HL7® International

March 21, 2023

Secretary Xavier Becerra
Office of the Secretary
Department of Health and Human Services
Attention: CMS-0053-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically to:
http://www.regulations.gov

Re: CMS-0053-P –Administrative Simplification: Adoption of Standards for Healthcare Transactions and Electronic Signatures and Modification to Referral Certification and Authorization Transaction Standard

Dear Secretary Xavier Becerra:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on HHS' proposed rule *Administrative Simplification: Adoption of Standards for Healthcare Transactions and Electronic Signatures and Modification to Referral Certification and Authorization Transaction Standard.* We refer in our correspondence here to the proposed rule as the "Attachments proposed rule." HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena. Our organization has more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors and consulting firms. HL7 standards, implementation guides (IGs) and related tools provide both a fundamental and innovative backbone to achieving our national goals of an interoperable health system.

The HL7 product family is robust end-to-end and is well supported by the healthcare industry, as reflected by our Accelerator community, long-standing Work Group structure, and expanding technical capabilities to support the HL7 development and implementation divisions. HL7 also actively supports cross-community terminology and value set needs to further benefit data driven policy and operational needs. Our HL7 FHIR Accelerators drive groundbreaking cross-sector innovation in interoperability and bridging historical investments through partnerships to provide capabilities needed in today's modern healthcare eco-system. Particularly important examples in relation to the proposed rule discussed here, are the Da Vinci Project that addresses value-based care data exchange efficiencies and the HL7 FHIR at Scale Taskforce *(FAST)* that works on critical healthcare infrastructure and connectivity issues.

HL7's detailed feedback on the proposed rule is below and reflects the perspectives of our leadership and Policy Advisory Committee, the HL7 Accelerators Da Vinci Project and the FAST Taskforce, as well as the Orders and Observations and the Payer/Provider Information Exchange (PIE) Work Groups. The HL7 Da Vinci Project gathered their members to provide in-depth feedback and their insights and direct comment excerpts are foundational to this HL7 submitted response which offers overarching comments, recommendations and implementation perspectives.

HL7 Recommendation to Withdraw HHS Attachments Rule

At the heart of our comments are contrasting perspectives. HL7 strongly supports HHS' multi-pronged efforts through this proposed rule to "provide valuable tools to support the electronic submission of healthcare information and promote more consistent, reliable communications among the partners involved in healthcare transactions, improving the care experience for all." However, HL7 is not in favor of finalizing the Attachments proposed rule with its current language. We concur with the Da Vinci Projects' comments that the proposed rule is at odds with the healthcare industry's technology-leveraging efforts to:

- Enhance the patient experience;
- Improve population health;
- Reduce costs; and
- Improve the work life of healthcare providers.

The Attachments proposed rule would also undermine both industry efforts to comply with the Advancing Interoperability and Improving Prior Authorization Processes proposed rule and the broader use of existing HL7 FHIR capabilities, if finalized as proposed.

Spotlight on HL7 FHIR-Based Exchange and CDex

HL7 highlights a specific FHIR exchange standard -- CDex -- and related implementation guides (IG) in our proposed rule comments that is of critical importance to innovative clinical data exchange. We believe that in today's landscape any regulation for Attachments should consider the Da Vinci Clinical Data Exchange FHIR Standard for Trial Use Version 2 Implementation Guide (CDex). We refer in our correspondence here to this implementation guide as the HL7 FHIR Da Vinci CDex Implementation Guide (IG). This guide defines a more current approach to support electronic Attachments. The CDex guide leverages electronic health record (EHR)-based FHIR capabilities to automate the exchange of both solicited and unsolicited Claims Attachments, as well as supporting requests for additional information not identified and exchanged during the initial prior authorization and quality measure exchange processes defined by other Da Vinci FHIR Implementation Guides. The CDex guide also aligns with the NCVHS March 2022 letter recommending regulatory flexibility to allow the use of FHIR standards along with X12 HIPAA adopted standards. As currently written, the proposed rule provisions are detrimental, as they would not permit real-world use of the clinical data exchange (CDex) standard that enables well-defined attachment information as data and/or documents across prior authorization or claims attachments. Use of FHIR and the CDex IG would have long lasting and positive implications for patients, providers, the government, commercial funders, payers and the broader healthcare community.

