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March 21, 2023

Centers For Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-0053-P  
P.O. Box 8013  
Baltimore, MD 21244-8013  
Washington, DC 20201

Submitted via the Federal Regulations Web Portal, <http://www.regulations.gov>

RE: CMS-0053-P; RIN 0938-AT38

Dear Administrator Brooks-LaSure,

Thank you for the opportunity to respond to the Notice of Proposed Rulemaking, [\*Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard\*](#). The industry has waited over two decades for federal requirements under HIPAA outlining the electronic exchange of supplemental medical information, otherwise known as attachments. This landmark proposal will reduce industry reliance on proprietary exchange solutions that have perpetuated manual workflows, costing the medical industry valuable time and dollars. Further, the persistent use of unsecure modalities – such as fax, phone, and email – only serves to jeopardize data integrity and patient safety. As such, CAQH CORE generally supports the proposals put forward by the Centers for Medicare and Medicaid Services (CMS).

CAQH CORE is designated by the Department of Health and Human Services (HHS) as the Operating Rule Authoring Entity for all HIPAA-mandated standards, including attachments. Our organization employs a consensus-based, industry-driven process to establish business rules that are otherwise not defined by standards. Under the Affordable Care Act (ACA), operating rules must be adopted for HIPAA-mandated standards, and they play a central role in promoting interoperability and automation. Wide-scale adoption of operating rules supports greater conformance with electronic standards, resulting in more uniform use of transactions and improved data exchange between industry trading partners. Operating rules also directly influence time and cost savings and, since their mandate in 2013, have contributed to one-third of the \$55 billion in reduced administrative costs associated with the adoption of HIPAA standards.

In alignment with the role of CAQH CORE as the designated Operating Rule Authoring Entity, in 2022 the [CAQH CORE Participating Organizations](#) developed and approved attachments operating rules for health care claims and prior authorization; receiving 88% and 90% support on final ballots, respectively. These rules are currently under consideration by the National Committee on Vital Health and Statistics (NCVHS) for recommendation for federal mandate under HIPAA. The benefit and impact of these rules are described in detail later in this response; however, CAQH CORE emphasizes the importance of adopting the operating rules simultaneously with the proposed attachment standards. Not only are operating rules a federal requirement, but they also streamline implementation and promote a more uniform approach across all industry stakeholders.

In summary, CAQH CORE recommends the following actions. Detailed responses are included in the Appendix below.

1. **Finalize the X12N and HL7 Standards:** The standards should be finalized consistent with Standard Development Organization guidance on versioning and alignment with other proposed regulations.
2. **Simultaneously adopt the CAQH CORE Attachments Operating Rules:** The CAQH CORE Attachments Operating Rules for health care claims and prior authorization maximize the positive impacts of the proposed standards, setting a uniform, reproducible framework for a fragmented industry.
3. **Consider other tested solutions, consistent with industry feedback:** CAQH CORE encourages HHS and CMS to consider iterations to the proposed standards as recommended by industry stakeholders, including tested, piloted versions that have proven to be effective in meeting the latest business needs.

Please contact me with any questions at [atodd@caqh.org](mailto:atodd@caqh.org).

Sincerely,



April Todd  
Chief Research & Policy Officer, CAQH

CC:  
Robin Thomashauer, CEO, CAQH  
Melissa Speck, Senior Director, Public Affairs, CAQH  
[CAQH CORE Board Members](#)

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## Appendix

### Support for adoption of electronic adoption standards

CAQH CORE supports the proposals naming standards for the electronic exchange of attachments. Adoption of electronic standards for HIPAA-mandated transactions accelerates interoperability, lessens the need for costly manual workflows, and allows industry stakeholders to realize significant cost savings – benefits that have gone unrealized for the electronic exchange of attachments. According to the 2022 CAQH Index, across 237 million attachments transactions in 2021 only 1 in 4 were performed fully electronically.

X12N standards are foundational across the medical industry and are widely implemented across provider, health plan and vendor stakeholders; therefore, CAQH CORE believes it is appropriate to name the X12N 275 as the basis for exchange to support adoption at scale. The HL7 C-CDA is also widely implemented and has demonstrated value in practice. The HL7 C-CDA accommodates the flexibility necessary to deliver solicited and unsolicited information in a variety of formats, including .PDF, video formats, and digital photos. Both standards have undergone real-world testing and utilization. CAQH CORE recommends CMS consult with the authoring SDOs to ensure the appropriate versions of the standards are finalized and that versioning is aligned across the impacted transactions and other proposed regulations, such as the CMS Interoperability and Prior Authorization Proposed Rule. Doing so will stimulate interoperability and automation and allow the industry at-large to realize significant cost savings.

CAQH CORE also supports the proposal to apply attachment standards to both health care claim and prior authorization transactions. While some of our Participating Organizations are concerned with the lack of alignment in prior authorization standards (X12 versus FHIR), CAQH CORE agrees with this initial approach given that the lack of an electronic attachment standard is contributing to low industry adoption rates for electronic prior authorization transactions. As stated in prior comment letters, CAQH CORE is concerned about the adoption of standards under different authorities within CMS, as is the case with this proposed rule and the CMS Interoperability and Prior Authorization Proposed Rule. Doing so causes industry confusion by working against the establishment of common expectations for data exchange.

