April 21, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: RIN 0938–AT38
Submitted electronically via http://www.regulations.gov

Dear Administrator Brooks-LaSure:

The Workgroup for Electronic Data Interchange (WEDI) writes today in response to the publication in the December 21, 2022, edition of the *Federal Register* entitled "*Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard"* released by the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

WEDI was formed in 1991 by then HHS Secretary Dr. Louis Sullivan to identify opportunities to improve the efficiency of health data exchange. WEDI was named in the HIPAA legislation as an advisor to the Secretary of HHS. Recognized and trusted as a formal advisor to the Secretary, WEDI is the leading authority on the use of health information technology (IT) to efficiently improve health information exchange, enhance care quality, and reduce costs. With a focus on advancing standards for electronic administrative transactions, and promoting data privacy and security, WEDI has been instrumental in aligning the industry to harmonize administrative and clinical data.

WEDI supports and shares CMS's goals of leveraging health IT's advanced capabilities and functions to decrease burden and streamline processes to improve the quality of care while minimizing administrative costs. We applaud CMS's decision to address the two congressional requirements and propose establishing a national standard for electronic attachments. Encouraging the industry to adopt and use a uniform set of standards is an important step toward enabling the efficient exchange of health information and achieving workflow automation.

WEDI Member Input

To address this Notice of Proposed Rulemaking (NPRM), WEDI leveraged our Member Position Advisory (MPA) process. Our MPA process engaged the WEDI membership through a virtual event and a survey asking questions specific to the proposals and questions focused on general implementation issues.

Virtual Events

As part of our MPA process, WEDI hosted multi-hour virtual member event where 75 participants shared their perspectives on the issues raised in the NPRM and how best to implement these new requirements. Throughout the MPA virtual events, WEDI conducted polls to capture additional viewpoints from the participants.

Survey

Another component of our MPA process was the collection of industry perspectives on the CMS proposals through a survey conducted February-March 2023. We received a total of 145 responses, and we will be incorporating responses to our survey in our comments below. The following table outlines the number of respondents who completed the surveys and the stakeholder groups they represent:

Survey Participants

Answer Choices	Responses (%)	Responses (Number)
Provider	38.6%	56
Payer	24.1%	35
Clearinghouse	6.2%	9
Vendor	22.0%	32
Other	9.0%	13
Total		145

Summary of Key Comments and Recommendations

1. Many of the provisions included in this proposed rule are based on the National Committee on Vital and Health Statistics (NCVHS) hearing on attachments conducted in February 2016. There have been significant events that have occurred after this hearing, including passage of the 21st Century Cures Act (Cures Act) and formation of the Health Level Seven (HL7) Da Vinci Project that has developed the Clinical Documentation Exchange (CDex) standard.

2. Despite no national mandate, some industry stakeholders have implemented the X12 275 electronic attachment transaction and Consolidated Clinical Documentation Architecture (C-CDA) standard in support of electronic claims and have realized a return on investment (ROI).

3. WEDI recognizes that there are significant differences of opinion within the industry regarding the optimum approach for the industry to take with electronic attachments. We strongly urge CMS to closely review all options for attachments standards for both claims and prior authorization transactions before issuing a

final regulation.

4. Based on MPA poll results and MPA discussion, WEDI members favor CMS taking an approach in the final rule that supports industry adoption of both the X12-based and FHIR-based standards options. WEDI stands ready to assist CMS identify the challenges and opportunities associated with each approach.

5. WEDI supports identifying an appropriate standardized approach to electronic signatures but urges CMS to limit their use to avoid adding unnecessary burden on impacted stakeholders. As there is an interrelationship between the attachments standard and the electronic signature standard, we recommend CMS ensure alignment of the two standards in the final regulation.

If CMS decides to move forward with this proposed rule based on the current provisions:

6. WEDI urges CMS to carefully review the availability of updated versions throughout the rulemaking process and seek to name the most current versions of the standards in the final rule.

7. WEDI recommends CMS give the industry a minimum of 24 months following the effective date of the final rule to comply with the requirements combined with a minimum 12-month enforcement discretion period.

8. WEDI supports the use of control numbers to ensure reassociation of the attachment with the transaction.

9. WEDI recommends that after the transition to a baseline set of standards has taken place, CMS should ensure the deployment of a known and predictable standards upgrade cycle.