Other key issues highlighted in HL7's proposed rule comments are:

- Compliance dates;
- Key considerations if the attachments rule advances;
- Adoption of HL7 IGs more broadly for healthcare attachment information;
- Adoption of X12N standards for healthcare transactions;
- Definition of electronic signatures;

- Special considerations for lab orders and electronic signatures; and
- Burden reduction issues.

Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We look forward to continuing this discussion and working with HHS as this rule is finalized and implemented.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
HL7 International

Andrew Truscott
Board of Directors, Chair
HL7 International

HL7 Responses

HL7's comments on the *Administrative Simplification: Adoption of Standards for Healthcare Transactions and Electronic Signatures and Modification to Referral Certification and Authorization Transaction Standard* proposed rule are below.

Overarching: HL7 FHIR-Based Exchange, CDex and Administrative Simplification

HL7 FHIR - HL7 supports HHS and CMS efforts to establish requirements for information exchange. Regarding HL7 and FHIR-based exchange specifically, use of HL7 FHIR reflects the choice of many to invest in application programming interfaces (APIs) as a key step in the health system optimization journey. APIs enhance system efficiencies through automated, secure, scalable, computer-to-computer communications to collect and exchange critical data without special effort.

The benefits of FHIR-based exchanges are also acknowledged in the Interoperability proposed rule, which was released shortly before the Attachments proposed rule. HL7 expresses substantial concern about the different approaches to facilitating interoperable, standards-based data sharing taken in the two proposed rules. The Interoperability proposed rule points to data-element driven data sharing via APIs while the Attachments proposed rule focuses on document and unstructured data sharing. The Attachments proposed rule embraces the NCVHS 2016 recommendations reflecting the best of breed thinking from industry testifiers to leverage document-based data sharing approaches favored at that time. We appreciate the Attachments proposed rule request for comments on other standards or alternative approaches in development, for example, the use of the HL7 FHIR Da Vinci CDex Implementation Guide (IG) including recognition of the evolution to data-driven transaction exchanges. NCVHS' 2022 letter also includes recommendations related to the need for flexible strategies to permit implementation of new technologies.

CDex - As HL7 and Da Vinci leadership previously shared with NCVHS in 2022 and early 2023, the HL7 FHIR Da Vinci CDex IG is an alternative standard aligned with federal and industry interoperability objectives, administrative simplification principles, and synergistic with certified electronic health record capabilities. The CDex IG supports any "clinical data", meaning any information a provider holds in a patient's health record. The format of the data exchanged is not limited to FHIR resources as individual data but includes Consolidated Clinical Document Architecture (C-CDA) documents, PDFs, text files, and other data formats. CDex supports the ability to:

- Request and send attachments for claims and prior authorization;
- Request documentation to support payer operations such as claims audits;
- Gather information for Quality programs and Risk Adjustment between payers and providers; and
- Exchange clinical data between referring providers.

HL7 has incorporated industry feedback regarding the current published version of CDex and is in the process of publishing a new version. This new version of CDex is compliant with the HIPAA and Affordable Care Act requirements for an Attachments standard and will provide support for claims, referrals and prior authorization. Further, CDex works seamlessly with the Interoperability proposed rule requirements, fully supports RESTful exchange, and aligns with FHIR standards adopted by the Office of National Coordinator (ONC) via the *21st Century Cures Act* final rule. In addition to supporting document-based requests, CDex also supports questionnaire-based requests for specific information required to demonstrate medical necessity for specific items and services ordered by providers.

HL7 Recommendation to Withdraw HHS Attachments Rule

HL7 strongly recommends withdrawal of HHS' proposed rule *Administrative Simplification: Adoption of Standards for Healthcare Transactions and Electronic Signatures and Modification to Referral Certification and Authorization Transaction Standard* and supports the input reflecting this, featured below. Withdrawal was the consistent, thematic feedback of HL7 Work Groups and Accelerators commenting on the proposed rule and the Da Vinci Project offered a public statement re-affirming this stance in their official letter to HHS. A sampling of perspectives HL7 received on this topic included:

FAST Taskforce

- Industry is moving to more modern technology, RESTful APIs and real-time solutions, a FHIR-based solution should be considered for healthcare attachments.

