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Terri Deutsch, M.S., RN, CMS
Senior Advisor
Centers for Medicare & Medicaid Services
National Standards Group (NSG)
7500 Security Boulevard
Baltimore, MD 21244-1850
Mail Stop: S2-26-17
Email: terri.deutsch@cms.hhs.gov

Dear Ms. Deutsch,

We would like to thank the committee for the opportunity given to the Accredited Standards Committee (ASC) X12 to provide written and oral testimony regarding the Phase IV Operating Rules and standards for attachments.

ASC X12 is an ANSI accredited standards setting organization (SDO) which was chartered more than 30 years ago. As an SDO, we develop and maintain EDI standards as well as XML schemas which drive business processes globally. ASC X12 membership includes technologists and business process experts, encompassing health care, insurance, transportation, finance, government, supply chain and other industries.

As you are aware, the majority of the administrative transactions adopted under the Health Insurance Portability and Accountability Act (HIPAA) were developed and are maintained by ASC X12. We are excited that the ASC X12 standards developed in support of attachments are also being consider for adoption and we encourage that adoption.

Please contact me if you need further information or have any questions.

Sincerely,

Stacey A. Barber
ASC X12N Chair

ASC X12 Testimony to the NCVHS Subcommittee on Standards

February 16, 2016

Operating Rules and Attachments Standards

Presented by Stacey Barber, ASC X12N Chair

ASC X12 was chartered by the American National Standards Institute more than 30 years ago and develops and maintains EDI standards and XML schemas which drive business processes globally. ASC X12 membership includes technologists and business process experts, encompassing health care, insurance, transportation, finance, government, supply chain and other industries. For additional information, visit www.x12.org.

Part 1 Operating Rules

Panel 1 – Health Care Claims

I would like to thank the committee for the opportunity to provide testimony on behalf of ASC X12 in regards to the Phase IV operation rules. Our position has not changed from when we provided testimony on the draft rules in February of 2015. ASC X12 feels that the business needs of the health care industry are met within the transaction content of the ASC X12 Technical Reports and we agree with the position CORE took in not including any data content requirements with the Phase IV rules.   The Phase IV operating rules are focused primarily on infrastructure and include requirements for the use of acknowledgments.   ASC X12 supports the adoption of acknowledgements through the regulatory process rather than by reference within the operation. We encourage the use of acknowledgements and recommend the ASC X12 Acknowledgement Reference Model (ARM) as guidance for adoption.

Furthermore, the Phase IV Connectivity rule limits submitter authentication requirements to a single method that was optional under previously adopted rules. This puts an undue burden on covered entities who are required to support the connectivity requirements while providers may choose to continue other methods.   We believe that any authentication supported in previously adopted rules for other transactions should automatically be supported in any operating rule that may be adopted for other covered transactions in the future.

Due to the fact that the Phase IV rules are infrastructure in nature, require use of acknowledgments that have not been formally adopted as transactions, and do not provide flexibility for user authentication, ASC X12 would not recommend any of the Phase IV operating rules for adoption.

Panel 2 – Enrollment/Disenrollment and Premium Payments

I would like to thank the committee for the opportunity to provide testimony on behalf of ASC X12 in regards to the Phase IV operation rules. Our position has not changed from when we provided testimony on the draft rules in February of 2015. ASC X12 feels that the business needs of the health care industry are met within the transaction content of the ASC X12 Technical Reports and we agree with the position CORE took in not including any data content requirements with the Phase IV rules. The Phase IV operating rules are focused primarily on infrastructure and include requirements for the use of acknowledgments. ASC X12 supports the adoption of acknowledgements through the regulatory process rather than by reference within the operation. We encourage the use of acknowledgements and recommend the ASC X12 Acknowledgement Reference Model (ARM) as guidance for adoption.

