Statement To
DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
SUBCOMMITTEE ON STANDARDS

Panel 2 - Attachments

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Members of the Subcommittee, I am Durwin Day, member of the Workgroup for Electronic Data Interchange (WEDI) Board of Directors and Supervisor at Health Care Service Corporation. I would like to thank you for the opportunity to present testimony today on behalf of WEDI concerning the adoption of standards for Attachments.

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

BACKGROUND

Section 1104 of the Patient Protection and Affordable Care Act 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 implementation guide and used LOINC codes to indicate what information was being requested. Providers responded to the ASC X12N 277 request by generating the ASC X12N 275 transaction with the embedded 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.

Responses to the Questions:

- How were the proposed standard and code sets developed? (Please provide timeline and industry input in the development; process for vetting, etc.)
  - Has there been an industry-wide representation of stakeholders that have agreed with the Proposed Standard and code sets?
  - What lessons learned from **previously adopted standards** have been applied to the proposed standard and code sets?

The HL7 Attachment Work Group (AWG) worked with payers and other industry stakeholders to identify the types of attachments needed to support claims and prior authorization of healthcare services.
The HL7 AWG collaborated with the Accredited Standards Committee (ASC) X12N Standard Development Organization (ASC X12) to define an electronic transaction that could be used to support the request for Attachments. The ASC X12 277 Health Care Information Status Notification Transaction Set was the most viable ASC X12 option.
The HL7 AWG determined that a proposed claims attachment standard combining the standards development efforts of ASC X12 and Health Level Seven (HL7) would be one of the possible options to support sending an Attachment. The proposed solution was the ASC X12 275 Patient Information Transaction Set with the HL7 Clinical Document embedded within the BDS/Binary segment.
The HL7 AWG determined it was in the best interest of providers and/or their vendors to support only one way for the exchange of the clinical information. Rather than one standard for the provider-to-provider information exchange and another for provider-to-payer information exchange, the HL7 AWG agreed to adapt their approach to leverage and be consistent with the HL7 C-CDA formatting of clinical documentation.
The HL7 C-CDA Documents by themselves do not fully satisfy the needs of the industry for Attachments. Additional metadata/enveloping is needed to assist in the correct pairing with a healthcare administrative activity and the Attachment itself.

- What testing (including pilots) of the proposed standard and code sets have been done?
  - Which stakeholder entities were included in the testing (pilots included)?
  - Was the sample size for the pilot/testing statistically significant?
  - What were the outcomes of the testing (pilots included)?

'97 - CMS Pilot 277 Request 275 Unstructured
Hospitals understood 80+% of requests
Needed the use of LOINC codes to identify requests

'04 - Arizona Medicaid build 275 Unstructured from portal
Expedited payments

'05 - WPS, Mayo Clinic - Unsolicited 275, Unstructured
Expedited payments for provider, cost savings for payer

'05 - Empire Medicare, NextGen, Sloan Kettering, Montefiore, Claredi
277 Request, 275 Unstructured
Dramatic reduction in claim processing time
Issues with character count in 275 BIN Segment

'05 - HCSC, Availity – Unsolicited, Unstructured 275
Expedited payments;
Move from paper documents to electronic images

'08 - Jopari, Property and Casualty - Commercial
277 Request, 275 Unstructured
5 Year Study stakeholders reported significant decrease cost and increase efficiencies

'13 - esMD, Unstructured 275

'14 - NGS Anthem, Mayo Clinic
Unsolicited, 275 Unstructured text

'15 - Humana, Availity, 3 Providers(Gould Medical, Ohio Health, TMH Physicians)
277 Request, 275 Unstructured

■ Does the proposed standard comply with and support existing standards used in other transactions and programs (for example, Meaningful Use)?
Absolutely!!!~

HL7 standard identified for Meaningful Use Stage 2 is also proposed for adoption for Attachments.

- *HL7 CDA R2 Consolidated CDA Templates for Clinical Notes R.2.1* – May 2014
  - Contains Implementation specification for 12 structured document types and Unstructured documents
    - Care Plan
    - Consultation Notes
    - Continuity of Care Document*
    - Discharge Summary
    - History and Physical
    - Diagnostic Imaging Reports
    - Operative Note
    - Patient Generated Document
    - Progress Note
    - Procedure Note
    - Referral Note
    - Transfer Note
    - Unstructured
- Providers can send the same clinical document to payers as they send to other providers.

■ In addition to the use of the proposed standards and code sets in health care claims transaction (Claim Attachments), what other transactions can the standard support (for example, eligibility, prior authorization, post-paid claim audits).

- *HL7 CDA R2 C-CDA Templates for Clinical Notes 2.1*
  - Implementation specification for structured document types and Unstructured documents
  - The 12 structured document types include attachments that are applicable to:
    - Eligibility
    - Prior Authorization
    - Referrals
    - Post Pay Audits
    - Notifications
- These are the same HL7 standard documents that are used for exchanging EHRs, PHRs, and other clinical information.

■ Do the proposed standard and code sets support the intended business function/intended use?

○ Does it provide a complete set of information needed to achieve the purpose of the transaction?

○ Does the standard achieve the transaction in the fastest, simplest, and cost –effective manner?

