April 21, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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 Administrator Brooks-LaSure:

On behalf of our member medical group practices, the Medical Group Management Association (MGMA) thanks you for the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS') Notice of Proposed Rule Making on Administrative Simplification ("proposed rule"). These proposed changes are a critical first step in implementing long-needed updates to the Health Insurance Portability and Accountability Act (HIPAA) attachment standards and reducing significant administrative burden for medical groups.

With a membership of more than 60,000 medical practice administrators, executives, and leaders, MGMA represents more than 15,000 medical groups in which more than 350,000 physicians practice. These groups range from small private practices in rural areas to large regional and national health systems, and cover the full spectrum of physician specialties and organizational forms, making MGMA well-positioned to offer the following feedback.

Key Comments and Recommendations

- **Implement a prior authorization attachment standard that is integrated with the rest of CMS' proposed prior authorization changes.** It is imperative that all of CMS' attempts to implement electronic prior authorization standards work in harmony to fully realize the potential benefits of a functional system. Incumbent to reducing administrative burden in this area is establishing electronic attachment standards that match with CMS' attempt to implement a prior authorization requirements, document, and decision (PARDD) API. The PARDD API is a Fast Healthcare Interoperability Resources (FHIR) standard, while the proposed standards in this rule are X12. We recommend that CMS postpone establishing this attachment standard until it aligns with the rest of CMS' other prior authorization reforms.
- **Institute an improved process for establishing HIPAA transaction standards that emphasizes real-world testing.** CMS and the Office of the National Coordinator for Health Information Technology (ONC) should work together to revitalize their current procedures for establishing HIPAA standards. The current rulemaking process does not keep pace with the industry's technological advancements and results in uncertainty and redundant workflows.

MGMA recommends CMS work with stakeholders and ONC to ensure HIPAA standards are properly piloted and truly meet the needs of medical groups.

- **Finalize a claims attachment standard that is rigorously tested and cost-effective.** CMS should move forward with finalizing an attachment standard for claims. We urge CMS to adopt a version of X12 that is thoroughly tested and backed by the industry. CMS has proposed the adoption of X12 version 6020 while providers and the industry have been using X12 version 5010 for many HIPAA-mandated business transactions over the last ten years. Further, X12 is currently working on version 8030. MGMA urges CMS to strike a balance and adopt a version that will work for all types of medical groups to deliver administration simplification and cost savings.
- **Publish the operating rules concurrently**. To avoid unnecessarily delays, MGMA suggests CMS publish the operating rules simultaneously with the attachment standards once they are finalized and thoroughly tested.
- **Ensure "trading partner agreements" are not able to establish disparate attachment standards.** CMS must implement guardrails to prevent "trading partner agreements" from setting attachment standards between health plans and providers. Allowing this practice would penalize providers by potentially requiring the adoption of multiple information technology (IT) processes for the same administrative transaction. This would result in increased burden and cost, and work against achieving interoperability.
- **Enforcement and Education.** Establish an oversight plan for industry compliance and hold plans accountable for non-adoption of the final standards. Work to educate all types of medical groups to efficiently adopt the final standards with minimal complications.

Background on the development of attachment standards

Since 1996, CMS has been mandated under HIPAA to implement attachment standards. Previous attempts to develop and adopt administrative standards for electronic attachments — such as the proposed standards issued in 2005 along with a pilot program that were subsequently withdrawn by CMS — have been fraught with delays. Without the requisite standards promulgated by CMS, health plans, providers, and other entities have been slow to institute electronic procedures for sending attachments.

Transmitting healthcare attachments continues to be a primarily manual process with clinical documentation normally communicated via fax, mail, or uploaded to proprietary health plan websites. The Council for Affordable Healthcare's (CAQH's) 2022 index report found that electronic adoption of attachments remains the lowest in the medical industry at 24%.[1] Issues with submitting attachments plague many areas of practice management such as claims and prior authorization.