On a separate note, the Phase IV rules for the Payroll Deducted and Other Group Premium Payment for Insurance (820) and Benefit Enrollment and Maintenance (834) transactions include requirements for using these transactions in real-time when these transactions have never been designed to be used real-time. As such, we feel that real-time requirements are out of scope for an operating rule and ASC X12 commented as such during the development of the rules. If the industry desires these transactions accommodate real-time exchange, ASC X12 is willing to address that in the development of future versions. Most trading partners are not currently conducting these transactions in a real-time environment as it is not feasible and further research on how these can be conducted in such an environment needs to be explored to ensure the standard accommodates all needs. Upon completion of such development, applying operating rules to that exchange is appropriate.

Furthermore, the Phase IV Connectivity rule limits submitter authentication requirements to a single method that was optional under previously adopted rules. This puts an undue burden on covered entities who are required to support the connectivity requirements while providers may choose to continue other methods. We believe that any authentication supported in previously adopted rules for other transactions should automatically be supported in any operating rule that may be adopted for other covered transactions in the future.

Due to the fact that the Phase IV rules are infrastructure in nature, require use of acknowledgments that have not been formally adopted as transactions, and do not provide flexibility for user authentication, ASC X12 would not recommend any of the Phase IV operating rules for adoption.

Panel 3– Prior Authorization

I would like to thank the committee for the opportunity to provide testimony on behalf of ASC X12 in regards to the Phase IV operation rules. Our position has not changed from when we provided testimony on the draft rules in February of 2015. ASC X12 feels that the business needs of the health care industry are met within the transaction content of the ASC X12 Technical Reports and we agree with the position CORE took in not including any data content requirements with the Phase IV rules. The Phase IV operating rules are focused primarily on infrastructure and include requirements for the use of acknowledgments. ASC X12 supports the adoption of acknowledgements through the regulatory process rather than by reference within the operation. We encourage the use of acknowledgements and recommend the ASC X12 Acknowledgement Reference Model (ARM) as guidance for adoption.

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Part 2 Attachments

Once again, thank you for opportunity to provide testimony on behalf of ASC X12 in regards to electronic attachments.

For close to 20 years now, ASC X12 and HL7 have been working together to develop standards for electronic attachments. Significant work has occurred to define the attachments and develop the standards to support those attachments. In testimony provided in February of 2013, ASC X12 recommended the following ASC X12 standards be adopted for electronic attachments:

- 278 Health Care Services Review – Request and Response version 5010
- 275 Additional Information to Support a Health Care Claim or Encounter version 6020
- 275 Additional Information to Support a Health Care Services Review version 6020
- 277 Health Care Claim Request for Additional Information version 6020

We stand by this recommendation with the exception of the 278 and are now recommending version 6020 of the 278 as well.

- ■ **How were the proposed standard and code sets developed? (Please provide timeline and industry input in the development; process for vetting, etc.)**

    - o **Has there been an industry-wide representation of stakeholders that have agreed with the Proposed Standard and code sets?**
    - o **What lessons learned from previously adopted standards have been applied to the proposed standard and code sets?**

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

All of the ASC X12 standards were developed following the ASC X12 standard technical report development process and are published in final form for voluntary use at this time. Industry-wide stakeholder representation was achieved through development, public comment, and informational forums leading up to ASC X12 approval and publication. ASC X12 evaluated issues identified from industry testing and limited implementation of the 5010 transactions supporting electronic attachment to improve the transactions in version 6020. Some testing has been conducted using version 6020 with entities preparing for production. ASC X12 is aware that the testing included providers, health plans, clearinghouses and vendor products. However, we are unable to quantify the sample size of the pilots.

- **Does the proposed standard comply with and support existing standards used in other transactions and programs (for example, Meaningful Use)?**

The ASC X12 standards recommended for electronic attachments align with other ASC X12 standards that have already been adopted. The 275 transactions support the movement of both structured and unstructured clinical data as a payload, allowing for flexibility in implementation. For example, the HL7 CCDA can be sent as structured data and images or PDFs can be sent as unstructured.

