AMERICAN CLINICAL LABORATORY ASSOCIATION

March 21, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
Attn: CMS-0053-P
P.O. Box 8013
Baltimore, Maryland 21244-1850

RE: Administrative Simplification: Adoption of Standards for Healthcare Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorized Transaction Standards (CMS-0053-P)

Dear Secretary Becerra,

The American Clinical Laboratory Association (ACLA) appreciates the opportunity to provide comments on the Department of Health and Human Services' (HHS's) December 21, 2022 proposed rule, Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standards (CMS-0053-P).[1] ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA members are at the forefront of driving diagnostic innovation to meet the country's evolving healthcare needs and provide vital clinical laboratory tests that help identify and prevent infectious, acute, and chronic disease. ACLA works to advance the next generation of healthcare delivery through policies that expand access to lifesaving testing services.

We appreciate HHS's intent to adopt standards for healthcare attachments transactions and electronic signatures used in conjunction with them. However, the Proposed Rule's scope is limited in a way that it does not address many of the persistent issues around medical documentation that laboratories and other healthcare providers continue to experience. ACLA urges HHS to give attention to these issues alongside the Proposed Rule's standards and makes the following recommendations:

1. **Revise the proposed definition of a "health care attachments transaction" to include only attachment information created and maintained by a health care provider.**

2. **Clarify that submission of an electronic order through a certified electronic health record (EHR) that includes a password-protected log-in is a signed laboratory order, providing relevant evidence that the order was made by an authorized clinician.**

3. **Convene a CMS-led stakeholder meeting that includes the Office of the National Coordinator for Health Information Technology (ONC), the CMS Clinical Laboratory Improvement Amendments (CLIA) office,[2] Health Level Seven (HL7), Electronic Health Records Association (EHRA), ACLA, and other stakeholders to resolve the critical issue of clarifying standards for electronic signatures on laboratory orders.**

A. Electronic Health Care Attachments Transaction Standards

ACLA recommends HHS revise the proposed definition of a "health care attachments transaction" to include only attachment information created and maintained by a health care

[1] 87 Fed. Reg. 78438 (Dec. 21, 2022).
[2] This issue is relevant to regulation of CLIA-certified laboratories, as a CLIA regulation states that a laboratory "must have a written or electronic request for patient testing from an authorized person." 42 C.F.R. § 1241(a).

provider.

HHS proposes to define "attachment information" as documentation that is not included in a health care claims or equivalent encounter information transaction or in a referral certification and authorization transaction and that enables the health plan to make decisions about care.[3] The Agency has "attempted to ensure that [its] proposed definition is broad and general enough to include all possible patient-related information that could be generated with respect to health care services."[4] A "health care attachments transaction" would be defined as the transmission of attachment information from a health care provider to a health plan in support of a referral certification and authorization transaction or a health care claim, or a request from a health plan to a health care provider for attachment information.

In proposing a definition of "attachment information" that is broad enough to include "all possible patient-related information that could be generated with respect to health care services," the Agency could inadvertently cause additional disruption to claims adjudication processes and greater burden on providers. The proposed definition does not limit attachment information to that which is <u>needed</u> for a plan to make decisions about care, and a health plan may feel empowered by the Agency's proposal to demand from a health care provider "all possible patient-related information that could be generated with respect to health care services" before making a decision about whether or not to cover an item or service, or when it conducts a post-payment audit.[5] This would place an enormous burden on health care providers to produce additional information – and a particularly heavy burden on laboratories and other entities that do not create and do not routinely maintain "all possible patient-related information that could be generated with respect to health care services."

Laboratories already struggle to obtain medical documentation from health care practitioners to support the medical necessity of tests that they perform pursuant to the health care practitioners' orders and for which they submit claims. The *ordering health care provider* creates and maintains the documentation about a patient encounter that supports the medical necessity of a test, yet the *performing laboratory's* reimbursement is at stake when the documentation is not produced or is insufficient. Health care practitioners have no incentive to spend extra time and resources responding to requests from laboratories or from health plans for medical documentation.