10. WEDI urges CMS to closely harmonize and align the electronic attachments final rule with the interoperability and prior authorization proposals and with other applicable federal health information technology (HIT) initiatives.

General Comments and Recommendations

WEDI's mission and work are driven by the goal of easing administrative burden, putting patients at the center of their care, implementing consensus based, mature standards that support automation, and maintaining appropriate safeguards for privacy, security, and confidentiality. WEDI broadly supports the purpose of this NPRM, and we commend the work of CMS to improve health information exchange and reduce administrative burden for all stakeholders.

Standards supporting the electronic exchange of attachments are critical for providers, payers, and the patients they serve. Voluntary adoption of electronic attachments has been low, with the 2022 CAQH Index indicating that just 24 percent of attachment transactions were carried out electronically. Further, the Index reports that just 28 percent

of prior authorization transactions utilize the X12 278 transaction. Many believe the low adoption rate of the 278 is due to a lack of a national standard for electronic attachments, as prior authorization often requires supporting clinical information to be exchanged between providers and payers.

We applaud CMS for releasing this proposed rule and for emphasizing the importance of improving health information exchange and facilitating patient, provider, and payer access to health records. Addressing the need for electronic attachments for both claims and prior authorization signals support for automating two critical administrative workflows. Importantly, this NPRM buttresses the recently-released *Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program* (Advancing Interoperability and Improving Prior Authorization) NPRM by proposing to improve the prior authorization process by establishing a standardized approach to information exchange.

CMS has requested specific comments and information in this NPRM. WEDI's comments are based on key guiding principles that are integral and essential considerations of any regulatory action. Specifically, meeting the goals of this proposed rule and the expected future CMS and Office of the National Coordinator for Health IT (ONC) regulatory action require that relevant stakeholders have ready access to several key capabilities and functions. It is important to design a transition to automation that:

- Promotes seamless, automated data exchange through mature, clear, and unambiguous standards that have been thoroughly tested and demonstrate meaningful return on investment (ROI).

- Integrates the data exchange easily within the payer, provider, and other end-users' workflows.

<u>Harmonize standards</u>

There is significant overlap between the Advancing Interoperability and Improving Prior Authorization NPRM and this Attachments NPRM, as electronic attachments are seen by the industry as a critical component of prior authorization automation. We strongly recommend that CMS harmonize the two final rules to ensure that each set of requirements work seamlessly with each other and result in reduced administrative burden for providers and payers and lead to an improved care delivery process.

CMS should also ensure that the attachment standards and associated data and transport requirements do not conflict with any federal health data interoperability program requirements and road maps of other HHS programs. We urge CMS to also ensure that all programs use the same connectivity and interoperability infrastructure to decrease implementation costs for impacted stakeholders.

Name appropriate implementation guide versions

The difficulty the government faces when naming implementation guides (IG) in a proposed rule is balancing the need to name an IG that is established with the need to avoid having the industry adopt an outdated IG. This challenge is exacerbated with the protracted nature of the rulemaking process. WEDI recommends CMS identify a "floor" for standards with identification of initial IG versions that support the functionality required by a CMS rule. Typically, IGs go through an important maturation process through balloting and implementation that constantly improves the product.

The industry has concerns around the potential lack maturity of IGs and the lack of real-world testing. There is also the concern that the available versions of the IGs propose changes and pre-adopt changes to dependent IGs, or request feedback on design considerations within the IGs that may impact compatibility between these versions and future versions.

With the potential of there being multiple versions of IGs, the CMS must be cautious not to permit the use of different versions of an IG so that health IT developers, payers, and providers are unable to support them. We urge the government to work with WEDI, Standards Development Organizations (SDOs) and the broader industry to identify the appropriate number of IGs that the industry would be required to support.

The following is one option of a process for adoption of updated published versions of each IG named in the regulation and subsequent incorporation into ONC certification requirements:

- Where these updated versions are required to meet the final rule requirements, the updates shall be established as the floor and the timelines in the final rule should apply.

- Updated versions of IGs can offer enhanced functionality. Those organizations subject to the final rule can implement the enhanced functionality but they must do so in a manner compliant with the updated IG version. At the same time, the organization is required to support all functionality in the "floor" version of the standard. The "floor" requirement can be updated to a more recent version of the IG, but that must be done officially through government regulation.

