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March 21, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code 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 the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the Notice of Proposed Rule Making (NPRM) proposing adoption of electronic transaction standards for health care attachments published in the Federal Register on December 21, 2022 (87 Fed. Reg. 78438). We commend CMS' strong commitment to reducing administrative burdens for physician practices and ensuring patients' timely access to care through automation of clinical data exchange. **Moreover, the AMA applauds CMS for acknowledging our concerns, as well as those of our patients, by addressing prior authorization (PA) reform in this and two other recent NPRMs, as fixing PA constitutes a key pillar in the AMA's Recovery Plan for America's Physicians.**[1]

While we appreciate the underlying intent of the proposals, we urge CMS to postpone adoption of any standards for PA attachments. As discussed in more detail below, we believe that recent technology and regulatory developments have significantly altered the electronic PA (ePA) transaction landscape, and we recommend further study prior to adoption of attachment standards for this purpose. However, we argue that claim attachments represent a separate and distinct use case that is ripe for automation via the proposed standards. **As such, we recommend that CMS finalize its proposals related to claim attachment standards as written to reduce administrative burdens and costs across the health care industry.**

PA Attachments Use Case

Current PA Landscape

The AMA recently released data from a 2022 survey of 1,001 practicing physicians detailing PA's negative impact on both patient care and practices.[2] An overwhelming majority (94 percent) of surveyed

[1] See https://www.ama-assn.org/amaone/ama-recovery-plan-america-s-physicians.
[2] 2022 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

physicians reported that PA delays necessary care, with 80 percent saying that PA can lead to patients abandoning treatment. The downstream effects are devastating: 89 percent of physicians reported that PA negatively impacts clinical outcomes, with one-third (33 percent) indicating that PA has led to a serious adverse event (e.g., hospitalization, permanent impairment, or even death) for a patient in their care. Beyond PA's alarming human costs, the survey captures the administrative burdens associated with the process: practices reported completing an average of 45 PAs per physician, per week, with this weekly workload for a single physician consuming nearly two business days (14 hours) of physician and staff time.

Holistic Approach to PA Reform

With mounting concerns regarding the impact of PA on timely, efficient care delivery, many stakeholders have called for PA reform. In 2017, the AMA, along with a coalition of organizations representing physicians, medical groups, hospitals, pharmacists, and patients, released the Prior Authorization and Utilization Management Reform Principles,[3] which outlined critical improvements needed to protect patients' access to necessary treatment. These principles spurred an industry dialog that culminated in the January 2018 publication of the Consensus Statement on Improving the Prior Authorization Process.[4] Notably, the Consensus Statement represented agreement between health care professional organizations and insurer trade associations on the need for PA reform. Unfortunately, subsequent AMA physician survey data illustrate that health plans' progress in voluntarily making the agreed-upon changes has been disappointingly slow.[5] This lack of forward momentum on PA reform underscores the necessity and timeliness of CMS' regulatory action.

The AMA consistently advocates for a holistic, cross-program approach to PA reform. While we fully support automation of the PA process, as considered in this NPRM, **any successful solution must address both the PA process and underlying decision-making.** Indeed, without addressing the underlying clinical criteria and PA program policies, even the most streamlined ePA system will fail both patients and physicians and simply deliver a faster inappropriate denial. **We therefore applaud CMS' wide-ranging approach to PA-related policy changes proposed in a "package" of recent rulemaking.** We urge CMS to finalize the critical policy reforms that will ensure the clinical validity of PA programs and protections for continuity of care proposed in the CY 2024 Part C and Part D NPRM, as detailed in both the sign-on letter of support signed by the AMA and 119 state medical associations and national medical specialty societies,[6] as well as the AMA's individual comments.[7] We also request CMS follow our recommendations in finalizing the CMS PA Interoperability NPRM's provisions related to

[3] Prior Authorization and Utilization Management Reform Principles. Available at: https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf.
[4] Consensus Statement on Improving the Prior Authorization Process. Available at: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.
[5] 2021 update: Measuring Progress in Improving Prior Authorization. Available at: https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf.
[6] February 13, 2023, sign-on letter to CMS Administrator. Available at: https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2FPA-sign-on-letter-Part-C-and-D-rule.zip%2FPA-sign-on-letter-Part-C-and-D-rule.pdf.
[7] February 13, 2023, AMA comment letter to CMS Administrator. Available at: https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2Flfr.zip%2F2023-2-13-Letter-to-Brooks-LaSure-re-CY-2024-Medicare-Advantage-v3.pdf.

