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Advancing Health in America

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March 21, 2023

Mary Greene, M.D.
Director of the Office of Burden Reduction & Health Informatics
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

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

Dear Dr. Greene:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations and our clinician partners — including more than 270,000 affiliated physicians, two million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the proposed Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard.

The AHA is appreciative of the Department of Health and Human Services (HHS) issuing a rule to standardize the attachments processes, the lack of which has been a significant source of administrative complexity and burden for hospitals and other providers. We believe that standardization of the transmission of clinical data to support claims and prior authorizations could greatly reduce the proliferation of inefficient manual processes used today and eliminate unnecessary processing delays.

Specifically, the AHA is largely supportive of the proposal to standardize claims attachments under the Health Insurance Portability and Accountability Act (HIPAA). This standard has the potential to improve the timeliness of patient billing, as well as provider cash flow, by reducing processing times between when a claim is submitted and a health insurer issues payment. At a time when several of the nation's largest health insurers are billions of dollars behind on payments to hospitals and providers, and hospitals' finances are in a precarious state, cutting down on processing times could help alleviate some of the financial strain that many of our members are facing.

The AHA recommends adoption of the proposed standard for claims attachments to help improve claims processing and eliminate unnecessary burdens on providers.

The AHA remains extremely supportive of a standardized approach to processing prior authorizations among health plans. As we have stressed previously, inefficient prior authorization processing creates delays in patient care, increases administrative waste and contributes to clinician burnout. However, the AHA believes that the specific standard proposed for prior authorization attachments is inconsistent with the recently released Centers for Medicare & Medicaid Services (CMS) standard for prior authorizations. Therefore, we are concerned that the lack of harmonization between the regulations could limit the intended improvements for which each rule was designed. **As a result, the AHA recommends that HHS refrain from proceeding with the proposed prior authorization implementation standard and instead pursue naming the technology established under the CMS proposed rule as the HIPAA standard for submission of clinical information for prior authorizations.**

Our detailed comments follow.

Bifurcate Consideration of Claims Attachment and Prior Authorization Attachment

The AHA appreciates the inclusive approach to standardization taken by HHS in this rule, as we believe the submission of clinical data to support both claims and prior authorization processes are desperately needed. However, given concerns with the specific technology named for prior authorization (discussed below), we encourage HHS to bifurcate consideration of these two components of the rule, thereby permitting standardization of a claims attachment only, notwithstanding the need for further consideration of the prior authorization requirements. Such split consideration would be consistent with section 1173(a)(1)(A) of the Social Security Act (SSA), which specifically calls for the establishment of a claims attachment standard but does not comment on the need for prior authorization attachments. Instead, the agency is creating the prior authorization process in accordance with section 1173(a)(1)(B) of the SSA, which calls on the secretary to name “other appropriate financial and administrative transactions, consistent with the goals of improving the operation of the health care system and reducing administrative costs.” As this section indicates, the HIPAA regulations view the claims and attachment standards separately, which should enable analysis of and action on each of the standards to be undertaken independently.

Additionally, the claims process occurs after care has been delivered, often completed by billing staff through consultation with the provider’s notes. Alternatively, prior authorization occurs in advance of care, frequently requiring involvement by physicians and other clinical staff. As a result, the claims and prior authorization processes occur at different points and already involve different workflows, thereby minimizing the need for the processes to mirror one another or for a standard to be adopted in tandem.

Benefits of Claims Attachment Standard

HHS recognized the need for claims attachments standardization since the creation of the initial HIPAA regulations in 2000. This standardization remains of critical importance, in particular given the increasingly complex benefit structures of health plans that require substantial information to supplement claims for adjudication. In instances where plans pend claims submissions that are not considered "clean," provider payments are often delayed by weeks or months as plans request and providers submit additional information necessary for adjudication in nonstandard ways. Creating a consistent method for a plan to request the specific documentation necessary to achieve a "clean" claim would exponentially reduce the burden of these processes, thereby enabling plans to issue payments to providers much sooner. This would help not only alleviate some financial stress by improving time-to-payment, but also would prevent delayed bills for patients.

HL7 Support for Clinical Document Architecture (CDA) Transactions

The AHA supports utilizing the HL7 CDA standard and Consolidated Clinical Document Architecture (C-CDA) implementation guide format for sharing clinical information via claims attachments. The process leverages the existing electronic health record (EHR) document structure and supports the most common document structures to ensure that necessary information can be transmitted. We note, however, that HL7 is no longer developing any new functionality nor issuing new implementation guides in this space. Although we do not anticipate the need for additional standards using this structure, we expect the inevitable need for upkeep and further refinement of this proposed standard as it is implemented by the industry. Given HL7's focus on the FHIR transactions, we urge HHS to ensure that HL7 will continue to support and develop the guides named in this standard as is warranted, regardless of their alternative work in the FHIR space.

