industry as well. **We recommend HHS establish guidelines to help accelerate review and adoption of standards and operating rules based on demonstrated value and burden reduction for industry.**

As a leadership group, we are committed to working together and with the Department to develop a set of clear guidelines that HHS could use to justify adopting a new standard and/or set of operating rules based on the extent of the change. This will provide transparency and confirm a strong business case before a major change is required given the resource investment to implement large system updates, while also providing a timelier mechanism for smaller changes to facilitate ongoing transitions.

One common challenge across all our organizations is garnering commitment from implementers to support end-to-end real-world testing and pilots. Industry stakeholders are understandably hesitant to make significant implementation investments without any assurances for long-term value, especially given the current pace of regulation. Federal funding to support these efforts could help ease the burden and cost for organizations willing to participate while ensuring comprehensive testing that considers not just technical feasibility but also operational and business impacts. HHS can use the findings from real-world testing to align the timing of new and updated standards and operating rules to ensure full industry benefit as soon as possible and consider when an update may be needed for a single transaction versus the entire suite of transactions. **We recommend that for each new major/substantial change, HHS should make available funds for three testing/measurement efforts with different organizations to conclude within no more than 12 months. This would encourage organizations to join and participate quickly given the limited number of participants and funding.**

3. <u>Opportunities to streamline HIPAA process for ease of implementation and effectiveness of standards</u>

Finally, our organizations strongly support implementing regulatory flexibility that facilitates the adoption of new technologies and improved standards as recommended by NCVHS. Based on our experience with testing new and updated standards and operating rules, we believe the current HIPAA Transactions Exceptions Process offers industry an opportunity to test new standards without fear of

non-compliance. However, we are concerned about the timelines associated with the process and lack of specificity for when evaluation of the testing period should occur.

While 45 C.F.R. 162.940 permits the Secretary to grant an initial exception period of no more than three years with no interim reporting requirements, we suggest this is too long a timeframe given the current pace of technology and industry advancement**. We encourage HHS to consider the value of "failing fast" and establish a process of earlier evaluation of effectiveness using clear criteria that results in more timely industry advancement. Further, with clear guidelines and criteria to measure impact and a simplified process, industry may be more willing to engage in the exceptions process. Funding to support these efforts, as previously mentioned, could also help drive industry towards meaningful progress.**

Leadership from across our organizations would welcome the opportunity to meet with you and the appropriate staff and determine the best way to work together to improve administrative standards, operating rules, and the standards development process. Please contact Charles Stellar, WEDI President and CEO, at 202.329.9700 or cstellar@wedi.org with any questions you may have on the issues we have raised in this letter or to discuss collaboration opportunities.

Sincerely,

CAQH Committee on Operating Rules for Information Exchange
Health Level Seven
National Council for Prescription Drug Programs
Workgroup for Electronic Data Interchange
X12

cc: Chiquita Brooks-LaSure, Administrator, CMS
Mary G. Greene, MD, Director, Office of Burden Reduction and Health Informatics, CMS
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