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November 22, 2016

The Honorable Sylvia Burwell
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

RE: Electronic Attachment Standard

Dear Secretary Burwell:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to submit the following comments in response to the recent National Committee on Vital and Health Statistics (NCVHS) letter “Recommendations for the Electronic Health Care Attachment Standard,” in which the NCVHS outlines the need for adoption of an electronic attachment standard under the Health Insurance Portability and Affordability Act (HIPAA) administrative simplification provisions. We applaud the NCVHS for soliciting industry feedback and for providing thoughtful recommendations on this challenging and important topic.

As detailed in the NCVHS letter, current attachment processes delay claim adjudication by an average of 25–30 days. Accordingly, physicians are eager for an electronic attachment standard, as it would foster more timely payment for rendered services. However, the advantages of an electronic attachment standard are not limited to physicians. All industry stakeholders and patients would benefit from a standard electronic method to exchange clinical data. The current process of sending supporting documentation by fax or mail is costly and burdensome to both the sender and recipient. Physician practices waste valuable dollars on postage and manual paper processing, while health plans bear the costs and inefficiencies of mailroom handling. The creation of an electronic attachment standard is extremely important in addressing these industry challenges and reducing administrative waste, and we commend the NCVHS for recommending timely action on this matter. The AMA sees a particularly urgent need for an electronic attachment standard due to its connection to prior authorization automation. The ability to electronically submit supporting clinical documentation using a standard format across health plans is a necessary and indeed critical component of an end-to-end automated prior authorization process.

In addition, we agree with the NCVHS recommendation that the attachment standard be released as a Notice of Proposed Rule Making (NPRM) rather than an Interim Final Rule, as significant stakeholder input and feedback will be essential to ensure that the mandated standard meets the needs of users and is widely adopted. As noted by the NCVHS, considerable time has elapsed since the previous NPRM on

attachments, and the industry should be allowed another opportunity to comment based on current technology and workflows.

As expressed in the NCVHS letter, the adoption of one standard definition of “attachment” under HIPAA is an essential step to achieving administrative simplification. To create a practical and impactful attachment standard for the industry, however, the U.S. Department of Health and Human Services (HHS) needs to provide more specificity regarding the scope of the attachment standard than what is offered in the NCVHS recommendations. **We encourage HHS to mirror its 2005 NPRM in delineating the application of the attachment standard. The 2005 NRPM recommended that the attachment standard be applicable to any processes used directly in the claims payment process**, such as when clinical information is needed to make a determination of benefits or to establish medical necessity. Other clinical information requests were ruled out of scope for the attachment standard: “Although additional clinical or administrative information may be required following adjudication of claims . . . we do not consider these post-adjudication requests for claims-related data to be part of the claims payment process. Therefore, post-adjudication processes are not covered by this proposal.”¹ We believe that this definition supports a clear application of the attachment standard and reflects a scope of work that can be realistically implemented by physicians and other stakeholders. Broad physician adoption will be critical in achieving the administrative simplification goals of the new attachment standard.

Our primary concern with the NCVHS recommendations is the allowance of multiple formats for both the clinical information and the transport mechanism to be used for electronic attachments. Although presented as a way of promoting flexibility in the standard, **the creation of multiple formats presents the potential for significant physician burdens and thus limits the ability to achieve the administrative simplification goals of the HIPAA legislation.**

Attachments and Administrative Simplification

Congress enacted the HIPAA administrative simplification provisions to enable physicians and other providers “to submit the same transaction to any health plan in the United States” electronically.² In support of this principle, HHS has mandated current HIPAA standards to streamline the process for electronically completing health care transactions. These standardized transactions promote efficiency in the industry by eliminating the need for physicians to reformat transactions to meet idiosyncratic health plan requirements.

In formulating its recommendations regarding an attachment standard, the NCVHS considered *consistency* (the ability to be implemented in the same manner across all health care entities) and *ambiguity* (differences in interpretation and in implementation). The concept of *flexibility* was also evaluated, and was defined as the ability to be adaptable and “allow for interim updates” (as opposed to permitting various methods of transmitting the same data). We strongly agree with this approach, as a standard that enhances consistency and reduces ambiguity, will better meet the overall goal of administrative simplification. Following this logic, the NCVHS advocates against the creation of multiple ways to exchange the same information through Recommendation 16, which asks HHS to

¹ 70 Fed. Reg. 55989 (Sept. 23, 2005). Available at <https://www.federalregister.gov/documents/2005/09/23/05-18927/hipaa-administrative-simplification-standards-for-electronic-health-care-claims-attachments>.