Close to 82% of MGMA members reported prior authorization as very or extremely burdensome, and their number one regulatory burden.[2] Manually processing prior authorization attachments often requires physician intervention thereby diverting critical resources away from delivering patient care. Further, 77% of practices had to hire or redistribute staff to work on prior authorizations due to increases in prior authorization requests.[3]

[1] Council for Affordable Healthcare, Inc., *2022 CAQH Index: A Decade of Progress*, 2023, https://www.caqh.org/sites/default/files/2022-caqh-index-report%20FINAL%20SPREAD%20VERSION.pdf
[2] MGMA, *Annual Regulatory Burden Report*, Oct. 2022, https://www.mgma.com/getmedia/4bfd2489-6099-49e5-837f-f787d6d0a30f/2022-MGMA-Regulatory-Burden-Report-FINAL.pdf.aspx?ext=.pdf.
[3] MGMA Prior Authorization Questionnaire, March 2023.

Similarly, manually processing claim attachments significantly delays claim payments and results in increased denials and write-offs. Since practices often do not know what a health plan requires to adjudicate a claim — as well as approve a prior authorization request — they may unintentionally send the wrong attachment or more information than necessary. Taken together, the effect of this laborious process hinders providers ability to deliver timely care — finalized electronic attachment standards would be a welcomed reprieve.

The establishment of transaction standards is necessary to facilitate the adoption of cost-effective, timesaving, and intuitive electronic attachment technology. MGMA has long advocated for electronic attachment standards; we have communicated to CMS individually and as part of a coalition of industry stakeholders over the last decade the importance of adhering to certain principles when rulemaking. Namely, the proposed attachment standards must:

- Be applicable to claims, prior authorization, referrals, and other administrative processes that directly relate to claims payments.
- Be defined and adopted for three types of transactions: query, response, and acknowledgement.
- Support both the submission of structured and unstructured data.
- Support both solicited and unsolicited attachments.
- Not allow data that is already part of the original transaction for which an attachment is being generated to be requested again by the health plan in an attachment.[4]

The benefits of instituting attachment standards in line with these principles would be manifold as it would: reduce staff time, paper, and postage costs; reduce unnecessary denials, appeals, and facilitate faster payment; reduce documentation requests from plans; and significantly reduce administrative burden. We hope that CMS will keep these principles in mind while reviewing our comments and when issuing the final rule.

Comments on Specific Regulatory Provisions

Expanded Definition of Health Care Claims Attachments

CMS proposes to change the HIPAA definition of attachments from "health claims attachments" (42 U.S.C §1329d-2(a)(2)(B)) to "health care attachments." The proposed rule states that "health care attachments" are meant to refer to attachments for both claims and prior authorization transaction requests instead of exclusively claims.

MGMA thanks CMS for expanding the definition of health care attachments under HIPAA. Further segmenting these processes and implementing different definitions would have added unnecessary confusion. The HIPAA statute contemplates encompassing additional business transactions aside from claims in the definition of attachments and gives the Department of Health and Human Services (HHS) discretion to adopt standards for "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."[5]

We encourage CMS to review and potentially add other administrative transactions that overlap, such as claim payment (or electronic funds transfer, EFT). Without a uniform definition allowing for closely

[4]Robert Tennant, *MGMA advocates for electronic attachments standards*, Aug. 31, 2017, https://www.mgma.com/resources/health-information-technology/mgma-advocates-for-electronic-attachments-standard.
[5] 42 U.S.C. §1320d-2(a)(1)(B).

related administrative transactions, there is room for inefficiencies when attachments are requested from providers outside of the two administrative transactions contemplated in this proposed rule. Standardizing as much as possible without impacting clinical care is vital to fulfilling the intention of administrative simplification, and that begins with consistent definitions to enable the adoption of functioning attachment standards.