A second, and preferable, option would have CMS carefully review the availability of updated IGs throughout the rulemaking process and seek to name the most current version of the IG in the final rule. This will ensure the industry will implement and take advantage of the most up-to-date IG. Should the requirements of the most up-to-date IG differ significantly from what was proposed by CMS, the agency has the option of releasing an Interim Final Rule with Comment and solicit public input on the changes.

Implement supporting operating rules

Section 1104 of the Patient Protection and Affordable Care Act (H.R. 3590) mandates the adoption of both attachment standards and operating rules. Presently, the CAQH CORE Attachments Operating Rules are under review by the NCVHS. Should the NCVHS recommend the CAQH CORE Attachment Operating Rules for federal adoption, we urge CMS to implement the electronic attachment standard and supporting operating rules

concurrently. This approach will maximize the return on investment (ROI) for providers and payers and ensure that the improvement to the delivery of patient care is accelerated.

Develop a known and predictable standards schedule.

We note that it is now more than 10 years since the industry moved to version 5010 of the HIPAA administrative transactions. This is far too long. We recommend moving forward to create a new baseline for the industry. Once the industry has transitioned to that baseline set of standards, the industry can then more efficiently move to a more incremental approach to standards updates. We note that this known and predictable transition cycle should apply to all standards implemented by the health care industry.

After the transition to this baseline set of standards has taken place, we urge the deployment of a known and predictable standards upgrade cycle. When the industry has moved to an incremental yearly or bi-yearly upgrade schedule, changes to transactions should be based on their value to the industry. Finally, we recommend working with WEDI and other industry stakeholders to develop the most appropriate glidepath for standards implementation.

We point to the Office of the National Coordinator for Health Information Technology's (ONC) Standards Version Advancement Process (SVAP) as a success story and a potential model for ensuring appropriate standards and versions of standards are identified and that these standards are updated with a cadence that best meets the needs of the industry.

Encourage real-world piloting and testing

The electronic prior authorization environment is constantly changing. HL7, X12 and others continue to develop new solutions and new IGs. While there is great promise with new standards, prior to any national mandate of a new health IT standard or process there should be comprehensive pilot testing using real-world scenarios and conducted in multiple types of care settings.

The value of piloting goes well beyond simply proving that a standard works outside a laboratory setting. Piloting a new standard or approach can identify workflow issues that will either need to be corrected by revising the standard itself or addressed by stakeholders during implementation. As well, successful piloting of a new standard or approach can serve to increase support from payers and providers and that in turn can accelerate development of the supporting software. This momentum building within each stakeholder group is critical to avoid an overly protracted compliance glidepath.

Revise the exceptions process

We appreciate CMS developing a process that permits non-mandated standards for use in administrative transactions. This ability for industry stakeholders to test new approaches is critical if we are to advance data exchange capabilities. We do believe that the exceptions process should be streamlined to ensure that there are minimal barriers to implement and test new standards. We also recognize that there is considerable cost for any organization implementing a new standard and modifying workflows. This financial

challenge is compounded as there is no guarantee that the new standard can and will be used beyond the three-year exception period. With that in mind, we urge CMS to explore opportunities to fund those organizations as an encouragement for organizations to investigate the viability of new standards.

Incentivize health IT developers

Health IT developers are a critical component of any successful national transition to new or revised health care administrative standards. As health It developers may not be HIPAA covered entities, they may not be required by law to support the attachment standards. However, the ONC certification program has proven successful in moving a significant number of electronic health records (EHR) software products toward a standardized set of functional capabilities. We are hopeful health IT developers will incorporate the named attachment standard not just because ONC will include it in its certification criteria, but to facilitate their provider customers' long-awaited transition to a more automated and efficient claims and prior authorization process that leverages electronic attachments.

There are potential challenges facing health IT developers on the path to electronic attachments. Developing and implementing new EHR functionality is time consuming, labor intensive, and expensive. Health IT developers demand certainty when it comes to writing code to support this new functionality. Uncertainty regarding what ONC will require for its certification will lead to delays in production and delays in certification. ONC should be clear what IGs will need to be supported and give health IT developers sufficient time to implement the IGs and all other attachment requirements.

