Statement To

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS

SUBCOMMITTEE ON STANDARDS

REGARDING: Attachments Standards and Operating Rules – Industry Perspectives

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on behalf of WEDI

Members of the Subcommittee, I am Durwin Day, Legal and Regulatory Implementation Strategist with Healthcare Services Corporation and a member of the Workgroup for Electronic Data Interchange (WEDI). I would like to thank you for the opportunity to present testimony today on behalf of WEDI, concerning the matter of attachments standards and operating rules.

WEDI represents a broad industry perspective of providers, clearinghouses, payers, vendors and other public and private organizations that partner together to collaborate on industry issues. WEDI is named as an advisor to Health and Human Services (HHS) under the Health Insurance Portability and Accountability Act (HIPAA) legislation and we take an objective approach to resolving issues.

BACKGROUND

Section 1104 of the Patient Protection and Affordable Care Act (ACA) contains the requirement that:

The Secretary shall promulgate a final rule to establish a transaction standard and a single set of associated operating rules for health claims attachments

In 2004, The WEDI Foundation convened a payer (Empire Medicare Services), a practice management system vendor (NextGen), and participating providers to conduct a pilot to test electronic health care claims attachments. The providers represented the Medicare Part A and Medicare Part B lines of Empire Medicare Services (both institutional and professional providers). Under the pilot, Empire Medicare services electronically provided requests for additional information from providers using the ASC X12N 277 Health Care Claim Request for Additional Information implementation guide and used Logical Observation Identifiers Names and Codes (LOINC) to indicate what information was being requested. Providers responded to the ASC X12N 277 request by generating the ASC X12N 275 Additional Information to Support a Health Care Claim or Encounter transaction with the embedded Health Level 7 (HL7) Clinical Document Architecture (HL7 CDA), sending that electronically back to the payer. This pilot identified several issues that needed to be addressed, while demonstrating the value / ROI of this transaction to the participants.

More recently, the WEDI Attachments sub work group has focused on gathering industry perspectives and developing comments in anticipation of this NCVHS hearing. This was not an official policy advisory group, so formal votes on recommendations were not taken. WEDI offers the following comments for your consideration.

1. Transaction Standard

   WEDI agrees with the ASC X12N recommendation to name the ASC X12N 277 (Health Care Claim Request for Additional Information) and ASC X12N 275 (Additional Information to Support a Health Care Claim or Encounter) in the Attachment Rule. However, the choice of version for these documents would need to be vetted within the industry in consideration of the multiple uses for attachments. For example, the ASC X12N 6020 versions were updated to accommodate requirements by the Medicare project, electronic submission of Medical Documents (esMD).

   The electronic exchange of data between the provider and the payer is an established process using trading partner agreements to manage the exchange of the ASC X12N transactions. To be cost effective for exchanging clinical information, we should build on that same process by using the ASC X12N 275 as an envelope for the attachments.

   Although we recognize that there are other methods to envelope and transport the attachment information, we believe that they should be identified as a trading partner option for now, and left for consideration in future regulation. With the emergence of Meaningful Use of Electronic Health Records (EHRs) and the use of Health Information Exchanges (HIEs) these and perhaps other options may prove to be viable alternatives.

2. HL7 recommendation

   WEDI agrees with the HL7 recommendation to name the HL7 Implementation Guides for CDA Release 2: IHE Health Story Consolidation, Draft Standards for Trial Use (DSTU Release 1.1), along with the HL7 Supplement to the Consolidated CDA Templated Guide. Both are HL7 CDA Release 2 standards that will give stakeholders the guidance they need to implement

the attachments at various levels of technical readiness. HL7 CDA allows for the exchange of unstructured medical documents and to also develop the capability to exchange structured documents, when available.

The HL7 CDA R2 Implementation Guide for Consolidated Templates is also named as the clinical document standard named under the Meaningful Use Stage2 requirements of EHRs. This will allow providers to send clinical documents to payers using the same mechanisms as they must use with other stakeholders.

3. LOINC Codes

WEDI agrees with HL7 that the Attachment Rule should not name the specific LOINC codes used to identify types of unstructured attachments. The external LOINC code set should be referenced in the rule as the code set to be used to identify the unstructured attachment types. This will allow the industry to continue to request and use additional LOINC codes for attachments which are needed to meet their business needs. This process will address industry needs not included in the structured Consolidated CDA Templated Implementation Guide.