We encourage CMS to use its existing authority established 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 across all payer types, including prior authorization and attachments, 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) 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.*

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. This 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.

CAQH CORE also notes that finalizing these standards as proposed should not inhibit future timely iteration. The industry is operating in a dynamic environment and new technologies hold promise in modernizing electronic exchange. The proposed standards are a good starting point, but CMS should consider updating the required attachment standards as new methods are introduced and proven through real-world testing to support adoption at scale.

### **The necessity of operating rules for uniform adoption**

Operating rules are required under the ACA to support the adoption and implementation of HIPAA-mandated electronic standards. Operating rules drive adoption and conformance with electronic standards and ensure that implementation efforts are uniform across the industry, minimizing costs and the perpetuation of manual workflows. For example, CAQH Index and CORE Certification data indicate that the CAQH CORE Eligibility and Benefits Operating Rules influenced a 25% increase in the volume of fully automated, electronic eligibility verification transactions (270/271), between the time the rules were mandated in 2013 and 2021.

The CAQH CORE Attachments Operating Rules developed by the CORE Participating Organizations support both health care claim and prior authorization transactions. These operating rules align with past guidance from HHS and the NCVHS and are currently under consideration for recommendation for federal adoption. The attachments operating rules are essential to a complete and uniform implementation of the proposed attachments standards within a two-year timeframe and, if recommended by NCVHS for federal adoption, should be concurrently finalized to unify the industry around a single approach to conformance. The rules include:

- [CAQH CORE Attachments Health Care Claims Infrastructure Rule vHC.1.0](#)
- [CAQH CORE Attachments Health Care Claims Data Content Rule vHC.1.0](#)
- [CAQH CORE Attachments Prior Authorization Infrastructure Rule vPA.1.0](#)
- [CAQH CORE Attachments Prior Authorization Data Content Rule vPA.1.0](#)

These operating rules establish consistent infrastructure, data content, and connectivity requirements for payload delivery using the X12N 275 transaction and other non-X12N transactions as needed. This facilitates the standard and safe exchange of supplementary clinical information packaged within the HL7 C-CDA framework. Key benefits of the attachments operating rules are:

- Consistent data in payload headers, including claim and prior authorization numbers, supports reassociation of attachments with their associated claims and prior authorizations.
- Submission of supplemental information for unsolicited attachments means they are less likely to be disregarded, misrouted, or lost.
- Requirements for health plans to maintain system availability at 90% and accepting file sizes of at least 64mb reduces the likelihood of rejections.
- An electronic access provision for health plans to make required information readily accessible, streamlining submission for unsolicited attachments by empowering submitters to include all required information at first submission.

Additionally, the operating rules have the requisite flexibility to adapt to new business scenarios as they arise, creating a durable framework. The operating rules were developed with the understanding that the industry is in transition and the adoption of attachment standards is being considered against emerging technologies. As before, CAQH CORE encourages CMS to iterate on standards as alternatives demonstrate their value through real-world testing. The operating rules facilitate future improvements because their requirements can be applied to any standard or format. Iteration, however, should not delay adoption, as the operating rules support necessary uniformity for a fragmented industry.

The perceived value of electronic attachments is predictably high given that 80% of attachments are currently conducted manually, as operating rules streamline burdensome workflows and immediately help organizations realize operational efficiencies. CAQH CORE offers support to CMS as the agency considers how to apply and incorporate the attachments operating rules into the proposed rule.

Pilot and impact assessment data received from healthcare stakeholders indicate ongoing industry cost savings resulting from operating rule implementation. One regional health plan estimates ~\$2.2 million in implementation costs for attachments standards and operating rules. This investment is offset by a nearly 50% decrease in annual maintenance costs and a 40% reduction in attachments related call center and fax volume. The estimated implementation timeline for standards and operating rules is between 18-24 months. This timeframe is offset by a more than 40% reduction in ongoing FTE support. Additionally, a national health plan currently piloting the attachments operating rules with the X12 275 is projected to save ~\$300k on an initial round of 76,000 attachments over 8 months.

### **Other considerations**

*Definition of Attachments:* CAQH CORE agrees with the proposed definition of attachments and believes it sufficiently captures what is necessary for solicited and unsolicited exchange of supplementary medical information. Attachments operating rules help enforce this definition, which is scoped to indicate attachments include supplementary medical information *required* to complete the health care claim or prior authorization transaction.

*Conformance Timelines:* CAQH CORE supports the 2-year conformance timeline put forth in the NPRM, submitting that it is reasonable and well-aligned with past implementation efforts. Further, it is likely that many organizations have begun some level of electronic implementation to streamline their own operations and early pilots can be leveraged to accelerate conformance with the proposed standards. The simultaneous mandate of the CAQH CORE Attachments Operating Rules will further strengthen the proposed timeline, aiding industry coalescence around a single set of business rules.