Expand industry education

CMS is in a unique position to assist impacted stakeholders understand the value of electronic attachments and encourage the deployment of supporting software and workflows. Providers, payers, and their supporting vendors all require technical and business process knowledge to successfully transition. We urge CMS to work with organizations like WEDI and others to disseminate up-to-date and actionable educational resources. We urge the agency to consider development of a dedicated CMS webpage, stakeholder-specific newsletter inserts, "open door" virtual forums, making available CMS officials to speak at industry events, and other methods of communicating regulatory and implementation updates.

Establish a Comprehensive Health IT Roadmap

The current health IT landscape is complex, challenging, and rapidly changing. The federal government has an extremely ambitious vision of how health care stakeholders must deploy technology for both administrative and clinical purposes. Requirements for new and updated HIPAA administrative standards and operating rules must compete with 21st Century Cures Act, interoperability requirements, No Surprises Act data exchange provisions, and other federal mandates for scarce human and financial resources. Exacerbating this, the nation's health infrastructure continues to face COVID-19 related difficulties. We urge the development of a comprehensive and achievable roadmap that

prioritizes these health IT requirements and recognizes the many implementation challenges faced by the industry.

Ongoing advisory process

The transition to electronic attachments will likely be a multi-stage process. In this ever-changing environment, it will be critical for CMS to have industry input from the entities directly impacted by these policies. As CMS further develops their approach to advancing interoperability in general and electronic attachments specifically, we encourage continued close collaboration with industry stakeholders such as WEDI. As an advisor to the HHS Secretary and a multi-stakeholder organization comprised of health plans, providers, vendors, and SDOs, WEDI offers the unique ability to bring stakeholders together and foster cross-industry collaboration.

Specific Comments on the NPRM

NPRM Issue: 2-Year Compliance Date
"We are proposing to adopt new standards and a modification to a standard in this proposed rule. Section 1104(c)(3) of the Affordable Care Act, which requires the Secretary to adopt a transaction standard for health claims attachments, prescribes a 2-year compliance date for all covered entities and makes no special provision for small health plans, unlike the original HIPAA. In this rule, we are proposing that the same health care attachments standards would apply to both claims and prior authorization attachments transmissions.

As the transmission standard for each type of attachment transaction transmission would be the same, we believe the compliance date for both types should also be the same. In addition, because we are proposing to treat the two attachments process together as one transaction in new Subpart T, adopting the same compliance timeframe for all covered entities would avoid the complications a bifurcated compliance timeframe—one for claims processes and another for prior authorization processes—would raise."

WEDI Response
We believe that providing adequate time for implementation at the start of the process will be most appropriate. **We recommended establishing a compliance date 24 months after the effective date of the final rule**. **CMS should also establish enforcement discretion for an additional minimum period of 12 months. We also recommend that the implementation date for this rule should, if possible, be harmonized with the compliance date of the Advancing Interoperability and Improving Prior Authorization final rule.** Synchronizing these regulations would help ensure that providers and payers can take advantage of the automation opportunities afforded by these standards.

Further, while the development of an ONC certification program that includes electronic prior authorization is an important step on the road to full industry adoption of this standard, we are concerned that if the appropriate timing for compliance is not developed, it could result in needless costs, delays, and burdens. We recommend CMS work closely

with ONC to ensure the appropriate implementation glidepath is established. We note that delays in implementing the attachments certification could create greater inertia, if not resistance, in the provider marketplace and create confusion for payers seeking to take advantage of automating prior authorization.

We believe the optimum glidepath would have the CMS electronic attachments final rule released followed by the rule setting the ONC electronic attachments requirements. We do not believe the ONC certification rule should be finalized prior to the CMS final rule to ensure that health IT developers will have confidence in the criteria they must incorporate into their software. In addition, the compliance date for the various stakeholder groups should be staggered, with health IT developer compliance with the ONC electronic prior authorization certification requirements to occur no less than six months prior to the date providers and payers will be required to exchange data using these new standards.

Finally, we have heard from our member organizations that January 1 represents the start date for many business and regulatory requirements. For example, health plans typically must transition many of their members on that date, either removing them or adding them. We recommend CMS identify an alternative date, such as April 1 or July 1 to implement these requirements.