ePA technology standards, as well as PA processing timelines, public reporting of PA metrics, and provision of decision rationale.[8]

Historical Perspective vs. Recent Developments Related to PA Attachments

The AMA notes our long-standing advocacy supporting adoption of electronic attachment standards to automate the exchange of supporting clinical information for PA processing. The lack of a uniform method to electronically exchange clinical data to meet health plans' documentation requirements has been a rate-limiting barrier to PA automation for decades. Many stakeholders have agreed on this point, and the previously referenced 2018 Consensus Statement specifically calls for "adoption of national standards for the electronic exchange of clinical documents (i.e., electronic attachment standards) to reduce administrative burdens associated with [PA]."[9] Furthermore, as noted in the NPRM, CMS proposes to adopt electronic standards for attachments that align with recommendations made by the National Committee on Vital and Health Statistics (NCVHS) in 2016.[10]

However, we note that there have been significant developments in both the technology and regulatory spaces since the 2016 NCVHS recommendations. First, major efforts are underway to automate PA-related data exchange leveraging Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) implementation guides. Secondly, and even more importantly, the recent CMS PA Interoperability NPRM would require Medicare Advantage, state Medicaid agencies and Medicaid managed care plans, Children's Health Insurance Program (CHIP) agencies and CHIP managed care entities, and issuers of Qualified Health Plans on the Federally-Facilitated Exchanges to offer Prior Authorization Requirements, Documentation, and Decision (PARDD) application programing interfaces (APIs) to support PA information exchange.[11] That NPRM recommends that impacted plans utilize three HL7 FHIR implementation guides when developing their PARDD APIs for provider-payer PA information exchange.

The AMA harbors significant concerns that the CMS PA Interoperability NPRM and the provisions of the current NPRM related to PA attachments would establish two different sets of standards and corresponding workflows to complete the PA process, depending on the type of health plan. We believe that there are at least two clear cases of contradictory workflows outlined in the different NPRMs:

- The CMS PA Interoperability NPRM would require impacted health plans to inform physicians of the specific clinical documentation needed to fulfill PA requirements via the PARDD API, for which CMS recommends use of the FHIR Documentation Templates and Rules implementation guide. However, under the attachments NPRM, health plans would be required to send Logical

[8] March 13, 2023, AMA comment letter to CMS Administrator. Available at: https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2FLetter.zip%2F2023-3-13-Letter-to-Brooks-LaSure-re-CMS-Interop-and-Prior-Authorization-Proposed-Regulation-v4.pdf.

[9] Consensus Statement on Improving the Prior Authorization Process. Available at: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.

[10] NCVHS letter to the HHS Secretary. Available at: https://ncvhs.hhs.gov/wp-content/uploads/2018/03/2016-Ltr-Attachments-July-1-Final-Chair-CLEAN-for-Submission-Publication.pdf.

[11] Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule CMS-0057-P. See: https://www.federalregister.gov/documents/2022/12/13/2022-26479/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability.

Observation Identifiers Names and Codes (LOINC) in an X12 278 version 6020 response indicating the specific clinical document template the physician needs to submit.

- Using the CMS PA Interoperability NPRM's proposed technology requirements, physicians would send FHIR "bundles," including completed FHIR clinical questionnaires populated with data from the electronic health record (EHR), to health plans via the PARDD API to provide supporting clinical data. In contrast, the attachments NPRM would adopt HL7 Consolidated Clinical Data Architecture (C-CDA) implementation guides as the standard for clinical data exchange. HL7 FHIR technical experts have indicated that there is currently no way to convert a completed FHIR questionnaire into a C-CDA, underscoring the lack of alignment between the two NPRMs.

Beyond these contradictions, we have heard suggestions that physicians could be required to utilize both FHIR APIs *and* the PA attachment standards to complete a *single PA*—first completing a FHIR questionnaire and then supplying a C-CDA to send additional clinical data. If true, this would represent a wildly complex and cumbersome process that counters the basic goals of administrative simplification.