² HHS Frequently Asked Questions about Electronic Transaction Standards Adopted Under HIPAA. Available at <https://aspe.hhs.gov/report/frequently-asked-questions-about-electronic-transaction-standards-adopted-under-hipaa>.

“ensure that providers, payers and other industry stakeholders are not obligated to establish and maintain different standards-based infrastructures for different programs that require the exchange of similar data.”
We agree that stakeholders should not be forced to support multiple ways of electronically transmitting the same information. We therefore encourage HHS to mandate a single format for clinical information and a single enveloping method in the attachment standard so that physicians are not required to accommodate the unique specifications of each particular health plan with which they do business.

Attachment Formatting

In order to standardize the exchange of clinical information for administrative purposes, an attachment solution must establish formats for both the transport of the clinical document (often called the “envelope”) and the clinical information itself. The Accredited Standards Committee X12 (ASC X12) has established and recommends usage of the 275 transaction as the standard administrative “envelope” format for electronic attachments. Additionally, Health Level Seven (HL7), the standards designation organization for electronic clinical data, has created the Consolidated Clinical Document Architecture Release 2.1 (C-CDA R2.1). Physicians routinely use the C-CDA R2.1 today to format patient care information to send to other provider clinical systems. Recently, HL7 also created the Clinical Documents for Payers – Set 1 (CDP1), which represents another format for clinical documentation.

Clinical Document Formatting:

Although the NCVHS recommends the C-CDA R2.1 as the clinical formatting standard, it also recommends that CDP1 be adopted as an additional, acceptable standard. We believe that allowing multiple ways of formatting clinical information under the adopted attachment standard could obligate physicians to use different processes and workflows for creating and exchanging the same clinical data. With physician systems and workflows already utilizing C-CDA R2.1, supporting the additional CDP1 standard for health plans requiring this format would create additional burdensome steps in the practice workflow. **For these reasons, we recommend that HHS mandate the C-CDA R2.1 as the single standard for formatting clinical information for electronic attachments.**

Document Transport (Enveloping):

The NCVHS recommends that the ASC X12 275 be mandated as the standard enveloping mechanism to transport clinical information from providers to health plans. We fully support this recommendation; however, we are concerned that the NCVHS also suggests that HHS “allow for alternative recognized standard envelope and transport options to transmit attachments to accommodate existing and future transport technologies.” This language creates the potential for significant administrative burden for physicians, who interact with multiple health plans and would need to support numerous enveloping options and track each plan’s required format. **As a result, we recommend that HHS establish the ASC X12 275 as the only enveloping standard for electronic attachments.**

Conclusion

We appreciate the NCVHS’s investment of time and resources in formulating its recommendations related to an electronic attachment standard, and we join the NCHVS in urging HHS to promptly address this significant industry need. While we agree with many of the NCVHS recommendations, we firmly

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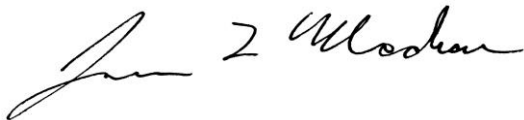
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believe that an electronic attachment standard that allows multiple ways of formatting and transporting clinical information fails to accomplish the legislative objectives of HIPAA and is effectively not a standard. To promote efficiency and meet the goals of the legislation, the industry needs a single, uniform, defined way of formatting and enveloping clinical information to be exchanged between physicians and other practices/providers or health plans. We urge HHS to release an NPRM that adheres to these concepts in order to achieve administrative simplification throughout the health care industry.

Thank you for the opportunity to comment on the electronic attachment standard. Should you have any questions or wish to discuss any of these issues, please contact Laura Hoffman, Assistant Director of Federal Affairs, at laura.hoffman@ama-assn.org or 202-789-7414.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD

cc: Shana Olshan