NPRM Issue: Expanded Definition
"Section 1173(a) of the Act requires the Secretary to adopt standards for ''Health claims attachments,'' and section 1104(c)(3) of the Affordable Care Act reiterated that requirement, directing the Secretary to promulgate a final rule to adopt a transaction standard and a single set of associated operating rules.

The attachments standards we are proposing satisfy the requirement to adopt a standard to support health care claims, but they also support prior authorization transactions. Hereafter we refer to ''health care attachments'' to refer to attachments for claims as well as prior authorization transactions instead of ''health claims attachments,'' which only includes the former."

WEDI Response
Our members believe there will be significant value in adopting a standard for exchanging the additional information that is required to support both claims and prior authorization. We concur with CMS that the Secretary has the statutory authority to establish electronic attachment standards to support both transactions. Section 1173 of the legislation gives the Secretary direction to adopt standards for other financial and administrative transactions determined appropriate by the Secretary, consistent with the goals of improving the operation of the health care system and reducing administrative costs.

In our survey, we asked the following question: *"CMS is proposing to have attachments support both claims and prior authorization. Which approach do you support?"* Participants answered: Yes for Both (67.9%), No-Should be Claims Only (6.1%), No-Should be Prior Authorization Only (6.1%), and Unsure (19.8%).

We do note, however, that while the term "attachment" is used for both claims and prior authorization (among other potential use cases), the nature of the data and the way it is

handled by both payers and providers is markedly different between the two transactions.

NPRM Issue: 6020 Version of the Electronic Attachments Standard
"*In its 2016 letter to the Secretary, the NCVHS recommended the adoption of the X12N 278 for health care attachments transactions, but did not recommend a specific version. Rather, the NCVHS recommended that the Secretary consider adopting the version expected to be in effect at the time the transactions standards are mandated. Version 6020 of the X12N 278 is the most current version of the referral certification and authorization transaction standard."*

WEDI Response
In its 2016 letter to the Secretary, the NCVHS specifically stated: *"(*) For all of the above X12 transactions, the Secretary should consider adopting the HIPAA version that will be expected to be in effect by the time these transactions are mandated."* As CMS has cited this letter in the NPRM, we urge the agency carefully review the availability of updated versions throughout the rulemaking process and seek to name the most current version of the standard in the final rule. This will ensure the industry will implement and take advantage of the most up-to-date version.

In our survey, we asked the following question: *"CMS has proposed to adopt the X12 6020 version of the 275 attachment standard. If CMS moves forward with the 275, what version of the standard should be implemented?*" Participants answered: 5010 (2.4%), 6020 (14.3%), 8020 (7.1%), The final rule should identify the most current X12 version of the standard (36.9%), and Unsure (39.3%).

We note that should CMS move forward with the proposed standard, and the requirements of the most up-to-date version differ significantly from what was proposed by CMS, we recommend the agency release an Interim Final Rule with Comment and solicit public input on the changes.

NPRM Issue: LOINC Codes
"The Attachment Implementation Guide contains three criteria that any document template to be used as a health care 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 health care attachments transaction. We invite comment on the proposed adoption of the HL7 standards—Volume One, Volume Two, and the Attachment Implementation Guide."

WEDI Response
We believe that the above statement from the NPRM permits flexibility for newly defined or updated templates to expand standards-based coverage of the currently permissible

Logical Observation Identifiers Names and Codes (LOINC) codes as well as any newly established LOINC codes. WEDI supports the approach of facilitating ongoing improvement in standards-based attachment content. We note that, typically, templates are maintained in the C-CDA Companion Guide. This guide is currently on Release 3, although work is underway at HL7 to upgrade to Release 4 using Regenstrief LOINC encoding of templates. As the SDO, HL7 believes the guide would be an appropriate place to maintain relevant and related templates.

This proposed approach would avoid having the final rule name the most current CDA C-CDA Companion Guide release and having CMS then required to publish frequent rule updates to enable new or updated templates to be available for health care attachments under HIPAA. The continuing development of templates is also frequently driven by the ONC United States Core Data for Interoperability (USCDI) requirement to include new data classes and elements to address emerging health equity, value-based care, and other health care requirements.