Due to the apparent misalignment between NPRMs and widespread industry confusion, we strongly caution CMS against proceeding with the PA attachments provisions of the current NPRM, as this would set the stage for multiple ePA standards and workflows based on payer type and lead to an untenable, fragmented approach to PA automation. Rather than the intended reduction in physician practice burdens, a regulatory system establishing two different sets of standards and respective workflows for ePA would *increase* administrative hassles and costs. As detailed in 2022 correspondence to both the Secretary[12] and NCVHS,[13] the AMA strongly objects to the concurrent use of multiple standards for the same business function. We believe that such a scenario would abandon the basic tenets underlying Health Insurance Portability and Accountability Act (HIPAA) administrative simplification—namely, that physicians and other providers should be able to interact with all health plans using the same transaction standard and enjoy the cost savings and improved efficiency resulting from this uniformity. **We stress that a future in which physician practices would have to support multiple ePA standards across health plans is simply an untenable financial proposition, particularly for small, solo, and rural clinics, which often serve marginalized and minoritized communities.**

For these reasons, the AMA urges CMS to postpone adoption of electronic PA attachment standards until all discrepancies between the relevant NPRMs can be fully resolved. **In addition, the AMA recommends that CMS leverage a regulatory pathway that will apply to all health plans when mandating PA-related implementation guides and transaction standards in any future rulemaking to avoid potential conflicts and confusion.** As highlighted in our comments on the PA Interoperability NPRM, any mandated ePA standards should be thoroughly tested in real-world settings, and of sufficient value to physician practices of all sizes, prior to any CMS mandates.

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[12] October 26, 2022, AMA letter to the HHS Secretary. Available at: https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2Flfdr.zip%2F2022-10-26-Letter-to-Becerra-re-NCVHS-Recommendations-v2%255B57%255D.pdf.

[13] December 15, 2022, AMA letter to NCVHS. Available at: https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2Fltrfdr.zip%2F2022-12-15-Letter-to-Monson-re-NCVHS-X12-and-CORE-RFC-Comments-v2.pdf.

Additional PA Attachment Technology Concerns

Beyond this critical concern regarding multiple ePA standards, we also question the specific standards being proposed for PA attachments. Under the provisions of this rule, physicians would be required to use, and health plans to accept, HL7 C-CDA templates to support PA requests. However, we are not aware of any health plans that have mapped their clinical criteria to C-CDA templates to ensure that all the data needed to make PA decisions are included in these documents. **Without real-world testing, we cannot presume that an ePA paradigm reliant on C-CDA templates will meet health plans' needs and solve our collective PA technology problem.** This is a critical issue, as state laws requiring use of standardized PA template forms have yielded disappointing results: such general, non-service-specific forms often do not capture the detailed questions or information needed by a health plan to approve a particular item or service, leading to follow-up requests and increased PA burdens—the exact opposite of the desired outcome. In addition, discussions during standards development organization meetings suggest that payers use a data-element approach (vs. clinical documents, e.g., operation report, visit summary, etc.) for PA processing. As such, FHIR questionnaires may represent a more efficient method to request and capture PA information. An additional benefit of a data-element vs. document-based approach is that populated FHIR questionnaires should be machine readable, thus enabling faster PA processing and minimizing patient care delays.

In addition, we do not believe it is appropriate to adopt the X12 278 version 6020 (vs. the current version 5010), as proposed in this rule. Through the AMA's active participation in the relevant X12 workgroup, we understand that version 6020 offers no additional functionality. Moreover, the X12 278 version 6020 is untested and may contain errors. We conclude that adoption of the 6020 version would increase costs for physician practices with no compensatory benefit. For this reason, should CMS choose to proceed with adoption of PA attachment standards, we recommend maintaining X12 278 version 5010 (vs. 6020).

