AMERICAN ACADEMY OF FAMILY PHYSICIANS

March 16, 2023

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

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

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

Dear Secretary Becerra and Administrator Brooks-LaSure:

On behalf of the American Academy of Family Physicians (AAFP), representing more than 129,600 family physicians and medical students across the country, I write in response to the proposed rule regarding health care attachments, as published in the Federal Register on December 21, 2022.

Per requirements in the Health Insurance Portability and Accountability Act (HIPAA), physician practices currently use X12 health information technology (IT) standards to transmit health service claims and prior authorization requests to the various payers they contract with. However, payers often require physicians to transmit documents in support of their claim or prior authorization request and there is currently no required standard to electronically share attachments. This creates additional administrative burden, delays patient care and physician payment, and disrupts the interoperability of health data. In this rule, the Centers for Medicare and Medicaid Services (CMS) proposes using the X12 standards for both health care claims attachments and prior authorization transaction attachments. The goal of these standards is to facilitate document sharing between physicians and payers in order to submit claims and prior authorization attachments electronically.

The AAFP has been a strong advocate for nationwide interoperability as well as reducing administrative burdens on family physicians and their practices. Our policy on IT used in health care calls for uniform, real-world tested standards and a national system of interoperability. The AAFP agrees that standardized electronic submission of supporting documents could help decrease administrative burdens, particularly relating to prior authorizations, and we appreciate the intention of CMS to advance interoperability through these proposals. However, **we are concerned that the proposal to require adoption of an X12 prior authorization attachment standard will hinder current and future advancements in the automation of prior authorization. As such, the AAFP recommends against finalizing the prior authorization attachment standard. We would support the implementation of a claims attachment standard once the standard has undergone and performed successfully in real-world testing across clinical settings and with physician end users.**

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We recognize that CMS proposes to adopt attachment standards in order to reduce administrative burden, comply with HIPAA, and implement recommendations from the National Committee on Vital and Health Statistics to adopt document-driven attachment standards. However, we are concerned that CMS is proposing to mandate the use of two standards that have not undergone or proven successful in real-world testing. **The AAFP strongly believes any standards for attachments transactions must undergo robust real-world testing in a variety of clinical settings, including small, independent, and rural physician practices, and with all end-users, including physicians, to ensure standards are effective, adoptable, and efficient.** Only with end-user engagement and feedback should standards be considered mature or mandated for use, and the AAFP encourages CMS to apply this approach to the proposals in this rule and future rulemaking related to standards.

Additionally, the prior authorization attachment standard proposed in this rule is not in line with the standard proposed in the companion proposed rule from CMS related to Advancing Interoperability and Improving Prior Authorization Processes. The interoperability and prior authorization proposed rule would require several payers to adopt the Fast Healthcare Interoperability Resources (FHIR) standard for exchanging prior authorization data, rather than the X12 standard. However, this rule would apply to all payers and therefore would require physician practices to be able to exchange prior authorization data using two different standards. **It would be costly, very challenging, and overly complex for physician practices to complete the same business process using two separate standards.** The lack of alignment between these two proposed rules creates confusion and runs counter to the purpose of the standards for electronic health information transactions under HIPAA, which is to increase efficiency and reduce costs.

Finally, the health IT industry is working to advance the FHIR standard and implementation guides (IGs) for prior authorization, and the AAFP believes that finalizing an X12 attachment standard will slow the maturation of the FHIR standards, prevent their adoption in 2026 (as proposed in the companion proposal), and inhibit meaningful administrative relief for physicians and patients. **The burdens and care delays caused by prior authorization will only begin to be meaningfully reduced when prior authorization volumes are reduced and their processes are successfully automated and standardized across payers. The most promising path to achieving automation and standardization is through swift implementation of the Prior Authorization Requirements, Documentation, and Decision (PARDD) FHIR API and eventual adoption of standards that enable fully automated prior authorization.** Finalizing an X12 standard would delay progress toward these goals.

We note that the optimal solution to reduce administrative burden and increase efficiency is data-driven transactions that don't involve attachments, which we feel FHIR can accomplish in the near future. **As such, the AAFP recommends against finalizing the proposed attachment standard for prior authorization. We are concerned that finalizing this proposal will slow progress toward a fully mature FHIR standard that fully facilitates end-to-end electronic prior authorization requests, from physician to payer and vice versa.**

Recommendation to Accelerate Standard Maturity and Regulatory Inclusion

To ensure standards are adoptable, effective, and usable in daily practice, the AAFP believes CMS should work with the Office of the National Coordinator for Health IT (ONC) to implement a maturation process for developing standards, available to the public, so stakeholders can adequately prepare for any future updates. We believe this process should support and accelerate real-world testing of standards and signal to the market that specific standards will be included in regulation when they are fully mature with estimated timelines to required or mandated use.

We urge CMS and other federal agencies to provide a federally supported process to engage stakeholders and establish a collaborative process to ensure that the IGs undergo timely real-world testing that provides transparent information to assess maturity and support adoption. As outlined in the Health IT End-Users Alliance consensus statement on real-world testing, that would include an understanding of whether the IGs will:

- Be implementable by health care organizations without significant effort beyond the value incurred by adoption;
- Be effective at achieving the desired goal;
- Encompass a complete solution to achieve the desired goal;
- Not result in unintended consequences that would harm individuals (caregivers, patients, physicians and other clinicians);
- Respect and accommodate the privacy needs of individual patients;
- Not add extraneous work to the care team;
- Ensure sufficient return on investment to justify the health IT spend; and
- Not disparately impact providers who care for communities that are underserved or marginalized.

CMS and other federal agencies should work with the broader health IT community to identify expectations for rigorous real-world testing of health IT standards and IGs, such as needed metrics, methods of accountability, assurance that testing results are impartial, external expert review of testing methods and results, impact on health equity, and public reporting of the outcome.

Engaging with end users to conduct real-world testing will increase the likelihood that these technical approaches will succeed and achieve the goals of improved prior authorization processes and reduced burden for patients, providers, and payers. This collaborative approach must include small, rural, independent, and other under-resourced practices to ensure standards are adoptable in all settings, and to highlight areas where these practices may need additional support from CMS or particular considerations amid implementation. Given the urgency of addressing the prior authorization challenges facing patients and providers, this testing must be done in a timely manner.

Standards should not be considered mature until real-world testing has been completed and proven successful, and comprehensive report-outs on the testing are made public. Inclusion of standards and IGs in regulation, including as recommended use, should also not be considered a mark of maturity.

With a robust real-world testing infrastructure in place, there will be transparency concerning where each standard sits on the path to maturity. Working with the community, HHS could set criteria for when standards will be considered mature enough for regulatory inclusion and denote that those standards will be mandatory once they have achieved maturity through the real-world testing infrastructure. By giving the industry a clear signal of HHS' intent to mandate the use of a standard, industry stakeholders would have more time to adequately prepare for any future, required adoption of standards.

Thank you for the opportunity to provide comments on this proposed rule. The AAFP looks forward to engaging with CMS on how to advance interoperability in a manner that reduces administrative burden on family physicians and their practices while ensuring standards are proven to be effective and adoptable in all settings. Should you have any questions, please contact Meredith Yinger, Manager, Regulatory Affairs at myinger@aafp.org or (202) 235-5126.

Sincerely,

Sterling N. Ransone, Jr., MD, FAAFP
Board Chair, American Academy of Family Physicians