

March 17, 2023

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244
Attention: CMS-0053-P

Submitted electronically to: <http://www.regulations.gov>

Re: Administrative Simplification: Adoption of Standards for Healthcare Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard (CMS-0053-P)

Dear Administrator Brooks-LaSure:

Premier Inc. appreciates the opportunity to submit comments to the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) regarding the Notice of Proposed Rulemaking (NPRM) to adopt standards for data transactions to support electronic prior authorization and healthcare claims transmission processes. The proposed rule seeks public comment on HHS' proposals to adopt standards for "healthcare attachments" transactions, which would support both healthcare claims and prior authorization transactions, and a standard for electronic signatures to be used in conjunction with healthcare attachments transactions. To better support the use of the proposed standards for attachments transactions with prior authorization transactions, this NRPM also proposes to adopt a modification to the standard for the referral certification and authorization transaction (X12 278) to move from Version 5010 to Version 6020.

Premier appreciates CMS' commitment to enabling more efficient data exchange among providers, patients and payers, as evidenced by the proposed policies in this rule. Specifically, Premier recommends the following:

- Finalize proposed standards for healthcare attachment transactions and electronic signatures, as well as the proposed updated referral certification and authorization transaction standards; and
- Commit to implementing the Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) standard by Jan. 1, 2026 to align with implementation of the proposals in the CMS proposed rule on advancing interoperability and streamlining prior authorization processes (CMS-0057-P).

Our detailed recommendations are included below.

I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,400 hospitals and approximately 250,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters and 131 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,400 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products. In addition, Premier

operates the nation's largest population health collaborative, having worked with more than 200 accountable care organizations (ACOs).

Stanson Health, a subsidiary of Premier, designs technology to reduce low-value and unnecessary care. Stanson leverages real-time alerts and relevant analytics to guide and influence physician's decisions through Clinical Decision Support technology, [providing higher-quality, lower-cost healthcare](#). Stanson's mission is to measurably improve the quality and safety of patient care while reducing the cost of care by enabling context-specific information integrated into the provider workflow.

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

II. PROPOSED STANDARDS FOR HEALTHCARE ATTACHMENTS AND ELECTRONIC SIGNATURES

Background

This rule proposes to adopt a set of standards for the electronic exchange of clinical and administrative data to support prior authorizations and healthcare claims adjudication. In conducting analysis for coverage determinations, health plans often request additional information from providers that cannot adequately be conveyed in the specified fields or data elements of the adopted prior authorization request or healthcare claims transaction. If adopted as proposed, this proposed rule would support electronic transmissions of this type of information, rather than forcing providers to rely on resource-intensive, manual processes such as mail or fax to transmit this information. CMS asserts that the proposed standards would facilitate prior authorization decisions and claims processing, reduce burden on providers and plans and result in more timely delivery of patient healthcare services.

Specifically, the proposed rule would implement requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act (HIPAA) and the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, enacted on March 30, 2010 — collectively, the Affordable Care Act. The proposed rule would adopt standards for “healthcare attachments” transactions, which would support healthcare claims and prior authorization transactions, and a standard for electronic signatures to be used in conjunction with healthcare attachments transactions. This rule also proposes modifying the referral certification and authorization transaction standard to move from the X12 278, Version 5010 to the X12 278, Version 6020.

Proposals and Recommendations

The new proposed healthcare attachments standards cover three general use cases wherein a provider submits documentation to a health plan:

- **Prior Authorization:** When a health plan requires prior approval for a service before it is rendered, the proposed rule implements a standardized electronic format for a provider to submit the necessary documentation supporting a prior authorization electronically using HIPAA standards, and for the health plan to provide a response. Specifically, the proposed rule adopts X12N 278 (Health Care Services Request for Review and Response (006020X315)) as the standard a health plan must use to electronically request attachment information from a healthcare provider to support a prior authorization transaction and X12N 275 (Additional Information to Support a Health Care Services Review (006020X316)) as the standard a provider must use to electronically transmit

attachment information to a health plan to support a healthcare provider's prior authorization request.

- **Solicited Documents:** When a health plan requests additional information to adjudicate a submitted claim, the proposed rule adopts a standardized electronic format for a provider to submit the requested documentation. Specifically, the proposed rule adopts X12N 277(Health Care Claim Request for Additional Information (006020X313)) as the standard a health plan must use to electronically request attachment information from a health care provider to support a healthcare claim.
- **Unsolicited Documents:** When a provider submits a claims attachment along with their initial submission of a health care claim (for instance, if required by the health plan's payment policies), the proposed rule adopts a standardized electronic format to submit such attachments. Specifically, the proposed rule adopts X12N 275 (Additional Information to Support a Health Care Claim or Encounter (006020X314)) as the standard a provider must use to electronically transmit attachment information to a health plan to support a healthcare claims or equivalent encounter information transaction.

The proposed rule also adopts the HL7 Clinical Document Architecture (CDA) standard for transmitting clinical information as part of these healthcare attachments. Specifically, HHS is proposing adopting the following three HL7 CDA standards:

- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 1 — Introductory Material, June 2019 with Errata
- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 2 — Templates and Supporting Material, June 2019 with Errata
- HL7 CDA R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1, March 2017

The proposed rule would also permit providers to sign healthcare attachments electronically. The proposed rule defines the term “electronic signature” broadly so that it encompasses current and future electronic signature technologies and adopts an implementation guide called the HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1 (Digital Signatures Guide). Finally, the proposed rule adopts a modification to the standard for the referral certification and authorization transaction (X12 278) to move from Version 5010 to Version 6020.

Premier supports the standards proposed in the NPRM as an interim step to move providers and payers to electronic data transmission. As proposed, the new standards would be enforced 24 months after the effective date of the final rule. However, in order to further advance electronic prior authorization processes and reduce administrative burden on providers, payers and vendors, it is critical to align standards across all components of the electronic prior authorization process, including the transmission of clinical information via healthcare attachments. ***Premier recommends that HHS commit to moving beyond the proposed standards and implementing the HL7 FHIR standard for healthcare attachments and electronic signatures by Jan. 1, 2026 to align with implementation of the proposals in the CMS proposed rule on advancing interoperability and streamlining prior authorization processes (CMS-0057-P).***

III. CONCLUSION

In closing, Premier appreciates the opportunity to submit comments on HHS' NPRM to adopt standards for data transactions to support electronic prior authorization and healthcare claims transmission processes. If

Standards for Health Care Attachments Transactions and Electronic Signatures

March 17, 2023

Page 4 of 4

you have any questions regarding our comments, or if Premier can serve as a resource on these issues to the agency in its policy development, please contact Mason Ingram, Director of Payer Policy, at Mason_Ingram@premierinc.com or 334.318.5016.

Sincerely,

A handwritten signature in black ink, appearing to read 'Soumi Saha', with a stylized flourish at the end.

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.