Laboratory Information Systems (LISs) most commonly use the HL7 Version 2 (HL7v2) messaging and content standard to interface with health care providers' EHRs to receive test orders and to communicate test results back to an ordering provider. To perform an ordered test and return test results, a laboratory does not need, and does not maintain, other documentation created by an ordering health care provider and stored in the ordering provider's EHR system, such as clinical notes, medication lists, and immunization records. If HHS's proposed definition remains unchanged, laboratories may receive innumerable requests from health plans for electronic attachment information that they did not create and do not maintain, which is already a major ongoing issue.

ACLA recommends the definition of a "health care attachments transaction" should include <u>only</u> attachment information created and maintained by a health care provider. More specifically, ACLA urges HHS amend the proposed definition of "health care attachments transaction" at 45 C.F.R. § 162.2001 to read:

A health care attachments transaction is the transmission:

> (a) By a health care provider to a health plan of attachment information created and maintained by the health care provider for any of the following purposes:
>
> (1) In support of a referral certification and authorization transaction, as

[3] *Id.* at 78444.
[4] *Id.* at 78445.
[5] HHS includes in the preamble a discussion of the NCVHS-recommended definition for "attachments", which does include the word "needed". We disagree with HHS that its use of the word "enables" is equivalent to NCHVH's use of the word "needs".

> described in § 162.1301(a).
>
> (2) In support of a health care claims or equivalent encounter transaction, as described in § 162.1101.
>
> (b) Of a request from a health plan to a health care provider for attachment information that the health care provider created and maintains.

This proposed definition would help reduce the burden on laboratories and similarly situated health care entities that do not routinely receive electronic attachment information from ordering clinicians and are not able to transmit it to health plans on request. It still would allow a health plan to request attachment information from an ordering clinician in support of a health care claim submitted by a laboratory (which is the appropriate place for such a request to be directed, in any event.) ACLA acknowledges that it would not address the problem of ordering clinicians failing to respond to requests from health plans and from laboratories for clinical documentation in support of claims, which we understand is outside the scope of the Proposed Rule. ACLA addressed this issue in our response to the recent CMS Request for Information: Improving the Exchange of Information in Medicare Fee-For-Service.[6]

B. Electronic Signature Standard

ACLA urges HHS to clarify that submission of an electronic order through a certified electronic health record (EHR) that includes a password-protected log-in is a signed laboratory order, providing relevant evidence that the order was made by an authorized clinician.

HHS proposes to define the term "electronic signature" broadly and to specify a narrow scope of the required use of electronic signatures: attachment information transmitted electronically in electronic health care attachments transactions.[7]

ACLA was surprised to see this example included in the section of the Proposed Rule that addresses electronic signatures:

> Signatures play a vital role with respect to the documentation of health care, as a signature is often the only indicator available to health plans and health care providers that attachment information has been reviewed and approved by the service provider or other clinician with appropriate authority to supervise care…For example, in order 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.

The Proposed Rule does not address the fact that currently, there is no practical way for a laboratory to obtain an electronic signature on an electronic test order. A laboratory cannot include a signature on an order in an X12 275 health care attachment because a clinical laboratory order does not contain a signature. EHRs and LISs do not support the HL7 Clinical Documentation Architecture (CDA) to exchange orders and results; they predominantly use HL7v2, which is a "transactional" standard that has been used for many years that can handle the data necessary to support high-volume clinical laboratory ordering and resulting. CDA, on the other hand, is a document-based standard, suitable for messaging a final laboratory result, but not suitable for the high-volume transactional exchange necessary for clinical laboratory orders and status changes, specimen details, "ask at order entry" questions, timing quantity, etc. To support including an electronic signature as part of an electronic order, the HL7v2 standard would have to be updated to enable this, and so would the associated HL7 Version 2.5.1 Implementation Guide:

---

[6] 87 Fed. Reg. 76238, 76324 (Dec. 13, 2022). ACLA's comments on the RFI may be accessed here: https://files.constantcontact.com/5b9f323f401/9d19a91c-425b-4cf8-878e-4f5cc6c0b99b.pdf?rdr=true

[7] *Id.* at 78449.

