EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

350 North Orleans Street, Suite S10000
Chicago, IL 60654

@EHRAssociation | ehra.org

March 21, 2023

Xavier Becerra
Secretary, U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Becerra,

On behalf of our 30 member companies, the HIMSS Electronic Health Record (EHR) Association is pleased to provide feedback on the *Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard* proposed rule (CMS-0053-P).

As a national trade association of EHR developers, EHR Association member companies serve the vast majority of hospital, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs and other health IT across the United States. Together, we work to improve the quality and efficiency of care through the adoption and use of innovative, interoperable, and secure health information technology.

The proposed electronic signature definition contained in CMS-0053-P and the use of a digital signature primarily aim to inform the use of such signatures for attachments as a whole, but also affirms the electronic process in place and recognized since the PFS rule in 2011 for attachment content such as electronic laboratory orders between a provider and laboratory using an EHR, HL7 v2-based transactions, and a laboratory information system. There is considerable confusion regarding what constitutes an electronic signature for such electronically placed orders between a provider using an EHR to enter and manage a lab order and the laboratory performing the associated tests and subsequently submitting a claim for the test performed.

We ask that CMS clarify that the current electronic ordering processes in place utilizing the HL7 v2 standards between certified EHRs and Laboratory systems are adequate for the purpose of furnishing evidence the order was placed by an authorized healthcare provider, and that the HHS proposal for digital signature is only applicable to the healthcare attachment as a distinct artifact prepared for submission by the provider to the payer in support of a healthcare claim or referral certification/prior authorization request, and does not bear impact for upstream clinical processes that create electronic medical record entries.

We welcome discussion with HHS should that be desired. The Association's leadership can be reached by contacting Kasey Nicholoff at knicholoff@ehra.org. We offer the following details and considerations regarding the NPRM.

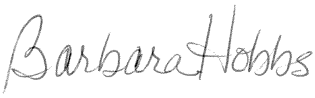
Sincerely,

David J. Bucciferro
Chair, EHR Association
Foothold Technology

William J. Hayes, M.D., M.B.A.
Vice Chair, EHR Association
CPSI

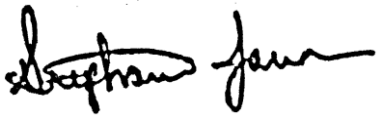
HIMSS EHR Association Executive Committee

Leigh Burchell
Altera Digital Health



Barbara Hobbs
MEDITECH, Inc.

Cherie Holmes-Henry
NextGen Healthcare



Stephanie Jamison
Greenway Health

Ida Mantashi
Modernizing Medicine

Kayla Thomas
Oracle Cerner

Established in 2004, the Electronic Health Record (EHR) Association is comprised of 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

Modifying the referral certification and authorization transaction standard to move from the X12 278, Version 5010, to the X12 278, Version 6020

The EHR Association is generally supportive of remaining current with newer versions of the X12 standard. Health IT developers and users face a number of noteworthy new regulatory requirements over the next few years that will require significant technology and workflow changes, including USCDI; the ONC Patient Engagement, Information Sharing, and Public Health Interoperability proposed rule; and the CMS Interoperability and electronic prior authorization (ePA) proposed rule. Therefore, though two years to upgrade to a newer X12 standard is generally a good starting point, the EHR Association recommends a subsequent two-year voluntary transition period during which both current and new X12 standards are allowed.

Alternatives Considered: (1) not adopt standards for health care attachments, allowing for the industry's continued use of multiple processes, (2) wait to adopt standards for health care attachments until alternate standards, such as FHIR standards, are ready for full implementation and recommended to the Secretary by the industry, and (3) adopt a different version of the X12 implementation specifications than Version 6020, the version proposed to adopt in this rule.

The EHR Association recommends encouraging future adoption of HL7 FHIR by supporting exceptions or, preferably, recognized alternative specifications to meet this requirement in addition to X12. This will allow systems to adopt and mature FHIR specifications such that greater advancement can be seen in this space. We do not recommend requiring a given FHIR standard at this point, as the relevant options and support for prior authorization attachments are still emerging, but simply allowing this to be permissible so that FHIR may be ready for full implementation in the coming years.

Use of C-CDA document types and modifiers to request attachments for both claims and prior authorization attachments.

The proposal suggests the use of C-CDA-based attachments in accordance with the HL7 CDA® R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1 – US Realm (STU) implementation guide and would cover approximately 106 recognized document types. The guide allows providers to respond with an existing C-CDA or newly generated C-CDA from among any of the 106 document types or another document type that most closely resembles the document requested if one does not have the specific document requested.