Adoption of Electronic Health Care Attachments Transaction Standards

CMS plans to adopt standards for health plans requesting attachment information and providers transmitting attachments. The agency is not proposing to adopt attachment standards for all business needs due to challenges it sees with the range of standard specifications. For health plans requesting attachment information, CMS proposes the following transaction standards:

- Claim-related attachment requests – ASC X12N 277 Health Care Claim Request for Additional Information (006020X313)
- Non-claim-related attachment requests – ASC X12N 278 Health Care Service Request for Review and Response (006020X315)

For provider responses to health plan requests for attachment information (routing/envelope), CMS proposes the following transaction standards:

- X12N 275 – Additional Information to Support a Health Care Claim or Encounter (006020X314)
- X12N 275 – Additional Information to Support a Health Care Service Review (006020X316)

While the National Committee on Vital and Health Statistics (NCVHS) did not recommend specific versions of the X12 attachments standards in the 2016 letter cited by CMS, the agency proposed X12 Versions 6020 for these transaction standards. MGMA thanks the agency for attempting to establish standards. Our recommendations about the proposal are as follows:

- **Align all aspects of prior authorization standards before publication to avoid creating bifurcated and burdensome workflows.** We agree with CMS' underlining goal to automate the prior authorization process, but all aspects of the agency's proposed changes must be unified and streamlined to improve the current untenable situation. MGMA submitted extensive comments on the recent electronic prior authorization reforms CMS put forward in its notice of proposed rulemaking outlining changes to advance interoperability and improve prior authorization ("ePA rule").[6] In the ePA rule, CMS proposed policies instituting the PARDD API, a FHIR-based standard, to facilitate prior authorizations. While a much-welcomed reform effort, the PARDD API does not integrate well with the attachment standards in this proposed rule. Specifically, the ePA rule requires certain plans — Medicare Advantage, Medicaid, CHIP, Qualified Health Plans — to use FHIR that will have to map to the HIPAA-mandated X12 278 standard. This would establish an inefficient process that requires additional steps by plans and providers in converting to and from FHIR. Further, commercial plans would use the X12 278 standard under this rule as they are not subject to the ePA rule, further partitioning IT workflows. All of CMS' reform efforts should be aligned to avoid regulating into law two separate processes for the same prior authorization transaction before moving forward with a prior authorization attachment standard.

[6] MGMA comments on interoperability and prior authorization proposed rule, Mar. 13, 2023, https://www.mgma.com/advocacy/advocacy-statements-letters/advocacy-letters/march-13,-2023-mgma-comments-on-interoperability-a.

- **Improve the standards development process at CMS.** The rate of technological innovation, along with the industry's need for guidance and standards from CMS, necessitates the formation of an improved standards development program within the agency. We recommend CMS coordinate with ONC to install a more predictable process that is responsive to provider needs. These standards must be thoroughly tested by all manner of medical groups —from large health systems to rural independent practitioners — to ensure they promote interoperability. We urge CMS and ONC to modernize their procedures to utilize mature and helpful standards.[7]
- **Adopt an X12 version for claim attachments that has been thoroughly tested and is provider approved.** The proposed X12 277 and 275 standards for claims attachments are conducive to practice administrative workflows as there are successful examples of the standards facilitating transactions. It is critical that the final rule includes an extensively vetted, mature, and industry backed X12 version that works for providers. CMS has proposed X12 version 6020 while current HIPAA standards for other administrative transactions are version 5010, and X12 version 8020 is in the process of obtaining approval from NCVHS. Implementing the latest transaction standard that has not been fully tested could set an unworkable baseline that may not meet the needs of providers and plans alike. We recommend CMS move forward with a version that has been comprehensively tested and will allow true interoperability and full functionality for practices.
- **Ensure all phases of the claims and prior authorization process allow for attachments.** Standards must be implemented that cover all facets of prior authorization and claims so that providers do not face barriers to submitting attachments. CMS should reinforce that the appeals processes and closely related transactions like claim payment and electronic remittance advice are able to receive electronic attachments. Beyond these areas, there are opportunities for automated clinical data exchange using mature attachment standards in the future to improve care coordination and management, quality reporting, and alternative payment models.

Required Code Set (LOINC for HIPAA Attachments)

For providers and health plans to have a clear method of specifying attachment information, CMS has proposed numerous implementation specifications using the LOINC code set for HIPAA attachments. The proposed rule details the three purposes of the LONIC code set: to identify the kind of information that a health plan electronically requests from a provider and a provider transmits to a plan; to specify optional modifier variables for attachment information; and to identify specific HL7 Implementation Guide: LOINC Document Ontology document templates. CMS outlined flexible criteria for document templates to be used in attachments that allows for updates from HL7.