Laboratory Orders (LOI) from EHR, Release 1 and each LIS-EHR interface that currently exists.

Per the Medicare Program Integrity Manual, a laboratory test order does not have to be signed.[8] ACLA agrees that a signature on an order is one way to provide evidence to a payer or an auditor that the clinician intended to order the test, but it is not the standard or scalable. A recent CMS-authored MLN Matters fact sheet has led some to believe that orders for laboratory tests must be signed, because it included this: "Unsigned physician orders and unsigned requisitions alone don't support physician intent to order. Physicians should sign all orders for diagnostic services to avoid potential denials."[9] This fact sheet conflicts with language regarding electronic signature and medical documentation requirements from the Program Integrity Manual and policy from the 2012 Medicare Physician Fee Schedule Final Rule, which states, "…we are finalizing our proposal to retract the policy that was finalized in the CY 2011 PFS final rule with comment period, which required a physician's or NPP's signature on a requisition for clinical diagnostic laboratory tests paid under the CLFS (75 FR 73483) and to reinstate our prior policy that the signature of the physician or NPP is not required on a requisition for a clinical diagnostic laboratory test paid under the CLFS for Medicare purposes."[10]

More recent guidance issued in 2022 includes a section on electronic signatures that raises more questions than it answers:

> "The medical review guidelines for using an electronic signature are:
>
> - Systems and software products must include protections against modification, and you should apply administrative safeguards that meet all standards and laws.
>
> - The individual's name on the alternate signature method and the provider accept responsibility for the authenticity of attested information."[11]

ACLA recommends that HHS clarify that submission of an electronic order through a certified EHR that includes a password-protected log-in is a signed laboratory order, providing relevant evidence that the order was made by an authorized clinician. An HL7v2 message used to communicate a laboratory order includes data that identifies the ordering practitioner, and it is possible to determine if that ordering practitioner was authorized to place the order. This type of process has been in place for more than a decade without concerns raised about the validity of such electronic orders, or clinicians' intent to submit such orders.

ACLA, HL7, EHRA, and other stakeholders have made requests to CMS for a multi-agency, multi-stakeholder meeting to clarify how an "electronic signature" on a test order could satisfy auditors looking for a clinician's intent to order a test, and the standards that would apply to an industry-developed method for an electronic order to be signed. Various guidance documents state that a signature can be "handwritten or electronic," yet there has been very little guidance about what constitutes an electronic signature. ACLA urges HHS to convene a CMS-led stakeholder meeting that includes representatives of CMS, ONC, the CMS CLIA office, HL7, EHRA, ACLA, and other stakeholders to resolve the critical issue of clarifying address standards for electronic signatures on laboratory orders.

---

[8] *See* Medicare Program Integrity Manual, Pub. No. 100-08, Ch. 3, Sec. 3.3.2.4, Signature Requirements ("There are some circumstances for which an order does not need to be signed. For example, orders for some clinical diagnostic tests are not required to be signed. The rules in 42 C.F.R. Part 410 and Pub.100-02 chapter 15, Section 80.6.1 state that if the order for the clinical diagnostic test is unsigned, there must be medical documentation (*e.g.*, a progress note) by the treating physician that he/she intended the clinical diagnostic test be performed. This documentation showing the intent that the test be performed must be authenticated by the author via a handwritten or electronic signature.")

[9] Complying with Laboratory Services Documentation Requirements, MLN Fact Sheet (Dec. 2020), *available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ProviderComplianceLabServices-Fact-Sheet-ICN909221.pdf.

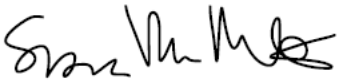
[10] 76 Fed. Reg. 73304.

[11] Complying with Medicare Signature Requirements, MLN Fact Sheet (Apr. 2022), *available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Signature_Requirements_Fact_Sheet_ICN905364.pdf.

* * *

ACLA appreciates the opportunity to provide these comments and the association would be pleased to provide additional information to the Agency.

Sincerely,



Susan Van Meter, President
American Clinical Laboratory Association