- **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).**

The attachment model supports unsolicited and solicited attachments. An unsolicited attachment refers to the act of providing attachment information that conforms to a set of rules-based criteria invoked at the time of the submittal of a healthcare administrative activity and in the absence of an explicit request. This information is based on advance knowledge of rules defined by the information receiver. A solicited attachment refers to the act of requesting and/or responding with attachment information which was requested after the healthcare entity determines a need for additional information to complete the healthcare administrative activity. The ASC X12 transactions for electronic attachments support claims, prior authorization and post-paid claim audits. Currently there is no functionality within the eligibility transaction to support attachment requests.

- **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?**

ASC X12 believes that the standards support the intended business need. In addition to the transactions, a joint effort between ASC X12, HL7 and WEDI has been ongoing to create a guiding principles document to assist the industry with the adoption of attachments. Through use and implementation of currently mandated standards and through testing of the attachment standards, we believe that conducting the proposed standards will provide the most efficient method of exchanging data.

- **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?

It is ASC X12's belief that the implementation of electronic attachment will be a benefit in the overall workflow and process. We also believe that expanded use of attachment for additional transactions other than claim benefits the industry. ASC X12 believes that through proven results in testing and limited implementation of the attachment standards, efficiency is achieved from the use of and processing of electronic attachments. As previously mentioned, most testing and implementation have used the 5010 versions. However, we are aware of some testing and implementations that have used 6020. We are also aware of organizations that have begun to evaluate the 6020 versions to future implementation. It is our understanding that operating rules in relation to attachments were put on hold due to no named standard. We are unable to evaluate if a decrease in cost and improved efficiencies have been achieved, but do believe that the conducting transactions electronically does provide the most efficient method to exchange data.

- **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 basis of the ASC X12 standards support and allow for changes in technologies. The ASC X12 275 transactions provide the linkage to associate the attachment to the claim or prior authorization and the wrapper of the structured and/or unstructured clinical data or other such attachment that must be transported and are agnostic to the transport method. Simply put it carries the clinical data and the information necessary to link the data to the related business document. As previously mentioned, the proposed standards can support both solicited and unsolicited models.

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

The adoption of a standard set of transactions for electronic attachments will impose consistent and uniform use of the transactions putting less of a burden on providers who are responsible for providing the various attachments as required for processing claims or prior authorizations. Through the testing and voluntary implementation of the ASC X12 proposed standards for attachments, efficiencies have been proven. By standardizing the encoding it allows vendors to support a single solutions across all stakeholders and all lines of health care business.

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

As the proposed standards accommodate both structured and unstructured data, a phased in implementation progressing from sending unstructured to structured data allows for flexibility in implementations. In addition, there are mechanisms to request specific information needed in the solicited model which removes the burden on the provider to "guess" what additional information is actually needed. This has been proven through the testing and voluntary implementation that has already been conducted.

- **Will system changes be required by the industry to implement the proposed standard and code sets?**
- **What amount of time is needed for the industry to implement the proposed standard?**

Yes. System changes will be necessary in order for entities to implement. ASC X12 recommends at least a 24 month implementation period.

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

We are unware of any impact analyses that have been conducted.

- **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?**

Since the proposed ASC X12 standards support the use both structured and unstructured clinical data, we feel that they meet the foreseeable needs of the industry. However, ASC X12 can enhance standards as needed.

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

We are unaware of any metrics that have been developed.

■ **Does the proposed standard incorporate privacy, security and confidentiality?**

They provide the same degree as other transactions that have been adopted. The infrastructure of the sender's and receiver's systems govern security and confidentiality and not the transaction themselves.

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

The proposed electronic attachment standards fit into a business model that supports interoperability. Again, it is the infrastructure of the sender and receiver that governs and provides the mechanism for stakeholders to achieve interoperability.

■ **Can the proposed standard be enforced? How?**

It is ASC X12's belief that the standards can be enforced based on the requirements outlined within the proposed standards.

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

There is a clear need in the industry to adopt electronic attachments. ASC X12 feels that our overall testimony has provided reasoning and basis for NCVHS to recommend the adoption of these standards.