NPRM Issue: Differing Opinions on the Appropriate Standard
"*Based on the NCVHS's previous recommendations to the Secretary, and particularly in consideration of its most recent March 30, 2022 recommendation, we propose here a document-based attachments standard. We acknowledge that there is a growing base of evidence that may, in the future, support our proposing attachment standards relying on other technologies such as FHIR®, and we will continue to monitor and evaluate emerging technologies for their readiness to potentially propose in future rulemaking…The HL7 CDA standard is the only currently available SSO-created, NCVHS-recommended standard in the United States with published implementation specifications designed to support the HIPAA transactions. Other standards for the exchange of clinical information are being developed and piloted but, due in part to its readiness, we believe the HL7 CDA is the most appropriate standard for adoption at this time.*"

WEDI Response
We recognize that there are different opinions in the industry regarding he optimum approach for electronic attachments. We are concerned that CMS has relied on the 2016 attachments recommendation letter from NCVHS when developing this NPRM. Those recommendations, issued almost seven years ago, were accurate at the time. However, several industry actions have taken place after the 2016 set of recommendations was submitted to HHS. For example, the bipartisan Cures Act had not been passed and the industry did not have the ONC requirement for health IT developers to certify compliance with Fast Healthcare Interoperability Resources (FHIR). As well, the industry did not have a patient access application programming interface (API) rule, which covered payers are now required to support. Finally, the NPRM proposing the Prior Authorization Requirements, Documentation, and Decision (PARDD) API had not been released.

As HHS did not act on the 2016 NCVHS recommendation, HL7 developed its Da Vinci Project to advance FHIR interoperable standards, including CDex. We note that CMS operational staff have been involved in the Da Vinci Project as well as private sector technical staff. CDex provides multiple real-time capabilities with attachments/supporting

documents between provider and payers for claims, including Solicited, Unsolicited, Request for information, Questionnaires.

While CMS cites in the NPRM the March 30, 2022 NCVHS recommendation letter in proposing only a documents-based attachments standard, we believe in that letter NCVHS is calling for a more flexible approach to attachments. We reference the following recommendation from that letter:

> *Recommendation 3: HIPAA transaction rules notwithstanding, evaluate and adopt regulatory flexibility strategies to permit HIPAA Covered Entities to implement new technologies such as FHIR standards and implementation guides (IGs).*

Further, we cite the NCVHS July 2022 letter to the HHS Secretary where they recommended the following:

- *"NCVHS recommends that HHS update relevant HIPAA policies to allow the adoption and use of more than one standard per business function.*
- *NCVHS recommends that HHS enable HIPAA Covered Entities to support one or more versions of adopted standards for business functions*."

As we noted earlier, absent a national standard, use of the X12 275 electronic attachments has been limited. However, we have heard from a number of our payer members that they are currently using the 275 transaction for claim attachments with some of their provider partners, and have been doing so for several years. They report that both payers and providers experience demonstrable value in conducting the transaction. (At the same time, we understand that payers and providers could deliver CDA documents using CDex.)

We also recognize that the industry has been without a standardized attachment solution. Members have commented that any improvement in the process of exchanging clinical data in support of claims and prior authorization would be a step in the right direction. For example, moving an unstructured PDF document from the provider to the payer, while not ideal and would still involve manual processes, would be a significant improvement from what typically occurs today and would be of benefit to both providers and payers. At the same time, the ultimate goal of this regulatory process should be to digitize and automate the data exchange process as much as possible.

Should they be nationally adopted by regulation, new API-based technologies could prove as or more efficient for attachment transactions, especially prior authorization. We believe FHIR offers potential advantages, including a reduced level of manual intervention in the transaction leading to decreased labor costs and more precise information exchange that could result in fewer follow up communications between providers and payers. As well, HL7 reports that CDex can effectively work in tandem with the PARDD API, leading to a more efficient prior authorization process for both providers and payers.

We also note that the FHIR CDex IG is a standard that supports current federal interoperability objectives, the administrative simplification goals of reducing burden and improving efficiency and aligned with the ONC certification program. Importantly, the CDex IG supports all commonly used data formats exchanged between providers and payers, including C-CDAs, PDFs, and text files. Further, we note that a FHIR-based data exchange process could be leveraged by providers and payers for purposes beyond prior

authorization transaction. For example, FHIR could potentially be used for audits, quality program reporting, risk adjustment reporting, and to support value-based care programs.

