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March 15, 2023

Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services US Department of Health and Human Services 7500 Security Boulevard Baltimore, Maryland 21244

Dear Administrator Brooks-LaSure:

On behalf of the American Health Information Management Association (AHIMA), I am responding to the Centers for Medicare & Medicaid Services' (CMS) *Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard* proposed rule, as published in the December 21, 2022 Federal Register.

AHIMA is a global nonprofit association of health information (HI) professionals who work with health data for more than one billion patient visits each year. The AHIMA mission of empowering people to impact health drives our members and credentialed HI professionals to ensure that health information is accurate, complete, and available to patients and providers. Our leaders work at the intersection of healthcare, technology, and business, and are found in data integrity and information privacy job functions worldwide.

The following are our responses to selected provisions and requests for information.

II. Background

E. NCVHS Recommendations to the Secretary

AHIMA recognizes the National Committee on Vital Health Statistics' (NCVHS') recommendation to the US Department of Health and Human Services Secretary (HHS) for this proposed rule to remain a "document-based attachments standard" as opposed to a "data-driven attachments standard" that would support a more data driven transaction enabled by the Fast Healthcare Interoperability Resource (FHIR). While we understand why NCVHS would make this recommendation and CMS would follow the recommendation in the proposed rule, it is crucial to highlight that by focusing on a document-based proposed rule as opposed to a data-driven one, CMS is proceeding down a standards pathway that makes the attachment standards incongruent with the standards mandated in other proposed and final rules.

This incongruence is crucially important to highlight as it relates to CMS' recently released Advancing Interoperability and Improving Prior Authorization Processes¹ proposed rule. In that proposed rule, CMS proposes the mandate of several application programming interfaces (APIs) that would exchange data between providers and payers to support electronic prior authorization. Those APIs have been proposed as FHIR based APIs. If both the HIPAA Attachment Standard proposed rule and the companion Electronic Prior Authorization Rule are finalized as written, it could result in significant incongruences between the technologies and implementation processes proposed to support electronic prior authorization.

AHIMA recommends CMS review both the standards proposed as part of the HIPAA Attachment Standard proposed rule and the Electronic Prior Authorization proposed rule and allow for providers to utilize both FHIR and X12 standards to meet the requirements that are included in both rules. Giving providers multiple technical options to achieve policy goals lessens the implementation burden on those providers and ensures that the success of the proposed policy outcomes does not hinge on one standard that is still achieving maturity. Additionally, by proposing multiple ways for providers to meet these requirements, CMS lessens the chance they will need to issue a second proposed rule to update the standards proposed in this rule.

III. Provisions of the Proposed Rule

B. Proposed Definition of Attachment Information

AHIMA supports the definitions proposed for key terms under this proposed rule. We recommend CMS review these definitions periodically to ensure the definitions continue to meet the needs of key stakeholders in the healthcare continuum utilizing these attachment standards.

C. Proposed Code Set, Transaction Definitions, and Standards

AHIMA supports CMS' efforts to update the standards aligned with the code sets used for health care attachments transactions, the X12 standards for requesting and transmitting attachment information, and HL7 standards for clinical information content, and electronic signatures standards. However, the process for updating these standards is often slower than the development underway in the private sector and is outpaced by what is being adopted at the implementation level.

There are multiple technical standard frameworks currently being implemented in the health IT marketplace. Many of these standards and their implementation guides are being updated at regular intervals and then implemented in the provider setting. Standards, such as FHIR, are increasingly mandated by HHS for implementation to move further down the nation's interoperability roadmap. Meanwhile, other standards – such as the X12 standards proposed in this rule – are part of a regular update process that evolves the standards on a regular basis. With both FHIR and X12 actively being implemented in the provider setting and updated regularly at different intervals, CMS is proposing a technical environment where providers could be forced to constantly exist in an upgrade cycle for their health IT products. This would add significant cost and burden to the provider sphere.

¹ https://www.federalregister.gov/documents/2022/12/13/2022-26479/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability

AHIMA has already highlighted the incongruencies included in this proposed rule with other proposed rules related to the utilization of FHIR APIs, but we feel it is important to bring to CMS' attention that the proposed X12 standards do not align with what is currently implemented or the latest adopted standard. Industry experts have indicated that the 6020 X12 standard proposed in this rule will be problematic in the long-term for attachment standard transactions because providers are currently using the 5020 X12 standard, while the 8020 X12 standard is the one being utilized by X12 itself. Given the three incongruencies, CMS is proposing a scenario where the transaction standard floor is lower than the one X12 will potentially recommend and that is currently used for claims transaction processing. It is important for CMS to work with X12 and key industry leaders to understand what the best standard to be proposed would be to prevent technical standard mismatches prior to finalizing the rule.

In addition to working with industry stakeholders, AHIMA recommends CMS engage health IT end users to ensure appropriate real-world testing takes place on these standards and the implementation of those standards prior to mandates taking effect. As a founding member of the Health IT End Users Alliance,² AHIMA believes the current standards and health IT policy development process does not include a robust real-world testing process – including end-to-end transaction testing – before standards and the accompanying implementation guides are solidified and mandated through policy. We urge CMS to recognize that there are opportunities for health IT end-users who use technology tools for care, as well as for patients to guide the development of policies and standards that meet real-world needs and reduce burden. As CMS works to solidify and implement these proposed standards, we recommend CMS ensure the above-mentioned health IT end users are consulted and involved in the implementation roadmap.

F. Proposed Compliance Dates

AHIMA accepts CMS' proposal for a 24-month compliance deadline for implementation of the new standards recognized within this proposed rule. We recommend CMS solicit feedback from impacted stakeholders, such as health IT developers and end users of the health IT products, to understand if 24 months is an acceptable timeline for implementation and testing of these new standards. The time allotted for real-world testing should include enough time to complete end-to-end transaction testing to verify the implemented standards work as advertised. If, after consulting with key external stakeholders, CMS determines more than 24 months is required for development, implementation, and testing of these standards, AHIMA recommends CMS extend the implementation date beyond 24 months to another date in the future that allows these activities to be completed.

AHIMA and its membership remain steadfast supporters of CMS' work and efforts to update standards tied to regulations such as HIPAA. As CMS continues down this regulatory pathway, please know AHIMA and its membership remain ready to provide real world operational insights regarding the above proposals and how they will impact the life of the patient and provider. If AHIMA can provide any further information related to the requests in this letter, or if there are any questions regarding this letter and its recommendations, please contact Andrew Tomlinson, Director of Regulatory Affairs, at 443-676-7106 or andrew.tomlinson@ahima.org.

² <u>https://hitenduser.org/wp-content/uploads/2022/09/Real-world-testing-consensus-statement_FINAL.pdf</u>

Sincerely,

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Lauren Riplinger, JD Chief Public Policy & Impact Officer