March 21, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington DC  20201

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

Comments submitted electronically via www.regulations.gov

Dear Administrator Brooks-LaSure:

The American Medical Informatics Association (AMIA) appreciates the opportunity to comment
on 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. AMIA is the professional home for more than 5,500
informatics professionals, representing frontline clinicians, researchers, and public health
experts who bring meaning to data, manage information, and generate new knowledge across
the health and healthcare enterprise.

AMIA commends the Centers for Medicare and Medicaid Services (CMS) for its effort to address
administrative simplification through proposing standards for health care attachments
transactions and electronic signatures. In theory, standards should be an important step to
reduce provider burden if the standards are current and enable a practical application
consistent with the current state of infrastructure and practice across the health care
ecosystem.

We have multiple concerns with this proposed rule, and we offer the following comments for
the Agency’s consideration.
AMIA members have expressed concerns about the challenge that end users, policy makers, and other stakeholders face when attempting to place this proposed rule in context with the provisions of the CMS proposed rulemaking on ‘Advancing Interoperability and Improving Prior Authorization Processes’ (CMS 0057-P). While the proposed administrative simplification is a desirable goal, there is a lack of clarity within this rulemaking regarding the interrelationship with the prior authorization proposed rule referenced above. For example, the proposed inclusion of prior authorization and referrals in the scope of this proposed rule – CMS 0053-P, appear to conflict with the proposed CMS interoperability and prior authorization rule CMS 0057-P.

We respectfully request that CMS precisely describe for the stakeholder community how the provisions of this proposed rulemaking align, overlap, or conflict with provisions of CMS 0057-P.

Out-of-Date Standards

AMIA supports national electronic healthcare claims and prior authorization attachment standards, but only if such standards make sense within the current landscape (the standards are current, practical and offer improvement over other standards in use). The standards set forth by CMS in this proposed rulemaking are outdated and reflect technology that would limit any practical application at this time. CMS should not require adherence to standards that lack contemporary relevance and in effect move the industry backward. This would impose undue administrative burden and create operational inefficiency for all stakeholders, who would soon be forced to repeat the process to comply with more up-to-date standards.

As we stated in our comments on CMS 0057-P, AMIA believes FHIR is critical to advance automation and reduce burden. AMIA encourages CMS to withdraw this proposed rule and conduct a re-review of the standards. We also strongly encourage CMS to further collaborate with the Office of the National Coordinator (ONC) for Health Information Technology and additional stakeholders in the standards-setting community, including the National Committee on Vital Health Statistics and the federal advisory committee for HIPAA Administrative Simplification, to determine needed steps to develop alternative approaches to meet the requirements for HIPAA Electronic Data Interchange in a more contemporary way than X12 transactions. Exchange should not require FHIR to X12 translation, and CMS should promote efforts to move in that direction.

Electronic Signatures and Interrelationship with Prior Authorization Proposed Rule

AMIA seeks clarification from CMS on how the electronic signature provisions of this proposed rule relate to, and perhaps conflict with, the provisions of CMS 0057-P. CMS 0057-P does not include any apparent proposed requirements for digitally signing medical documentation provided in support of electronic prior authorization using the PARDD API. CMS 0053-P does
include a requirement for doing so for a healthcare attachment in support of an X-12 278 referral certification and prior authorization request. We ask CMS to address why the proposed rules have seemingly contradictory provisions related to electronic signatures for healthcare attachments. Additionally, we ask CMS to confirm if the proposed digital signature requirements apply only to healthcare attachments and not to other areas of clinical workflow.

Thank you or your consideration of these comments. If you have any questions, please contact Tayler Williams, AMIA Public Policy Manager, at twilliams@amia.org.

Sincerely,

Gretchen Purcell Jackson, MD, PhD, FACS, FACMI, FAMIA
President and Board Chair, AMIA
Vice President & Scientific Medical Officer, Intuitive Surgical
Associate Professor of Surgery, Pediatrics, and Biomedical Informatics, Vanderbilt University Medical Center