The NCVHS recommendations on attachments were based on a hearing that was conducted in February 2016. We urge CMS to closely review all potential attachments standards for both claims and prior authorization prior to issuing a final regulation.

Our MPA event included a question to the attendees asking them to rate their preference in terms of a standard for electronic attachments. Below is the question and attendee responses:

QUESTION: What option do most support?

Answer	% of Votes
Option 1-finalize the proposals (with or without modifications) for claim and prior authorization	14%
Option 2-split the regulation and support only claim attachments	7%
Option 3-withdraw the entire NPRM and reissue a new NPRM	7%
Option 4- Allow both standards to be used	68%
Option 5- Adopt only a FHIR Solution	4%

Based on this poll result and MPA discussion, WEDI members favor CMS taking an approach in the final rule that supports industry adoption of both the X12-based and FHIR-based standards options. WEDI stands ready to aid CMS in better understanding the potential challenges and potential benefits of each attachments approach and assist CMS and the industry identify and deploy best practices for implementation.

NPRM Issue: Named Standards
"*For requesting attachments, the following standards:*

- *For claim-related attachment requests, the ASC X12N 277 Health Care Claim Request for Additional Information.*
- *For non-claim-related attachment requests, the ASC X12N 278 Health Care Service Review—Request for Review and Response—Response.*
- *For attachment message content and format in the transmission of attachment information, the following standards:*
    - *The HL7 CDA R2—Consolidated CDA Templates for Clinical Notes R2.1.*
    - *The HL7 Attachment Supplement Specification Request and Response Implementation Guide R1.*
    - *The Attachment Type Value Set: Logical Observation Identifier Names and Codes (LOINC) developed and maintained by the Regenstrief Institute, Inc."*
    - *The HL7 Implementation Guide for CDA Release 2: Additional CDA R2 Templates—Clinical Documents for Payers—Set 1.*

- *For the routing/envelope of attachment information, the following standards:*
    - *The ASC X12N 275 Additional Information to Support a Health Care Claim or Encounter.*
    - *The ASC X12N 275 Additional Information to Support a Health Care Services Review.*

We are proposing to adopt the following three HL7 implementation guides as HIPAA standards for the attachment information included in health care attachments transactions:

- *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 (hereafter Volume One or C–CDA Volume One or C–CDA 2.1)*
- *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 (hereafter Volume Two or C–CDA Volume Two or C–CDA 2.1)*
- *HL7 CDA R2 Attachment Implementation Guide: Exchange of C–CDA Based Documents, Release 1, March 2017 (hereafter the Attachment Implementation Guide).“*

WEDI Response
We note that the HL7 CDA R2 Attachments Implementation Guide: Exchange of C-CDA Based Documents, Release 1 (March 2021) is a retired version. An updated IG was released in March 2022. As well, The CDP1 was never used and the HL7 Attachments WG now Payer/Provider information exchange WG retired this guide.

As we have previously stated, we urge CMS to carefully review the availability of updated versions throughout the rulemaking process and seek to name the most current version of a standard in the final rule. This will ensure the industry will implement and take advantage of the most up-to-date version.

NPRM Issue: Control Number
“The X12N 277 contains two noteworthy fields, which we discuss sequentially. The first is the health plan assigned claim control number, which allows for document reassociation. A health plan assigns a claim control number to associate its request with a provider’s electronic health care claim. The health care provider then uses the health plan assigned claim control number in the X12 275 standard in the health care attachments transaction, discussed later in this proposed rule, that it transmits to the health plan, enabling the health plan to associate the attachment information with the previously submitted health care claim.”

WEDI Response
WEDI supports the proposed approach to assign a claim control number. This will simplify data exchange and most importantly permit document reassociation. We note that this

approach is already used in health care with the Trace Number Segment requirement to reassociate the electronic payment with the electronic remittance. We heard from members that have implemented the 275 that they have been utilizing control numbers for over 10 years across different lines of health care business and have encountered no issues. We also understand that CDex has simplified data elements for submission and request of electronic documentation for claims and prior authorization. Included in CDex is the Tracking ID (Provider or Payer Assigned). Provider or Payer assigned tracking control number to support solicited and unsolicited supporting documentation.