X12N 6020 Versions

The proposed rule recommends standardization of the 6020 versions of the X12N 275—Additional Information to Support a Health Care Claim or Encounter Version and X12N 277—Health Care Claim Request for Additional Information to facilitate the request for and transmission of claims attachment information. The AHA recognizes that the X12N 6020 275 transaction includes the Binary Data Segment necessary for transmitting properly encoded clinical data, which was not part of the 5010 transaction. Additionally, we appreciate the that 6020 versions for claims attachment transmission have been tested and implemented in real-world settings, which provides a degree of reliability needed for provider implementation of new technologies.[1]

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[1] https://www.ngsmedicare.com/documents/20124/121705/2294_0521_06_Elec_Att_AB_508.pdf/34c682e0-80ca-1c3d-40b6-d20dc3f9285b?t=1619062389874

We are, however, concerned about the potential of establishing a standard that may be updated prior to or shortly after the standard is adopted. X12N has already created new versions (X12N 8020) of the 275 and 277 transactions, which they could presumably recommend for implementation in the short term. In order to ensure that provider investment in necessary technology upgrades will achieve adequate return on investment, we encourage HHS to ensure that the named technical standards are supported, compliant and not mandated for replacement, absent functionality issues, for no less than five years after the named implementation date.

Logical Observation Identifiers Names and Codes (LOINC)

The AHA is supportive of the utilization of a standard code set used to identify the specific kind of information communicated in both an attachment request and response. LOINC enables health plans to request specific documents from providers for the adjudication of claims, which should improve processing delays caused by inefficient document request processes. To ensure that health plans can request documents that currently are not included in the LOINC code set, plans will need to be able to request establishment of new codes, and providers' systems will need to be given time to incorporate necessary updates to support new documents. We encourage HHS to establish clear guidelines for when new codes can be requested and how long systems will have to incorporate new LOINC documents within their systems.

PRIOR AUTHORIZATION ATTACHMENT STANDARDS

The AHA has long been supportive of standardizing prior authorization processes. Inappropriate use of prior authorization can negatively impact patient care. A survey of more than 1,000 physicians found that more than 93% of respondents said prior authorization results in delayed patient access to necessary care. Prior authorization approvals can take anywhere from a few hours to a few weeks and, as a result, can get in the way of delivering quality care. Treatment delays can then lead to treatment abandonment, worsening of conditions and serious adverse events including hospitalization, disability or even death. Therefore, we commend HHS for seeking to streamline electronic prior authorization through the creation of an attachment standard.

Although supportive of the proposal to create a standard for prior authorization, the AHA disagrees with the proposed regulation's technical approach to standardizing prior authorization. Specifically, we believe that HHS should not standardize a process that differs from the HL7 FHIR-based approach proposed by CMS on Dec. 13, 2022. Instead, we recommend HHS take the necessary steps to name the CMS-proposed technology as the industry-wide HIPAA standard.

Undermining of CMS Proposed Solution

In the proposed rule, HHS recognizes that there might be other technologies, such as HL7 FHIR, that could be considered for naming under the HIPAA standard, stating, "We acknowledge that there is a growing base of evidence that may, in the future, support our proposing attachment standards relying on other technologies such as FHIR, and we will continue to monitor and evaluate emerging technologies for their readiness to potentially propose in future rulemaking." Although correct in recognizing the potential utility of this process, the proposal fails to recognize that regulators have already named a FHIR-based transaction in a recent CMS' notice of proposed rulemaking, which should accelerate consideration of this technology to now, rather than be considered a prospect for future rulemaking.

The CMS proposal would establish the Prior Authorization Requirements, Documentation, and Decision (PARDD) Application Programming Interface (API) to complete the necessary steps in the prior authorization process. This process gives providers a standard way of identifying which services are subject to prior authorization, gathering the specific information necessary from a patient's record, and submitting prior authorization requests and receiving responses. The AHA is supportive of this technology, which streamlines three burdensome processes involved in prior authorizations, should enable clinicians to submit prior authorizations from within their EHRs at the point of care, and creates the potential for meaningful, real-time prior authorization processing. Conversely, the proposal in this rule requires the utilization of the HIPAA 278 and 275 transactions. Furthermore, the transaction would not support requests or responses of a FHIR-based questionnaire, an essential component of the CMS prior authorization process.

