HL7 Responses
National Committee on Vital and Health Statistics
Subcommittee on Standards
Hearing on Attachments,
February 27, 2013

BACKGROUND

Founded in 1987, Health Level Seven International is the global authority for healthcare information interoperability and standards with affiliates established in more than 30 countries. HL7 is a non-profit, ANSI accredited standards development organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7's more than 2,300 members represent approximately 500 corporate members, which include more than 90 percent of the information systems vendors serving healthcare. HL7 collaborates with other standards developers and provider, payer, philanthropic and government agencies at the highest levels to ensure the development of comprehensive and reliable standards and successful interoperability efforts. Its efforts are sponsored, in part, by the support of its benefactors.

On behalf of the HL7 Attachments Work Group (WG) we would like to thank the committee for the opportunity to provide comments on the current status of the Standards that support Attachments.

My name is Durwin Day, and I am a co-chair for the HL7 Attachments Work Group.
I am a Legal and Regulatory Implementation Strategist with Healthcare Services Corporation (HCSC), the Blue Cross and Blue Shield Plans for Illinois, Texas, New Mexico and Oklahoma. HCSC serves over 10 million subscribers, making us the largest non-for-profit insurer and the fourth largest insurer in the country.
HCSC has been a committed member and participant at HL7 since the establishment of the claim attachment workgroup in 1996.

My name is Jim McKinley, and I am also a co-chair of the HL7 Attachments WG. I work for Blue Cross and Blue Shield of Alabama and on my companies behalf have been actively involved with the attachments workgroup since 2005, serving as a co-chair the last 4 years.

1) **Are there multiple definitions of attachments under discussion, and what is the recommended definition of 'attachments' to be adopted under regulations?**

We define an Attachment as:

"An electronic attachment is supplemental documentation needed to support a specific health care related event (ex. Health care claim, authorizations, referral, etc.) using a standardized format".

The primary focus for attachments should address additional information for payer administrative functions to support claim processing.

Although we believe that there are other business uses for attachments to support prior authorizations, referrals, notifications and post adjudicated needs.
We further see attachments supporting other functions related to care management, care transition, care coordination, and risk adjustment.

The HL7 Attachment standards provide the industry with a path for growth that is platform and transport agnostic, and can be deployed on mobile platforms as well as mainframes and servers. These HL7 Standards can be leveraged to provide the information and support as the industry needs advance for patient centric transparency and new models for health care delivery.

2) **What are the priority business (health related) areas for which 'attachments' are necessary? How is this expected to change in the next five or 10 years?**

Attachments initially intended to meet payer needs for correct benefit administration and medical policy adherence for adjudication of a health care claim.

In the near future, we believe payer needs may expand to include needs for additional information of a clinical nature in support of care management, care coordination, transition of care, quality measurement and risk adjustment operational needs.

Migration away from Fee for Service to other re-imbursement models may alter the timing of additional information needs, from a pre-adjudication to a post-adjudication timeframe.

Attachment information may be utilized in telemedicine and patient centric health care models.

3) **What are the recommended approaches to the submission of 'attachments'?**

HL7 Clinical Document Architecture Standards support approaches to structured and unstructured document types. Structured CDA is designed to capture clinical information in an organized and codified manner. CDA allows for the parsing of clinical information specifying conformance criteria. Unstructured CDA allows the exchange of virtually ANY type of information in an electronic form. Use of external set of values for identification of valid attachment types allows for quick addition of new types of attachments.

Today payers and providers have a significant investment in their EDI departments for the sending and receiving of HIPAA ASC X12 transaction standards. One of the benefits of the HL7 CDA based standard for Attachments is it is transport agnostic and can be transported using a variety of transport protocols. NCVHS might consider allowing the adoption of various transport protocols either by trading partner agreement or operating rules.

4) **What is the status of development of 'attachment' standards?**

HL7 standards for attachments include:

- HL7 Implementation Guides for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1. This guide is a HL7 CDA R2 standard, it was balloted and published in July 2012. The guide includes 8 structured document types, and a general unstructured type for attachments.

- HL7 Supplement to the Consolidated CDA Templated Guide was balloted and approved for publication in January 2013. This guide provides the criteria and information needed by stakeholders to utilize the HL7 CDA R2: IHE Health Story Consolidation Guide for the request and response of Attachments.

- LOINC Code "HIPAA Attachment" panel on Regenstrief DB lists and describes the types of unstructured attachment documents.