Yes. As business needs change and the standards are widely implemented, the list of Attachment types may need to change. A process is described in the Supplemental Guide under the LOINC section.

Through the HL7 Attachment Work Group:

New LOINC codes can be added to the Unstructured Panel to allow trading partners to identify the new documents they want to exchange. If desired, a new document template can be created as a future structured document that could become part of the Consolidated CDA or exist as an independent CDA document.

■ What is the potential impact of the standard to various health care entities (providers, payers, etc.) on the daily workflow/transaction process; administrative costs, required capabilities and agility to implement the operating rules changes?

○ Does the proposed standard provide efficiency improvement opportunities for administrative and/or clinical processes in health care?

○ Has the potential for decrease in cost and improved efficiency been demonstrated by using the proposed standard

- Payers perspective
  - Under HIPAA a Payer must be able to receive and send the standards, if a provider elects to do electronic exchange.
    - HL7 CDA standards will be new to most payers
    - LOINC codes will also be new to payers
    - Other methods of transport may also impact payer workflow
- Providers perspective
  - Providers will need to automate their EHR system to link with their Practice Management System (billing)
  - Providers would like to have one standard to create, not multiple standards that would require them to create a different 'version' of a clinical document depending on varied payer requirements.

- Does the proposed standard and code sets support changes in technology and health care models? Does it support different forms of performing the transactions they relate to? Does it support the new, emerging alternative payment models?

The HL7 CDA standards are agnostic to transport methods and should therefore be transparent to emerging technology for transport.

These standards are designated for 'trial use' and can be open to changes for emerging payment models. The attachment standard provides an industry on-ramp to provide integration of clinical and administrative data.

- How will the proposed standard provide consistency or limit the degree of variability to achieve optimal intended results?

Using the EDI X12 Standards provides consistency in the information exchange between providers/payers. Allows use of existing infrastructure

HL7 C-CDA R2.1 allows for minimal required data and flexible optional data.

HL7 CDP1 requires similar data content as HL7 C-CDA, but conformance statements that requires a response for all elements. In the CDP1, if there isn't any data to report, then a null-value must be used.

- How will the proposed standard and code sets demonstrate or ensure ease in adoption and use?

Implementers will need different skill sets than those used for EDI.

Pilots demonstrated sending and receiving unstructured documents was the low-bar to rapid implementation.

WEDI can help the industry with building a roadmap for implementation and to gather experiences from other industry stakeholders as they implement.

- Will system changes be required by the industry to implement the proposed standard and code sets?

Yes, providers, payers EHR vendors and clearing houses that have not implemented these transactions will have to update their systems.

- What amount of time is needed for the industry to implement the proposed standard?

Depending on the experience, education and skill set, it could be a year or more for analysis and planning.

New standards, code sets and work flows impact the implementation schedule.

Development and Implementation time could be 2-3 years from the date of the final rule.

Using HL7 Standards and LOINC codes will be relatively new to Payers that currently process EDI transactions.
Providers have experience with clinical information exchange in their clinical environment but not in their administrative departments.
Vendors and clearinghouses will need to be early adopters.

- Has HL7, ASC X12 & LOINC developed strategies to measure the impact of adopting the proposed standard on the industry?

WEDI could assist the industry in developing strategies.

- What is the envisioned product life cycle, i.e., how long will the proposed claim attachment standards meet industry needs and what is the frequency and size of maintenance updates to the standards and associated code sets?

CDA templates provide a reusable architecture. Document templates are built from Section Templates. Section templates can be copied and used in other Document templates, much like Lego Blocks. This architecture provides the flexibility to build new documents to implement new business needs. As the new structured document templates are being created, the use of unstructured document types can be used to satisfy the business needs.

This will be on ongoing process. And new standards are emerging with advances in technology.

At HL7 the DSTUs have two years to make changes from the industry user's experiences before becoming a normative standard.

ASC X12 is in the process of internal review for version 7030 that will complete by end of 2016.

- Has HL7, ASC X12 & LOINC developed metrics to measure the effectiveness and value of adopting the proposed standard? What are they?

Not aware that any metrics exist.

WEDI can assist the industry on this topic.

- Does the proposed standard incorporate privacy, security and confidentiality?

Use of the ASC X12 transactions allow attachments to use the same secure channels used by today's HIPAA transactions.

- How will the attachment standard support interoperability and efficiencies in a health care system?

HL7 C-CDA is maturing as more implementations are experienced.
Having a defined standard will bring consistency across the industry.

- Can the proposed standard be enforced? How?

Yes. By compliance with conformance statements defined in HL7 C-CDA templates.

- Why should NCVHS recommend the adoption of the standard and code sets?

To have the industry use the transactions so we can build adoption and drive enhancements and efficiencies.
Experience has shown that there are benefits and cost savings to providers and payers that have implemented these transactions.

CONCLUSION

In recognition of the value of the electronic Attachments discussed in today's testimony, we would urge the Subcommittee to strongly consider the items noted above. With more stakeholders in the industry implementing Attachments, it is an opportunity to avoid proprietary implementations by adoption of the proposed standards for Attachments. Thank you for the opportunity to testify; WEDI offers our continuing support to the Secretary and the healthcare industry.