The document template modifiers allow a reference to a specific C-CDA template version, but only a limited number (three templates each with one or more versions) have been identified in the LOINC code system, referencing a particular version of a published implementation guide.

C-CDA R2.1 includes guidance for only 13 published document types, of which 3 are recognized in ONC's certification program and 1 other in CMS programs. No clear implementation guidance is provided for the remaining 90+ document types that are referenced. Therefore, the ability to improve on the current state of automated support – producing the relevant data to populate the requested document type with the minimum necessary information without substantive user involvement – is extremely limited.

Because X12 does not currently support claims attachments other than those formatted as a C-CDA (structured or unstructured), prior authorization using the proposed implementation guide in CMS' Interoperability and Prior Authorization NPRM (CMS-0057-P) would be primarily based on representing data sets that are tailored to the item or service of each specific authorization request. Da Vinci Clinical Data Exchange (CDex), the relevant implementation guide for prior authorization to enable document-based attachments when X12 is in the flow, has not yet been published. Updates to this as-of-yet unpublished guide will be necessary to facilitate a consistent and focused approach to specify data requirements.

Additionally, the necessary guidance to support payers to precisely request or providers to confidently know when specific document types are needed for specific services in support of claims, and from what source relevant clinical systems, have not been fully defined. The proposed prior authorization guides do provide such guidance for targeted data sets using HL7 FHIR Questionnaire and CQL, but as per above, they have not yet been published with the necessary guidance on how to fulfill document-based attachments consistently for claims and prior authorizations.

Considering these challenges in the absence of the necessary guidance to address all relevant cross-system interactions across the full workflow, and recognizing the substantial advances being made in the FHIR-based approaches for prior authorization, we recommend that the proposed rule is not finalized to include prior authorization at this time. Doing so will further compound current challenges.

The EHR Association urges CMS to work with ONC, HL7 Da Vinci, and X12 to enable a co-existence and transition between the X12 and FHIR-based approaches to yield right-sized attachments, whether expressed as documents or as a small set of targeted data elements.

We also urge HHS and CMS to reconsider finalizing the claims attachment, given the substantial guidance still needed to enable supporting a substantially less burdensome documents-based approach. To support a consistent exchange through FHIR-based or X12-based transactions, the attachment approaches between the CDex guide and the HL7 CDA® R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1 – US Realm (STU) implementation guide require alignment.

Proposed adoption of the HL7 standards — C-CDA 2.1 Volume One, Volume Two, and the C-CDA 2.1 based Attachment Implementation Guide.

The proposal does suggest a method by which new C-CDA 2.1-based attachment templates can be adopted without additional rulemaking. On page 78449, CMS describes an approach that a template can be used when it is created and published using the HL7 processes with a LOINC code issued by Regenstrief. The EHR Association supports this approach to enable continuous advances in standards-based attachment content. As templates are currently predominantly maintained in the CDA C-CDA

Companion Guide (currently Release 3 and soon to be upgraded to Release 4, published through HL7 ballot and publication processes using Regenstrief LOINC encoding of templates), that guide would be the likely vehicle to maintain relevant and related templates that also can be used for attachments, recognizing that not all documents relevant for attachments may be subject to certification thus documented elsewhere.

We are concerned that it is unclear whether the CDA C-CDA Companion Guide, not referenced in the proposed rule, is eligible to be used under this approach. We suggest that it should be eligible without specifically being referenced under the eligibility approach described above, so updates to templates documented in the Companion Guide – plus any future templates that may be appropriate for inclusion in that guide – can be immediately used upon publication through the accepted process.

We request that HHS confirm this is accurate, while also acknowledging that specifically citing this guide in a final rule would require additional rulemaking following the publication of each future version, which would substantially delay and hinder its use in any relevant attachments, thus purposefully excluding the guide.

e-Signatures are addressed with a general definition and requirement for attachment to have a digital signature according to the CDA guide.

The EHR Association appreciates the inclusion of a proposed definition of an electronic signature (page 78449: "Electronic signature means an electronic sound, symbol, or process, attached to or logically associated with attachment information and executed by a person with the intent to sign the attachment information.") in the proposed healthcare attachments rulemaking.