MGMA appreciates CMS including these provisions as it will allow providers to better identify clinical data needed by plans to adjudicate claims. In a presentation at a CMS stakeholder meeting in 2017, MGMA discussed developing standards for electronic attachments, and we recommended the LOINC code set.[8] We echo those recommendations here and support CMS implementing the LOINC code set for claims attachments as it is broadly used by practitioners to identify clinical observations in electronic health record systems. We emphasize the significance of medical groups' ability to use LONIC code sets

[7] *See* the Health IT End-Users Alliance consensus statement that reviews principles that would improve standards development, https://hitenduser.org/wp-content/uploads/2022/09/Real-world-testing-consensus-statement_FINAL.pdf.

[8] Robert Tennant, *Electronic Attachments: The Group Practice Perspective*, Presentation at CMS Stakeholder Meeting, July 18, 2017, https://www.mgma.com/MGMA/media/files/ga%20resources/MGMA-CMS-Attachments-Meeting.pdf.

in claim attachments when finalizing this rule. We recommend CMS work with stakeholders to implement a code set for prior authorization attachment transactions that works for providers and is compatible with the PARDD API.

Adoption of HL7 Implementation Guides for Attachment Information

CMS is proposing to adopt three HL7 implementation guides as HIPAA standards for the clinical information content included in the above X12 attachment transaction 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 20019 with Errata ("C-CDA 2.1") (this is a retired version as of March 2021, updated guide
- 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 ("C-CDA Volume Two")
- HL7 CDA R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1, March 2017 ("Attachment Implementation Guide")

MGMA appreciates CMS' concern regarding these HL7 guides being the only available SSO-created, NCVHS-recommended guides designed to support HIPAA transactions. In 2017, we endorsed the C-CDA 2.1 and HL7 CDA R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents.[9] Our underlying rationale remains true behind recommending these two implementation guides as C-CDA is widely used by practices tor format information and share between practices and clinical systems.

There have been myriad developments in the HL7 implementation guides as the C-CDA 2.1 was retired in 2021 and updated last year. We urge CMS to review the new C-CDA guides and work with stakeholders to determine whether it is more appropriate to use them for claims attachments. These implementation guides must be piloted in the real-world by providers and the industry before ultimate adoption.

If CMS moves forward with a FHIR standard for prior authorization requirements as discussed in the ePA rule, MGMA urges the agency to adopt implementation guides for attachments that are compatible with FHIR. Currently, FHIR uses a separate system of questionnaires while C-CDA uses a clinical document template. It is our understanding that the technology is not presently available to seamlessly convert a FHIR questionnaire to a C-CDA template. CMS needs to resolve this misalignment to prevent an unnecessary duplication of procedures.

Compliance Timeline and Cost

MGMA understands that the Affordable Care Act prescribes 24 months from the publication of the final rule until the initial compliance date. MGMA hopes that CMS will expediate the publication of electronic attachment standards for claims and prior authorizations that are robustly tested and ready to be adopted with minimal complications. We reiterate that while the publication of standards is overdue, CMS should not issue prior authorization attachment standards that conflict with the other ePA rulemaking. It is crucial that the compliance timeline for both claims and prior authorization attachments is appropriate to avoid

[9] *Id.*

unintended consequences medical groups have seen in the past with the adoption of HIPAA-mandated standards.[10]

CMS cites CAQH's 2019 report that states a fully electronic system for prior authorization attachments could result in $454 million in annual savings, with $373 million in savings for full adoption of electronic attachments for claims. To truly realize these savings and reduce burden, mandating redundant workflows must be avoided, and attachments must be easily transmitted throughout all aspects of the claims and prior authorization processes. Seventy-four percent of medical groups reported their health IT compliance expense increased in the past year.[11] Medical groups must train staff to use the new systems, install new workflows and technology, and pay vendor monthly costs. We caution CMS to be mindful of the full breadth of practice sizes and varying levels of resources available. MGMA emphasizes the need to mitigate undue costs when developing standards — without a holistic approach to promoting interoperability, these projected cost savings will remain unrealized.