4. Definition

WEDI offers the following definition for attachments:

- An electronic attachment is supplemental documentation needed to support a specific health care related event (e.g. health care claim, authorization, referral, etc.) using a standardized format.

As such, the requirements associated with attachments should not focus so narrowly on claims that it would restrict the capability to use attachments for other business transactions.

5. Other Uses

WEDI believes that the Attachment Rule should be limited to Claim Attachments. However, the rule should recognize and allow for the standard to be used for purposes such as Authorizations, Referrals, and Post Payment Audit situations. The Attachment Rule should be aligned with other attachment standards being used for Meaningful Use and exchange between providers. With this recommendation, the Attachment Rule may need to recognize the potential usage of the ASC X12N 275 (Additional Information to Support a Health Care Service Review) as well as the already named ASC X12N 278 (Services Review Request for Review) guides. However, there is a concern that a mandate that includes attachments for transactions other than claims may impact the implementation of attachments by broadening the scope. WEDI is prepared to assist the industry with the implementation of any mandated Attachment types.

6. Solicited versus Unsolicited Attachments

WEDI believes that the Attachment Rule should mandate the use of "Solicited" Attachments, while "Unsolicited" attachments could be implemented based on trading partner agreements. Both 'solicited and unsolicited' can expedite the time required for the adjudication and payment process. Under the 'Unsolicited' method, trading partner agreements will define the criteria for specific conditions when an attachment is needed. The benefits would be realized when a provider sends the attachment information without expending the time and resources to have to respond to a request for additional information.

7. Rule Type

   WEDI believes that the attachment rule should be published as a Notice of Proposed Rule Making (NPRM). Since the publication of a NPRM on Attachments in 2005, the industry has been aware of the business benefits and technical requirements to implement Attachments. With the guidance from that NPRM, some stakeholders have voluntarily implemented attachments. They have reported benefits from electronically exchanging attachment information, and we encourage others in the industry to realize these benefits as well.

   While use of an NPRM now could potentially delay publication of a final rule, it is essential that the industry have additional opportunity to comment on this important item. It has been eight years since the original NPRM and much has happened during that time. Since it is unknown what might be included in an Interim Final Rule and the reduced ability to amend provisions, use of an NPRM would allow the industry to identify any critical concerns that may be present or clarifications that may be needed. WEDI would also be willing to conduct a Policy Advisory Group in order to gather industry input.

8. Education and Outreach

   WEDI encourages the Department of Health and Human Services (HHS) to work with WEDI to promote education and outreach in order to facilitate industry implementation.

9. Transaction Acknowledgements

   WEDI supports Acknowledgements to be named as regulation. However, WEDI believes that the Attachment Rule should not address application Acknowledgements for Attachments at this time. The Standard Development Organizations have not come to a consensus on how to acknowledge the combined standard transaction of the ASCN X12 and HL7 at the application level. The SDO's continue to work on an industry solution that will acknowledge the XML piece of the 275 transaction. Until the acknowledgement development is complete the Attachment acknowledgement should not be included in the Attachment Rule. WEDI encourages the Department to consider WEDI's previous recommendations on the use of Acknowledgements.

OTHER CONSIDERATIONS

1. What is the current state of industry with respect to the exchange of standard clinical information to support administrative or financial transactions? Since the publication of a NPRM on Attachments in 2005, the industry has been aware of the business benefits and technical requirements to implement Attachments.

   Most of the industry is still using paper methods and postage delivery. Some are sending fax documents in response to phoned requests. Resulting issues include: increased cost of postage and handling, loss of documents, and delayed processing of claims.

   Few have implemented an electronic solution based on the guidance in the 2005 NPRM. Known electronic implementations are using the ASC X12N 275 with an unstructured embedded document, such as a pdf or jpeg. Some provider/payer trading partners have agreed to rules for sending unsolicited attachments, such as the presence of a Modifier 22.

   Most of the current implementations utilize the ASC X12N 275 to envelope the attachment information for the delivery. The electronic submission of medical documentation (esMD) project used the ASC X12N 275 in addition to using an IHE XDS (Integrating the Healthcare Enterprise – Cross-Enterprise Document Sharing) profile to envelope the attachment documents. They also use the ASC X12N 277 to request the documents. These implementations used an unstructured format for the clinical content. Structured clinical content for the attachments has yet to be used for the exchange between providers and payers. The original HL7 Attachment guides and the HL7 Consolidated CDA Templated Guide are both HL7 CDA Release 2 standards with similar clinical content.