Payer/Provider Information Exchange (PIE) Work Group

- This proposed rule is based on work and comments from X12, HL7 and others that NCVHS received in 2016 and transmitted to Secretary of HHS July 5, 2016. The testimony that NCVHS used to inform the rule is 7 years old. The industry has moved toward end-to-end real-time capabilities for our healthcare communities. We do not want to be bound by a technology that is no longer relevant and need a framework that allows FHIR.

- If this rule is withdrawn it will alleviate burden and cost on providers and Electronic Medical Records (EMR)/vendors to update their platforms first for HIPAA X12 275 (old technology) and then for FHIR updates for real-time interactive solutions like HL7 CDex.

- We support a national electronic healthcare claims and Prior Authorization (PA) attachment standard, but there are more flexible technologies to enhance efficient exchange of clinical information and reduce complexity.

Da Vinci Project

While we recognize the long-standing interest in naming an Attachments standard and concerns with the status quo, we are not in favor of proceeding with 2016-based thinking in 2023 because doing so presents a variety of risks including:

- If the Attachment proposed rule is finalized deployments of the proposed solutions will directly and negatively impact the ability to improve clinical workflows related to prior authorization:
    - The proposed Attachment standards do not explicitly support the exchange of a FHIR bundle as a C-CDA unstructured document type. In other words, the media types for unstructured documents in the proposed C-CDA specification do not currently include "application/json+fhir".
    - The proposed Attachment standards would conflict with the Interoperability proposed rule proposed standards, especially the Documentation Templates and Rules specification, that allow use of a FHIR Questionnaire and FHIR QuestionnaireResponse functionality essential to enabling automated, template-based exchanges between provider and payer systems.
    - The proposed Attachment standard embraces asynchronous exchange methodologies in contrast to the Interoperability's proposed rule's use of RESTful real-time, synchronous exchanges that support a

provider's need for data during a patient interaction determining diagnostic and care treatment decisions.

- Requiring investments in new, mandated X12 standards will make further evolution of requesting and responding to supplemental data needs that much harder and burdensome.
- Formalizing the disconnect with 21st Century Cures capabilities and related investments designed to support interoperability, reduced burden, and better patient outcomes made in response to the ONC 21st Century Cures Act and CMS Interoperability and Patient Access final rules in 2020.
- Diverting precious staff resources to comply with a mandate for document-based Attachments limiting collaboration on shoring up the foundation of frameworks, standards, and operational realities across domains such as equity, social drivers, public health, administrative, financial, clinical, and certified technologies.
- Forcing industry focus on this compliance project rather than development and implementation of modern, efficient capabilities to exchange and harness high fidelity, discrete data to better meet patient needs and expectations, and address provider and staff burnout in our healthcare system.

Key Considerations if HHS Attachments Rule Advances

HHS may move forward to finalize the *Administrative Simplification: Adoption of Standards for Healthcare Transactions and Electronic Signatures and Modification to Referral Certification and Authorization Transaction Standard* rule. Specific HL7 recommendations related to this scenario are below. If the Attachments proposed rule moves forward, there is a critical need to:

- Continue industry's role in defining when electronic signatures are required.
- Reduce the scope by removing any reference to referrals and prior authorization as the Interoperability proposed rule effectively provides a solution to address those use cases, workflows, and clinical information requirements for timely exchange of discrete data via patient, provider, and payer APIs to assist with improving patient care, supporting the patient in being an informed decision-maker in their own care, and reducing the burden on providers to document a patients need for specific items and treatments by extracting item and service specific information from the clinical record to satisfy payers prior authorization requirements.
- Improve the clarity of the Attachment Information definition. The proposed definition and scope of use could be interpreted as applying to all use cases versus the attachments definition being tied to "a specific transaction" such as the claims transactions (a.k.a. X12N 837s). Further, the current definition potentially includes any information exchange between a provider and other information source (e.g., a clinical laboratory or immunization registry) and a payer.
- Support the industry using FHIR APIs, including CDex, via a simplified HIPAA exception process.
- Update specifications related to CDA and FHIR content and corresponding electronic signatures:
    - HL7 believes that the statement on page 78449 of the Attachments proposed rule essentially affords flexibility for newly defined or updated templates to expand standards-based coverage of the currently permissible LOINC codes as well as any newly established LOINC codes:

      "The Attachment Implementation Guide contains three criteria that any document template to be used as a healthcare attachment must meet if it is not already specified in one of the proposed implementation guides: (1) the template must be developed and published through the HL7 standards process; (2) the new template must be designated by HL7 as being compatible with a

C–CDA 2.1 implementation specification and for use in the United States; and (3) a LOINC code for the template must be created by Regenstrief via its code creation process as previously described. This means that once a C–CDA 2.1 implementation guide-compatible document template has been created by HL7 and is assigned a LOINC code, which happens upon request of the HL7 Payer/Provider Information Exchange Workgroup once HL7 creates a new template, it may be used as attachment information in a healthcare attachments transaction. We invite comment on the proposed adoption of the HL7 standards—Volume One, Volume Two, and the Attachment Implementation Guide."

We fully support this approach enabling 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. If this proposed approach is not cited in the final rule or the current publication and release process is inconsistent with the final rule, the final rule would have to name the most current CDA C-CDA Companion Guide release and issue frequent rule updates to enable new or updated templates to be available for healthcare attachments under HIPAA. We note that continued evolution of templates is also frequently driven by the ONC USCDI requirement to include new data classes and elements to meet evolving clinical and administrative needs (e.g., health equity, care settings, and clinical concepts).

- Attachment IG referenced in § 162.2002, a, is a 2017 version which has been retired and replaced by the following 2022 version: http://www.hl7.org/documentcenter/private/standards/Attachment_Specifications/CDAR2_AIG_CCDA_EXCHANGE_R2_INFORM_2022MAR.pdf
- In addition to supporting HL7 C-CDA standards for Attachment's content standard, we recommend that the inclusion of the FHIR content standard also be allowed to enable a more flexible response to a payer's request for additional information for claims. The appropriate standard would be the HL7 FHIR Bundle resource standard http://hl7.org/fhir/R4/bundle.html that is normative in the version of FHIR adopted by ONC for EHR certification under the 21st Century Cures Act. In addition, the final regulation could cite the FHIR digital signature standard http://hl7.org/fhir/R4/datatypes.html#Signature that is supported by the HL7 FHIR bundle resource.

In addition to our views on overarching issues expressed above, HL7's comments on specific portions of the Attachments proposed rule, are below.

Compliance Dates (p. 78452)

CMS proposes to implement a compliance deadline for all proposed standards 24 months following the finalized effective date. **HL7 puts forth the following:**

- Consider implementation overload with Interoperability proposed rule API update requirements (currently proposed for 2026) along with the possibility of the X12 Claims and Remittance Advice version 8020 rule, *No Surprises Act* and other mandated activities.

- Providers and vendors likely haven't included updating the 278/275 in their 2023 business plans, so moving forward with the final Attachments rule would have to account for 2023 not being an implementation year.

- A change in date of the final rule and/or the effective date of the rule should be considered.

Electronic Healthcare Attachments Transactions (p. 78445) and Proposed Adoption of X12N Standards for Healthcare Attachments Transactions (p. 78447)

Prior Authorization
CMS proposes X12N 278—Healthcare Services Request for Review and Response (006020X315) as the standard a health plan must use to electronically request attachment information from a healthcare provider to support a prior authorization transaction. And, CMS proposes X12N 275—Additional Information to Support a Healthcare Services Review (006020X316) as the standard a provider must use to electronically transmit attachment information supporting a prior authorization request. **HL7 observes that:**

- These provisions do not account for the HL7 FHIR Coverage Requirements Discovery (CRD), Documentation Templates and Payer Rules (DTR) and Prior Authorization Support (PAS) IGs built for an interoperable, modern prior authorization process, as recognized by the Interoperability proposed rule.

- The CDex IG for should be adopted for attachments. Harmonization is in order for all use cases for supporting documentation.

Solicited Documents
CMS proposes to adopt X12N 277—Healthcare Claim Request for Additional Information (006020X313).