Proposed Electronic Signature Standard

Initially, CMS proposed to adopt the HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1 (Digital Signatures Guide). This was conveyed in the original proposed rule's preamble but was left out of the regulatory text. CMS issued a correction and extended the deadline to comment another 30 days. MGMA appreciates the agency addressing this discrepancy within the proposed rule and adding time to allow the public to review its proposed changes.

MGMA agrees with the rationale of setting electronic signature standards to include the ability the authenticate the person attesting to the data that is being transmitted, ensuring the message integrity, and guaranteeing non-repudiation. We support adoption of the HL7 Guide for digital signatures for claims attachments, but urge CMS to ensure that digital signatures remain permanent and do not disappear after initial entry to avoid duplicative work should a question arise later in the claims process.

The electronic signature implementation guide ultimately adopted should be compatible with the FHIR-based PARDD API CMS has put forward in the ePA rule. Again, alignment across all aspects of the prior authorization process is needed for a functioning system.

Additional Recommendations

In the final rule adopted by CMS, MGMA recommends the inclusion of the following policies to promote more equitable electronic attachment standards, help expediate the establishment of workable final standards, and help alleviate administrative burden:

- **Simultaneously publish the operating rules associated with these standards.** MGMA recommends the adoption of the electronic attachment standards simultaneously with their supporting operating rules. Publishing the operating rules potentially a few years after the standard — as was the case for other transactions like electronic remittance advice — would further impede adoption by the industry. There are many benefits of concurrent adoption, such as improving efficiency and providing clarity to how the standards will work in practice. CMS

[10] Dan Bowman, *MGMA calls on HHS to issue HIPAA contingency plan*, Fierce Healthcare, Oct. 25, 2011, https://www.fiercehealthcare.com/it/mgma-calls-hhs-to-issue-hipaa-5010-contingency-plan.
[11] MGMA Stat Poll, Mar. 14, 2023, https://www.mgma.com/data/data-stories/medical-groups-report-significant-health-it-expens#:~:text=MGMA%20Staff%20Members&text=Today%2C%20that%20same%20conversion%20factor,Cost%20and%20Revenue%20survey%20report.

discussed possibly adopting CAQH CORE operating rules in the proposed rule should NCVHS recommend them. MGMA supports the adoption of operating rules that have been tested in real-world workflows and are viable for all types of medical practices.

- **Prohibit "trading partner agreements" from setting the attachment standards.** MGMA urges CMS to include language prohibiting "trading partner agreements" from setting attachment standards. Providers would be penalized if health plans are able to set different standards due to disparities in negotiating power. Implementing multiple IT workflows for differing health plan requirements will compound the current administrative costs and lost staff time. CMS must set a national standard that is adhered to by all health plans, providers, and other entities to truly promote interoperability.
- **Enforcement and education.** MGMA applauds CMS for undertaking numerous modernizing rulemaking efforts that, if implemented correctly, could greatly reduce administrative burden for medical groups and ultimately improve patient care. MGMA surveyed over 600 members in 2023 and found that 97.39% of members saw patients experience delays or denials for medical necessary care due to prior authorization requirements.[12] We urge CMS to monitor adoption and establish an oversight plan for both this proposed rule and the ePA rule, given their intersecting aims. The agency must ensure health plans are complying with the proposed attachment standards once finalized and the responsibility for enforcement should not fall solely on providers to raise issues of non-adoption. We hope CMS will undertake education efforts for medical groups as well once these standards are finalized as it will help increase adoption.

Conclusion

MGMA thanks CMS for proposing to establish standards for the electronic transmission of attachments. Many of the policies put forth in the proposed rule will advance interoperability, reduce administrative burden, and result in savings for both health plans and providers. We appreciate the opportunity to offer feedback and hope CMS will consider our comments when promulgating a final rule. MGMA remains committed to promoting administrative simplification and supporting the ability of our members to provide high-quality, timely care to patients across the country. Should you have any questions, please contact James Haynes at jhaynes@mgma.org or 202-293-3450.

Sincerely,

/s/

Anders Gilberg

Senior Vice President, Government Affairs

[12] MGMA Prior Authorization Questionnaire, March 2023.