2. For this transaction, can we predict the technological state of the industry so that we adopt standard(s) that provide consistency, yet are flexible enough to take advantage of emerging systems and technologies?

   HL7 CDA is designed to allow for the growth of the industry. HL7 CDA provides for 'unstructured' documents (pdf, jpeg) to be exchanged and rendered as human readable information. HL7 CDA structured documents can be either rendered as human readable or it can be processed by a computer. By using HL7 CDA, the industry can easily mature new attachment types by first introducing the type as an unstructured document, and then developing the attachment as a structured document with defined data requirements.

   The HL7 CDA standard is transport agnostic and can therefore be exchanged through a variety of available environments. For the foreseeable future, the ASC X12N 275 transaction would be used as an envelope for the attachment.

3. With regard to claims attachment or attachments in general, what is the role of operating rules in relation to the transactions; i.e. what problems could they solve? What problems do they create? How can the process of development be improved?

Operating rules can provide the industry with guidance on the enveloping and transport options to exchange attachment documents. Other operating rules may need to be defined once the standards for attachments have been identified and understood.

4. Overall, what would you say are the most significant benefits we should expect to see (i.e., efficiency, quality, safety, economic, other) that we can rely upon to monitor progress and measure success? Where do you think would benefit realization be most challenging?

   Both providers and payers should realize dollar savings by eliminating postage and handling. Electronic processing should also prevent loss of documents and can expedite the processing of claims. The attachment will be handled and viewed only by appropriate staff and provides for better control of PHI. Requests and responses will be for specified document types, and not just an entire medical record. Attachments may also provide improved services and quality of care for patients through support for care management, transition of care and care coordination.

5. How would use of existing infrastructure or infrastructure that will be in place by 2016 impact costs and savings? Providers, health plans and vendors are asked to speak about this from their individual perspectives.

   With the development of EHR technology, the availability of software to providers (large and small) to produce and access many of these clinical documents is becoming more commonplace and necessary with Meaningful Use requirements. This increased participation of exchanging these documents using Health Information Exchanges and web portals will also provide another method for these documents to be exchanged among trading partners. Many organizations already have some infrastructure in place for information exchange, and follow suggested operating rules.

6. With respect to operating rules, what areas related to attachment transactions do you see are most important to address through the creation of operating rules?

   WEDI would be willing to conduct a Policy Advisory Group to help address this issue.

   Some examples of areas that may need to be addressed include guidance and criteria on the options for exchanging (transporting) the attachment documents. Another may be timeframes for how long a provider would have to respond to a request. This should not be determined by operating rules, but the operating rules should describe the need for the time frames and how each party could be impacted. It should be a relatively simple process to understand and shouldn't require ongoing monitoring of thousands of entities and their unique processes.

7. Are the current set of standards (and operating rules) you have heard about applicable only to claim attachments, or will they be applicable also to other types of attachments?

   WEDI supports the usage of the attachment standards for functions in addition to the need of claim payment. These same attachment types can support prior authorization and post pay. The attachment standards and support other types of documents that could be exchanged for care management, However, for the reasons stated above (#5 Other Uses), we believe that the rule should be limited at this time.

8. What are some of the most important business and technical issues surrounding attachments for providers, health plans, and vendors, and how would you recommend addressing them?

   Education will be needed to prepare stakeholders in the industry to understand and implement the standards and operating rules for Attachments. HL7 CDA standards and LOINC codes will be a new technical challenge to implement.

   Options on how to exchange attachments and clinical information will need to be coordinated between trading partners.

   Providers will be challenged with capturing the requested document and executing the choice of delivery methods. EHRs and transcription software should develop and mature over time to help ease these tasks for providers.

CONCLUSION

WEDI supports the need to assure that attachments standards and associated operating rules are implemented in a timely and effective manner to enhance the use of EDI in healthcare. While use of electronic attachments will be beneficial, it is important to consider the return on investment and to devise a process that minimizes cost and maximizes benefits. The process must add value, be easy to understand and easy to follow. It must consider not just the impact to providers and health plans, but the cost to trading partners and software vendors.

We want to emphasize the need for all entities to work together, in close collaboration, to avoid conflicts and ensure successful implementations and more industry consistency both now and in future implementations. Moving forward the industry should carefully consider how best to ensure that the iterative process between operating rules and standards provides the most ROI and industry structures speak to the evolving landscape. WEDI in its advisory role offers our support to NCVHS and HHS in helping to achieve these goals and stands ready to assist as needed.

Members of the Subcommittee, thank you for the opportunity to testify. This concludes our statement.