HL7:

- Recommends adoption of CDex, as it covers all attachment use cases including Request for Additional information and submission of supporting documentation.

- Observes that the Dec 2022 X12 proposal to upgrade to Claims and Remittance Advice version 8020 conflicts with the claims 5010 upgrade mentioned in this 2016 proposed rule for attachments.

Unsolicited Documents
CMS proposes to adopt X12N 275—Additional Information to Support a Healthcare Claim or Encounter (006020X314).

HL7:

- Recommends adoption of CDex as it covers all attachment/supplemental documentation use cases including Request for Additional information and submission of supporting documentation.

- Observes that the Dec 2022 X12 proposal to upgrade to Claims and Remittance Advice version 8020 conflicts with the claims 5010 upgrade mentioned in this 2016 proposed rule for attachments.

Expanding the HIPAA X12 Electronic Standard Transaction for Claims Attachments: Use Cases and Unified Submission Methods
HL7 emphasizes:

- There are a large number of use cases for attachments/supplemental documentation. Having a unified submission method capable of handling authorization, claim, quality, audit, and other use cases would be

beneficial to both payers and providers. Ideally, such an end-to-end electronic prior authorization (ePA) solution should not require a FHIR to X12 translation.

- HL7 Clinical Data Exchange (CDex) could be used to request documentation needed for ePA. As the CDex IG has been updated for solicited and unsolicited medical record/attachments for claims, PA and other payer use cases. The HL7 Provider/Payer Information Exchange WG is supporting this work for solicited and unsolicited documentation.

Referral Certification and Authorization Transaction

CMS proposes to advance the standard for the referral certification and authorization transaction (X12N 278) from Version 5010 to Version 6020. **HL7 observes:**

- Since NCVHS' recommendation 6 years ago, the industry has moved on to develop alternative solutions. Updating the 278 to 6020 at this point does not make good sense.

- Practically speaking, there are issues with managing multiple standards and versions (i.e., the 837 claims transaction proposed version 8020, while these transactions will be at 6020, and there may be others at 5010).

- A significant challenge with the X12N 278 standard is the wide range of prior authorization workflows and lack of agreement on data element standardization. States, systems, providers, and payers have slightly different, and often conflicting, definitions on common terms such as authorization, certification, and review. In addition, a high percentage of prior authorization transactions require additional documentation and even with the X12N 275 attachment standard, getting that additional data is a high friction process for both providers and payers.

- The X12N 278 standard has never been fully implemented by providers and payers and is not an end-to-end solution for the prior authorization process. Ideally, a new ePA standard should be able to both function independently of the X12N 278 standard, not requiring any translation, and also support such a translation for systems that may still have part of their process reliant on the X12 standard.

- Importantly, any electronic standard that is adopted for prior authorizations should be capable of providing an end-to-end replacement for all elements of the manual processes that exist today. The HL7 Da Vinci FHIR IGs (CRD, DTR and PAS) have the potential for creating such an end-to-end ePA standard.

- HL7 Clinical Data Exchange (CDex) could be used to request documentation needed for ePA. As the CDex IG has been updated for solicited and unsolicited medical record/attachments for claims, PA and other payer use cases. The HL7 Provider/Payer Information Exchange WG is supporting this work for solicited and unsolicited documentation.

- This proposed rule should be withdrawn and HHS can work with standards setting organizations on the best path forward.

Adoption of HL7 Implementation Guides for Healthcare Attachment Information (p. 78448)

CMS proposes to adopt the following three HL7 CDA standards:

- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 1—Introductory Material, June 2019 with Errata

- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 2—Templates and Supporting Material, June 2019 with Errata
- HL7 CDA R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1, March 2017

HL7 notes that:

- The HL7 CDA R2 Attachments Implementation Guide: Exchange of C-CDA Based Documents, Release 1. March 2017 is a retired version. The updated IG was released in March 2022
  The new IG link is:
  http://www.hl7.org/documentcenter/private/standards/Attachment_Specifications/CDAR2_AIG_CCDA_EXCHANGE_R2_INFORM_2022MAR.pdf

Definition of Electronic Signature (p. 78449)

CMS proposes to permit providers to sign healthcare attachments electronically and would define the term "electronic signature" broadly to encompass current and future electronic signature technologies. It does not propose to specify when an electronic signature is required, but, instead, proposes to defer to the industry to continue to establish those expectation.