Claim Attachments Use Case

In contrast to PA attachment standards, the AMA urges CMS to promptly finalize requirements regarding electronic standards for claim attachments. As the AMA and many other stakeholders have noted over the years, physician practices must rely on highly manual, cumbersome, and costly methods to submit clinical documentation supporting claim payment to health plans. In a striking recent example, a major national health plan will soon require practices to submit supporting documentation for all claims including a certain CPT modifier via a *dedicated fax line or email address*. Putting aside the highly problematic nature of this policy, the fact that physicians are being instructed to exit their EHR workflow and *fax or use a one-off email address* to send clinical documents in our digital age is shocking. Such antiquated processes not only burden physicians and their staff, but they challenge health plans with claim-to-attachment reassociation problems—not to mention the risk unintended exposure of protected health information. We believe adoption of electronic attachment standards for claims will significantly reduce administrative costs across the health care industry and recommend that CMS proceed accordingly with finalizing the proposed claim attachment standards.

Successful voluntary implementations of electronic claim attachments further strengthen the case for immediate standards adoption. In a well-publicized example, National Government Services (NGS) has successfully implemented the electronic attachment standards proposed in the NPRM with over 1,600 provider partners.[14] NGS' experience illustrates that the proposed attachment standards can perform

[14] "NGS Electronic Attachment Program" presentation by Mary Lynn Bushman, Senior Business Analyst, National Government Services, at WEDI National Conference, October 19, 2021.

technically, as well as achieve significant efficiencies for both health plans and providers: NGS has observed an 80 percent reduction in medical review denials and appeals associated with missing documentation. In addition, NGS' time to payment has decreased from an average of 35 days to an average of 17 days following implementation of claim attachment electronic standards. **This real-world implementation success and return-on-investment makes a strong case for adoption of claim attachment standards.** These data also confirm that clinical documents (vs. granular data elements) are sufficient to meet health plans' requirements for claim processing, further bolstering the case for adoption of the proposed attachment standards.

The Council for Affordable Quality Healthcare Committee on Operating Rules for Information Exchange (CAQH CORE) has recommended adoption of operating rules for attachment standards to NCVHS.[15] The AMA believes that operating rules significantly increase the value of electronic transaction standards by supporting consistent implementation and maximizing the promise of HIPAA administrative simplification. As stated in our December 2022 letter to NCVHS, the AMA supports concurrent adoption of electronic transaction standards for claim attachments and associated operating rules.[16] The health care industry has waited for many years for claim attachment standards to address the inefficiencies and administrative costs detailed above. **We therefore urge CMS to concurrently adopt claim attachment standards and CAQH CORE's associated operating rules to avoid further implementation delays and ensure conformant, consistent implementation.**

We support CMS proceeding with a 24-month implementation timeframe for electronic standards for claim attachments and associated operating rules. We believe this allows all stakeholders ample time to prepare for this change without further delaying access to this critical burden-reducing technology. As previously mentioned, current voluntary use of the attachment standards described in the NPRM should ease implementation and ensure the feasibility of a 24-month transition period. Finally, we note that limiting the scope to just claim attachments as we recommend should ensure that the industry can meet the 24-month development timeframe.

Standard for Electronic Signatures

The AMA appreciates that CMS is not proposing to establish requirements for when or by whom an electronic document must be signed. We also agree that it is appropriate to limit the required use of electronic signatures to adopted electronic attachment standard transactions. **As such, we support the adoption of the Digital Signatures Guide as the electronic signature standard for use in health care claim attachment standard transactions, as we believe this will ensure the authentication, message integrity, and nonrepudiation of electronic signatures for claim attachments, as CMS described by CMS in the NPRM.**

Conclusion

We reiterate our sincere gratitude to CMS for addressing the serious challenges that PA poses to our member physicians and their patients. We appreciate CMS' prioritization of reducing administrative burdens for clinicians and the Administration's focus on addressing burnout in the medical profession.

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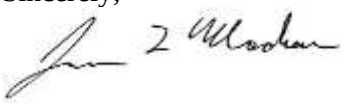
[15] CAQH CORE letter to NCVHS. Available at: https://ncvhs.hhs.gov/wp-content/uploads/2022/09/CAQH-CORE-Board-Letter-to-NCVHS-re-New-Updated-OR-052322-508.pdf\.

[16] December 25, 2022, AMA letter to NCVHS. Available at: https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2Fltrfdr.zip%2F2022-12-15-Letter-to-Monson-re-NCVHS-X12-and-CORE-RFC-Comments-v2.pdf.

The AMA welcomes the opportunity to discuss our comments on this and other PA-related NPRMs with CMS and looks forward to our continued partnership to improve PA programs to ensure patients' access to timely care. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



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