We have concerns that the proposal may bear consequences for upstream clinical workflows that involve electronic (but not digital) signatures, and that clarity regarding the scope of the HHS electronic signature proposal is lacking. We first seek clarification that the scope of proposed requirements for digital signature in CMS-0053-P applies only to the signing of healthcare attachments. Second, we seek to ensure that HHS is not proposing that the original forms of medical record entries are subject to the proposed digital signature requirements for healthcare attachments and that the definition proposed for electronic signature for healthcare attachments does not change our current understanding of policy regarding upstream clinical workflows.

While this definition is specific to a health care attachment, we believe that this definition could impact what would be considered an appropriate electronic signature for individual data and medical records included in health care attachments – such as the laboratory order examples referenced on page 78438 of the NPRM, "For example, for a laboratory to submit a claim for reimbursement of a laboratory test, a health plan may first require a physician visit and a signed physician order. When the laboratory later bills a health plan for the test, the plan may ask for evidence that it was ordered by an authorized health care provider; if the laboratory is unable to produce a signed order, it may not be reimbursed."

We note there is considerable confusion around what constitutes an electronic signature for electronically placed orders between a provider using an EHR to enter and manage a lab order and the laboratory performing the associated tests and subsequently submitting a claim for the test performed. We have been informed by laboratories that claims for laboratory tests have been declined for payment

yet were placed electronically in an EHR and subsequently transmitted over a secure connection using standard HL7 v2 messages.

Since CMS published updated guidance in December 2020 (Complying with Laboratory Services Documentation Requirements - CMS MLN Fact Sheet), some auditors are denying laboratory claims because there is no signature for the electronically ordered clinical laboratory test. This has forced some laboratories to revert to paper requisitions, which only adds burden for providers, laboratories, and patients. Reverting to paper requisitions moves the healthcare industry backward and fails to realize the possibilities of electronic health records began in 2004 when ONC was established to advance the adoption of health IT.

Further, CMS' final PFS rule dated November 28, 2011, specifically addressed the need for a signature indicating that it "…only applies to requisitions, which are paper forms" but "does not impact stakeholders who utilize an electronic process for ordering clinical diagnostic laboratory tests". The final rule further stated, "We believe that the requirement for a signature on the requisition does not impact stakeholders who utilize an electronic process for ordering clinical diagnostic laboratory tests because the policy only applies to requisitions, which are paper forms. Our intent was not to suggest that a requisition was necessary in those cases."

No further rulemaking identified a change to this guidance. Considering that the proposed definition recognizes a process to indicate a signature which is reflected in the 2011 PFS language as well as the utilization of an electronic process, we request that CMS clarifies that the use of EHRs that electronically transmit the necessary data to the laboratory constitutes a valid, signed laboratory order that provides the relevant evidence that it was ordered by an authorized health care provider.

We point out that the HL7 v2 messages used to communicate the laboratory order include data that identifies the ordering provider, which in turn can be traced to the ordering provider and their privileges at the time of order to have been authorized to place such an order. Moreover, this process has been in place for over a decade without concerns having been raised about the validity of the orders and without demonstrable evidence that the process did not prevent billing for unauthorized tests.

Given that the currently proposed electronic signature definition specifically includes the electronic process in place and recognized since the PFS rule in 2011 but also explicitly requires a digital signature process, the EHR Association urges that HHS make it clear that the widely deployed current electronic laboratory ordering process is not impacted by the HHS digital signature proposal, and therefore does not place additional signature requirements on the laboratory ordering process to provide the necessary evidence that the order was placed by an authorized healthcare provider.

Accommodating the requirements of a digital signature as described in the HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1, which is applicable to a CDA-based document but cannot be used in an HL7 v2 message that solely contributes data that may be included in a health care attachment would require substantial changes to the commonly used HL7 v2 message format. Additionally, workflow changes at the time of order entry would be required to capture any additional data or authentications beyond those already managed through the ordering system increasing documentation burden without a clear benefit. And lastly, all operational interfaces between

EHRs and laboratories will have to be upgraded and possibly replaced to accommodate the additional data.

Guidance documents issued since 2011 without materially changing the definition of a signature:

- December 2020 – Complying with Laboratory Services Documentation Requirements Fact Sheet by CMS
- January 2022 – The fact sheet (MLN905364) was announced in the March 2022 CMS Medicare Learning Network (MLN) Newsletter but later retracted. The retracted version contained language (Page 3) aligned to the Electronic Signatures in Global and National Commerce Act, a.k.a. as the "E-Sign Act",[1] which was released June 30, 2000. An embedded pdf copy is included below in these comments because the document is no longer available on the CMS website.
- April 2022 – The revised Fact Sheet (MLN905364) posted removed the "E-Sign Act" reference.