CMS proposes to require that, where a healthcare provider uses an electronic signature in a healthcare attachments transaction, the signature must conform to the implementation specifications in the HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1 (Digital Signatures Guide).

- HL7 recommends the final rule state that digital signature should be included for claims only when payers require them.

HL7 provides recommendations and context below regarding the proposed rule's definition of e-Signature and how that impacts lab orders that form the basis and substantiation of the claim.

- HL7 appreciates the inclusion of a proposed definition of an e-signature in the proposed healthcare attachments rulemaking and offers considerations and requests as we are concerned that the proposal may bear consequence for upstream clinical workflows that involve electronic (but not digital) signature and that there is a lack of clarity about the scope of the HHS electronic signature proposal.
- While the e-signature definition is specific to a healthcare attachment, HL7 believes that this definition could impact what would be considered an appropriate e-signature for individual data and medical records included in healthcare attachments such as the laboratory order examples referenced in the proposed rule. Specifically, on page 78438, "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 healthcare provider; if the laboratory is unable to produce a signed order, it may not be reimbursed."
- HL7 notes there is considerable confusion around what constitutes an e-signature for electronically placed orders between a provider using an EHR to enter and manage that lab order and the laboratory performing the associated tests and subsequently submitting a claim for the test performed. HL7 has 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 relevant laboratories to go back

to paper requisitions, which only adds burden for providers, laboratories, and patients. Reverting back to paper requisitions moves the healthcare industry backward and fails to realize the possibilities of electronic health records begun in 2004 when ONC was established to advance adoption of health information technology in healthcare.

Further, CMS' final physician fee schedule (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 rule making 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 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 healthcare provider. We note 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. We further note that 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.

Further guidance has been issued since 2011, including:

- 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*, which was released June 30, 2000.
- April 2022 – A revised Fact Sheet (MLN905364) posted removed the *E-Sign Act* reference.

These guidance documents did not materially change the definition of a signature. Therefore, considering the currently proposed e-signature definition that specifically includes the notion of a process, which is inclusive of the electronic process in place and recognized since the PFS rule in 2011 but which also explicitly requires a digital signature process. **HL7 requests 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.

Substantial changes to the commonly used HL7 v2 message format would be required to accommodate 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 lab order message that solely contributes data that may be included in a healthcare attachment. 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.

HL7 requests and strongly recommends that:

- CMS clarify that the current electronic ordering processes in place utilizing the HL7 v2 standards between certified EHRs and Laboratory systems is 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.

- HHS convene a meeting including CMS (including representation from CLIA addressing compliance requirements), ONC, the Electronic Health Record Association (EHRA), HL7, and the American Clinical Laboratory Association (ACLA) to define a plan to resolve the variations in interpretations of what constitutes an electronic signature where providers order and receive results from laboratories using EHRs and LIS systems with HL7 v2 messages.

References: HL7 and Materials

HL7 highlights the following changes that should be made in publishing the final rule:

- Regarding the proposed rule HL7 implementation reference below, a fee is not charged for HL7 implementation guides and this needs to be clarified in final regulatory text.
  "The materials we propose to incorporate by reference are available to interested parties and can be inspected at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244-1850. The X12 implementation guides are available at GLASS, *sso.x12.org*. The HL7 implementation guides are also available through the internet at *www.HL7.org*. A fee is charged for all implementation guides. Charging for such publications is consistent with the policies of other publishers of standards. If we wish to adopt any changes in this edition of the Code, we would submit the revised document to notice and comment rulemaking."

  References
  https://www.federalregister.gov/d/2022-27437/p-210
  https://www.federalregister.gov/documents/2022/12/21/2022-27437/administrative-simplification-adoption-of-standards-for-health-care-attachments-transactions-and#p-351

- **There is no dash in the HL7 reference below:**

  e) Health Level Seven International **(HL-7),** 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104; Telephone (734) 677-7777; FAX (734) 677-6622; *www.hl7.org*.