NPRM Issue: Electronic Signatures

"*We are proposing to define the term ''electronic signature'' as broadly as possible to ensure that it meets health care providers' and health plans' needs now and can also encompass future electronic signature technologies. However, we propose to narrowly specify the scope of the required use of electronic signatures, such that their required use would be limited to just attachment information transmitted electronically in electronic health care attachments transactions. Accordingly, the electronic signature standard we are proposing at § 162.2002(f) would pertain only to electronic signatures for attachment information transmitted by a health care provider in an electronic health care attachments transaction.''*

WEDI Response

Obtaining a signature can be an important component of the revenue cycle process. It can be the indicator to the payer that the submitted patient data has been reviewed and approved by a provider who has the appropriate authority to supervise care. Health care entities recognize numerous legal and compliance standards and best practices for clinician attestation of medical record documentation consistent with applicable federal and state laws, accreditation standards, payer requirements, and documentation requirements for clinical services offered.

The electronic signature requirement, outlined in the preamble of the NPRM, supports specific uses, including the ability to authenticate the user (whoever is actually attesting to the data being transmitted), ensuring the message integrity of the notification, and guaranteeing non-repudiation. The proposed rule also proposes to define the term "electronic signature" as broadly as possible to ensure that it meets current and future stakeholder needs and available technologies. We concur with CMS to limit the scope to of electronic signatures to attachment information transmitted electronically.

We have heard from members that some platforms can delete electronic signatures upon submission. We recommend CMS explore adding an attestation element that a provider would either check or have in their documentation that attests to the signature being present upon submission. Otherwise, there could be 'electronic signatures' that disappear with an electronic submission, giving the impression that there was never a signature which could problematic should an audit be conducted.

Finally, in today's current attachments environment, especially with claim submission, most attachments are being transmitted without a signature. They are, however, authenticated between trusted trading partners. We caution CMS to avoid adding unnecessary burden on the industry by requiring electronic signature for every transmitted

attachment. Electronic signatures should only be used when there is a specific request for one by the payer.

As electronic signature standards will need to be harmonized with a named attachment standard, we strongly recommend CMS harmonize this standard with its approach to claims and prior authorization attachments.

NPRM Issue: Implementation Specifications
"Accordingly, we are proposing to require that, where a health care provider uses an electronic signature in a health care attachments transaction, the signature must conform to the implementation specifications in the Digital Signatures Guide. Specifically, we propose to adopt, at § 162.2002(f), the HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1 for electronic signatures for attachment information transmitted by a health care provider in an electronic health care attachments transactions specified in § 162.2001(a). We also propose to incorporate the same by reference in § 162.920."

WEDI Response
CMS is proposing to adopt the HL7 Implementation Guide for CDA® Release 2: Digital Signatures and Delegation of Rights, Release 1 (Digital Signatures Guide). We concur that this guide ensures the implementation of the three necessary features by utilizing digital signature technology to implement identity management using digital certificates, encryption requirements to support message integrity, and multiple signed elements to support non-repudiation.

We note, however, that CMS did not include the digital signature implementation guide in the regulation language and the codification of the electronic signature standard that was named in the preamble was not included in list of codified changes. As well, the guide cited in the preamble is only relevant for the C-CDA and would not, for example, apply to a FHIR bundle. Should CMS move forward and include the ability to exchange FHIR-based information, we recommend also using one of the FHIR solutions for applying a digital signature.

Conclusion

We commend CMS for seeking to advance administrative simplification and address the long-standing need for electronic attachments standards. We are confident that the identification of appropriate attachments standards will reduce health care costs for payers and providers, increase efficiency, and improve the care delivery process for patients.

It is important to recognize, however, that there are divergent viewpoints on the best direction for the industry to take on attachments. With the most recent NCVHS hearing now more than seven years ago, we believe the best approach would be for CMS to closely review each attachments option in support of claims and prior authorization transactions before issuing a final regulation. We appreciate the opportunity to share our perspective regarding this important NPRM and we stand ready to work with CMS to identify the optimum pathway forward. Please contact Charles Stellar, WEDI President & CEO, at cstellar@WEDI.org to discuss these comments and recommendations or explore

opportunities to educate impacted stakeholders.

Sincerely,
/s/
Ed Hafner
Chair, WEDI

cc: WEDI Board of Directors