5) **Are there other standards for clinical information exchange rather than or in addition to HL7 C-CDA that should be considered?**

Beyond that of the HL7 and X12 standards, we are unaware of any additional candidate standards able to provide comparable functionality

6) **What metadata or pieces of information would be necessary to include in the envelope that is not available today in the HL7 C-CDA?**

The following metadata SHALL accompany the attachment information being exchanged:

- Requestor (Payer/UMO) Name and Identifier (plan ID, HPID, etc)
- Request receiver Name and ID (ETIN, etc)
- Provider of Service Name and ID (NPI)
- Attachment Control ID (payer or provider assigned, depending on solicited/unsolictied)
- Attachment Information ID needed (LOINC Code), both in request and response

- Date Requested and Response Due Date
- Payer Contact Information
- Date of Service/Encounter

In addition to the metadata above, the following MAY be included:

- Patient Control Number (assigned by provider on claim)
- Patient Medical Record Number (assigned by provider on claim)
- Property and Casualty Claim Number
- Case Reference ID
- Attachment Request Tracking ID

Guidance is provided in the HL7 Supplemental Attachment guide for use of the metadata.

NOTE: Some of the above apply to the request, some to the response, and some to both.

7) **With respect to the 'envelope' of the message, should more than one enveloping standard be permitted to wrap the standard clinical information? What are examples of these standards that build on existing or future infrastructures?**

The HL7 Standards are agnostic to the envelope standard, provided it adheres to conformance of the metadata requirements specified within the Supplemental Attachment Guide. While the HL7 Standard was initially designed to work in conjunction with the HIPAA ASC X12 transactions, HL7 CDA attachments can also be transported using web based transport protocols like Soap and Rest with the appropriate metadata.

Again, the X12 standards are built on a time tested infrastructure for Electronic Data Interchange of HIPAA Transactions and Code sets, since 2003. Consideration might also be made to use different enveloping standards in conjunction with the X12 standards through trading partner agreement or operating rules. Potential use of infrastructure supported by Health Information Exchange, such as IHE Profiles, might also be utilized and adapted to provide necessary enveloping features.

8) **With respect to transport, how would you envision the routing/transport (sending or receiving) of clinical/medical information occurring? How does it relate to HealtheWay and/or ONC Direct and/or ONC Connect?**

Through the establishment of HIPAA, current routing/transport between HIPAA covered entities (i.e., providers, clearinghouses and payers) is done primarily using secured FTP. Clinical/medical information could leverage those same routing/transports for exchange between those same covered entities.

With the addition of Health Information Exchange (HIE) for clinical/medical information exchange, additional transport options for exchange should be considered.

The potential for real-time versus batch exchange should consider appropriate transport vehicles for the exchange. Also, portal applications may be used for direct data entry.

The HL7 Attachment standard could be adapted to be issued over the public internet using HTTPS and the appropriate metadata and security protocols. This would allow secure clinical data to be made available for clinicians, payers and patients as the standard and platforms evolve (i.e. mobile health).

9) **Should we consider optional or situational enveloping (and/or transport) standards?**

The additional (or attachment) information exchanged using the attachment standard is considered an electronic document. It is important to note that additional information from a clinical record system may already exist as a complete electronic document or as one generated by software from information in that clinical record system. In either case, that electronic document should be at integrity with itself from a clinical perspective and be comprised of clinical information appropriate to the document type while omitting information not a part of the medical record. Hence, it is creating a need for a whole new set of interfaces between the EHR System and the AR system (or Practice Management system) to request and get the attachment so that the envelope could be properly created with correct content and then the two sent together. Mixing clinical data originating the

EHR System and payment data contained in the AR system creates a whole new set of possible use cases for interaction between the two systems that does not exist otherwise today.

In the attachments model, requests from a payer to a provider for attachment information requires necessary 're-association' information which is not typically found within the medical document as it exists on the providers clinical records system. This information is used to uniquely match the additional information with the request as triggered by a claim, prior auth, referral, etc. Enveloping provides a consistent place for that necessary re-association information from the requesting payer to be echoed back by the provider to facilitate the accurate re-association of attachment information to the original request. The Attachments Supplement identifies needed metadata for that re-association, and any enveloping methodology that conforms to those requirements would be acceptable.

10) What is the set of attachment standards being recommended for adoption?

HL7 is recommending the following standards be adopted:

- **HL7 Implementation Guides for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1**. This standard provides guidance for creating a compliant electronic document based on the Clinical Document Architecture (CDA). Compliant documents include both structured and unstructured electronic documents. A structured document contains discrete data that's available for extract/parsing within the document and may be used for computer processing. Alternatively, an unstructured document will contain information that don't contain discrete data that doesn't lend itself to extract/parsing and made up of word processing/narrative and graphic formats.
- **HL7 Attachment Specification: Supplement to Consolidated CDA Templated Guide, Release 1**. This standard is intended to be used in conjunction with the standard above and provides guidance and conformance requirements for that standards implementation for attachment purposes. In addition to conformance requirements

for metadata (i.e., attachment re-association information), use of LOINC codes in structured and unstructured attachment types, and use of preferred LOINC codes in attachment requests and responses, the supplement also provides business case and scenario examples, expanded applicability of solicited/unsolicited and structured/unstructured attachments, use of modifier LOINC codes on the request, etc.