If finalized, this proposal would require the PAS FHIR Bundle to be translated into and out of the X12 278 transaction, thereby requiring an intermediary between the provider's and the payer's FHIR-based systems. The translation into and out of the 278 simply to maintain HIPAA compliance would provide no value to either payers or providers. Rather, the translation of FHIR data into and out of the X12 278 will likely require the use of clearinghouses serving as middlemen in the process, which runs contrary to HIPAA's administrative simplification goals and undermines the provider and industry savings achieved in the process. In addition, translating the PAS FHIR Bundle into and out of the X12 278 only serves to increase the potential for processing errors. In fact, the mapping between FHIR and the X12 278 is incomplete and has not been properly vetted or tested and has been primarily done using the 5010 (rather than 6020) standards, creating an unnecessary technical hurdle. Moreover, the PARDD API is written in such a way that it enables a FHIR-to-FHIR transaction without unnecessary translation that can degrade the functionality of the transaction. This is illustrated by the Da Vinci HIPAA Exception that was approved by CMS through July 14, 2024, for a number of payers and their trading partners.[2]

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[2] HL7, Da Vinci HIPAA Exemption, Available at https://confluence.hl7.org/display/DVP/Da+Vinci+HIPAA+Exception

Furthermore, finalization of HHS' proposed prior authorization attachment process would establish two different workflows for the processing of prior authorizations: one process using the emerging FHIR technology for the governmental-based plans covered by the CMS rule and another for commercial entities that will build systems designed to comply with the HIPAA regulations. Although CMS envisions the FHIR-technology to be voluntarily adopted by plans due to its application to a high number of plans, including Medicare Advantage, Medicaid managed care and Federal Exchange plans, the dynamic differences in plan structure and processing edits may cause plans to elect to support the two plan types with differing technologies. This would ultimately require providers to support two different systems and workflows for prior authorizations. Additionally, this need to support two differing technologies will create inequitable delays for patients on commercial plans using this transaction, whose prior authorizations could require considerably more manual intervention and longer plan processing times. As a result, **we urge HHS not to name the X12 275 and X12 278 as the standards utilized for the transmission of necessary clinical information and processing of prior authorizations.**

Consistency with X12 Versions Requirement

The regulation requests comment on how regulators could consider naming FHIR transactions for attachments in a manner that is "consistent with the X12 5010 version transaction standards," seeming to indicate that they are required to adopt a process for leveraging X12 transactions for this process. We disagree with this interpretation because the cited language applies only to development of the claims attachment standard rather than prior authorizations.

The statute clearly establishes that only the claims attachment standard is required to comply with X12 version standards. Section 1104 of the ACA specifically establishes, "The Secretary shall promulgate a final rule to establish a transaction standard and a single set of associated operating rules for health claims attachments (as described in section 1173(a)(2)(B) of the Social Security Act (42 U.S.C. 1320d–2(a)(2)(B))) that is consistent with the X12 Version 5010 transaction standards." While we agree that this language requires the claims attachment standard to be consistent with X12 standards, nothing in the law would require its application to prior authorization attachments. As HHS clearly establishes in this rule, standardization of the prior authorization attachments process is not explicitly required under existing statute, but rather is being created under the secretary's authority to "name other appropriate financial and administrative transactions, consistent with the goals of improving the operation of the health care system and reducing administrative costs." **As a result, HHS should not feel obligated to adopt a prior authorization standard that is applicable to the existing X12 standards.**

Moreover, Sec. 1172 of the SSA [42 U.S.C. 1320d–1] enables the secretary to adopt a standard that differs from the standards developed, adopted or modified by standard

setting organizations if the standard will substantially reduce administrative costs to health care providers and plans and is promulgated according to appropriate rulemaking procedures. As a result, the secretary has the authority to name the PARDD process for prior authorizations and prior authorization attachments if he agrees with the projected efficiencies and reduced administrative costs detailed in that rule. Furthermore, if the secretary does not believe the FHIR standard has been sufficiently developed or proven to name under HIPAA at this time, we encourage HHS to treat the CMS implementation as a pilot to prove the reliability of this process.

CONCLUSION

We thank you for the opportunity to comment on the proposed HIPAA attachment standards. We are thankful for HHS's efforts to further streamline administrative processes and promulgate industry savings, and we appreciate the opportunity to provide our recommendations to finalize the proposed claims attachment transaction while reconsidering the proposed prior authorization attachment standard. Please contact me if you have any questions, or feel free to have a member of your team contact Terrence Cunningham, AHA's director of administrative simplification policy, at tcunningham@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President