- Logical Observation Identifiers Names and Codes (LOINC®). This standard value set segregates a subset of LOINC Codes that identify the valid attachment types that may be exchanged using the two standards above. It also identifies modifier LOINC codes to be used to constrain the time window and item selection of the additional information being requested as a part of that subset.

HL7 has worked closely with ASC X12 in their development of a set of enveloping standards and we expect them to speak to those standards.

The overall concept of attachments was originally tied closely to the HIPAA transactions for claim submittal, referral and prior authorizations, which rely heavily on ASC X12 standards and supporting infrastructure for their exchange. Those same stakeholders would also be exchanging attachment information and would have minimal impact by simply adding the attachments standards to that infrastructure. For that reason, consideration of the ASC X12 standards should be given to include them, at a minimum, as a permitted option.

11) Are there any known limitations or gaps in the recommended standards? How will they be addressed?

The HL7 Standard "HL7 Implementation Guides for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1" provides guidance and conformance requirements to create both electronic structured and unstructured documents. Structured documents lend themselves to computer processing, and are potentially advantageous to the

consumer of attachment information. The structured document/attachment types currently included in the standard above are:

- History and Physical
- CCD
- Discharge Summary
- Diagnostic Imaging Report
- Operative Report
- Procedure Note
- Progress Note
- Consultation Note

Any other attachment types needed but not satisfied by the eight (8) listed above can be accommodated via use of the unstructured document/attachment types described within the standard. These attachment types are identified on the LOINC database as available for use as an unstructured document. The process for acquiring a new attachment type is as simple as following the recommended process found in the supplement for obtaining an approved LOINC code.

HL7 standards are designed to be relevant to their stakeholders. As new codified attachments are required by the industry, HL7 is prepared to develop and add new content through the use of new development tools such as FHIR to reduce standards development time while promoting efficient high quality standards.

12) **Are there any Operating Rules to be recommended for adoption at this time? Which would they be? Are the 'infrastructure' related operating rules in place applicable to attachments? What are the plans for developing further 'attachment' operating rules? What processes/steps have been taken to identify/develop such operating rules? What might be some of the lessons learned thus far from the development of previous operating rules that may be applicable to the development of attachments operating rules?**

In general, potential operating rules would address implementation issues not already specifically addressed within the standards proposed for adoption by HL7.C-CDA. Optionally, some of those may also make sense as a part of the regulation.

Potential operating rules could include guidance on transport protocols, or business rules that address the appropriate time between request and response before the requestor of attachment information can take action based on no response.

13) **Are the recommended standards (and operating rules, if any) applicable only to claim attachments, or will they be applicable also to other types of attachments?**

The types of attachments appropriate for support of claim benefit and medical policy adherence are also consistent with those needed for other attachments, such as prior authorizations, referrals, post-adjudicated claim activity, care management, quality measures, etc. The HL7 standards currently support healthcare activities that include claims, referrals, prior authorizations and post adjudicated claim activity.

14) **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?**

HL7 understands that an extensive architecture already exists for information exchange between providers and payers (and clearinghouses) to support the HIPAA transactions and code sets. This architecture is currently used by the same stakeholders anticipated to participate in attachments information exchange. Adoption of this could have the least impact on payers, providers and clearinghouse.

HL7 also understands the provider to provider exchange of medical information is utilizing technical solutions used only by providers currently (i.e., not payers/clearinghouses) and may be limited to only providers participating in the Medicare/Medicaid EHR Meaningful Use Incentive Program. If true, architectures other than those mentioned for HIPAA Transactions and codesets could require most payers as

well as providers not participating in EHR MU tool up to conform to architectures for EHR MU. Adoption of this solution could force payers, providers and their vendors to build the necessary infrastructure similar to that of the EHR MU Providers presently.

If use of either architectural solution is optionally available to the providers, it could require payers to support all.

Since the HL7 standard is XML based, the industry will require resources that are versed in web-based services, protocols and security. Current payer EDI departments may not be versed in web based services and will have to leverage resources from other departments. This should not be a show stopper for the standard given the industry time to respond by the 2016 implementation date.

15) What acknowledgement functions, if any, would you suggest?

Acknowledgement functions could be made available at the functional and content levels.