**HL7 Responses**
**National Committee on Vital and Health Statistics**
**Subcommittee on Standards**
**Hearing on Attachments, Session #2 Questions**
**November 17, 2011**

1. What is the current status of development of standards for attachments and implementation guides? What is the timing for development, testing standards?

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 have the honor of being one of the co-chairs for the HL7 Attachments Work Group (WG). I work for Health Care Service Corporation, 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 3 years.

In response to Question 1 to HL7:

HL7 has developed a suite of electronic clinical information exchange guides which include the Attachment Information Specifications (AIS), the Continuity of Care Document (CCD) and the CDA Consolidated Guide, all of which are based on the HL7 Clinical Document Architecture (CDA) Release 2 standard. The difference now from the previous work we have done in the past with CMS on HIPAA attachment standards is that the CCD and CDA Consolidated guides are developed using templates. Utilizing the concept of templated guide development, the Attachments WG is converting their Application Information Specifications into the template format. Wherever possible, we will use the same content as found in the CDA Consolidated Guide. Where it is not possible, the section templates are reusable making development of a guide easier, quicker and assures harmonization.

The majority of the AIS's for Clinical Reports have been harmonized into the CDA Consolidated Guide. Work is in progress to harmonize the remaining AIS's (Rehabilitation Services, Medications, Laboratory Results and Ambulance) with the CDA Consolidated Guide.

We have the next 14-15 months to convert the remaining specifications to template guides. Testing can begin now with existing CDA Consolidation documents for History and Physical, Op Notes and Discharge Summary,.

It is important to understand that by using the CDA Consolidated Guide, HL7 is closely aligning both the form and content of the exchanged clinical information between providers and between a provider and the patient's payers. CDA Consolidated Guide is the current development work going on right now within HL7 and ONC for Meaningful Use Stage 2 Requirements. Provider and payer organizations will be able to use appropriately edited forms of the same structured and unstructured data to support both patient care and payment processes.

2. Where do you see the standards for attachments going? How are these standards being harmonized with the standards developed/adopted for exchange of clinical information under the Meaningful Use program?

My name is John Quinn. I am the CTO of HL7 and one if its original founders dating back HL7's inception in March 1987.

In response to Question 2 to HL7:

As we stated at the end of our answer to the previous question, we see the attachments as a standardized method for transporting information in a variety of scenarios among a variety of stakeholders. For instance:

- Attachments can and should continue to develop and be used to augment claim information to support prior authorization of services and complete the adjudication of claims;
- Also beyond "attachments to payer transactions" we envision that the same information that populates an attachment, with proper privacy and consent controls, could be suitable for:

- Supporting Meaningful Use requirements for accessing patient clinical information that exists on EHR Systems beyond the current provider's organization;
- Reporting individual patient information to local, state and national public health and quality agencies for later aggregation and analysis;
- Other similar requirements that are evolving from the state HIE projects now under development.
- Transfer of a patient's current medical record to another provider at a patient's request to support a patient's relocation to another area, need for medical treatment

while traveling, or a clinical referral of a patient to a specialty care organization (e.g., oncology).

CDA documents provide a means of creating an electronic document of both structured (i.e., partially or completely coded data) and unstructured (e.g., text) data. They support attestation, electronic signature and other features that document its authorship and support non-repudiation. They support the job of capturing all or part of a patient's clinical information for purposes of clinical care and documentation for payment. They do not, however, support concurrent and possibly complex processes surrounding clinical functions such as electronic ordering and resulting of diagnostic tests or remedial treatment.

Finally, ONC's CDA Consolidation project does not address procedures for requesting (i.e., soliciting) an attachment document. At this time we have worked closely with X12 to use their 277 transaction to accommodate this process as it relates to the example of a payers response to a provider who solicits a claim status.

3. Are all the 'priority' areas identified by provider and payers being addressed in the development of the standards? Which areas might not be addressed? What other gaps have been identified? How can those gaps be addressed?

The set of attachment types that comprise the five current Attachment Implementation Specifications were determined from industry (payer and provider) outreach and analysis, and indicated what additional information was most commonly requested.

If "priority" requirements for attachments are out in the industry but are not brought to the attention of the HL7 Attachments WG then we wouldn't know about them and therefore we wouldn't have a way of addressing them.

Certainly, not every attachment can be developed at once, particularly when the Attachment WG continues to focus on moving existing "HIPAA" attachments to be aligned with current technology when a Final Rule is published. The current version we are working on is the 6th iteration since we started in 1996—the year that the HIPAA law was passed. This work started with close collaboration among HL7, ASC X12N and CMS.

The HL7 Attachment Work Group's message to anyone bringing forward a request to develop a new attachment type is that we absolutely want to work with them.
Our general process for consideration of new work is:

- We have to prioritize our work (e.g., federal regulations are a priority);

- The requestor must bring constituents (i.e., domain experts) to the process. The Attachments Work Group does not necessarily know the requestors business. The requestor must be involved, and agree to co-sponsor the work and also be prepared to provide venues for field testing of draft standards for trial use once the initial balloting of the standard is completed.

This process has worked for attachments such as Home health, Prior Authorization, and Children's Preventative Health Services (CPHS), dental. These are all 'post HIPAA development' attachments.

As for current priorities; members of the Attachments WG are analyzing the current practices by their organizations. Among the eight document types named in the CDA Consolidated Guide, the most commonly used are: Operative Note, Discharge Summary, and History & Physical. These document types were part of our original Clinical Reports Attachment Implementation Specifications and have been harmonized with and/or added to the CDA Consolidated Guide.

The document types named in the Attachment Implementation Specification and the CDA Consolidated Guide have discrete data elements listed that allow users to exchange clinical information as both an unstructured or structured document. Any needs by the industry for additional attachment types could be exchanged as an unstructured document by obtaining a LOINC code to identify the attachment type.

Lastly, to the prioritization and identification of gaps for attachment types, we have developed a "placeholder" attachment called the Patient Information Unspecified Content (PIUC). The PIUC was created specifically to accommodate those trading partners who are willing to agree on data content for the attachment (instead of waiting for it to be done in the standards development process by the Attachments Work Group). Once the Standard is completed, the PIUC for that attachment is no longer in use. This allows for the immediate exchange for those requesting the development of that attachment standard but also allows for proprietary content as an *interim solution only*.

In a slightly different analysis of the technology around attachments HL7 has also prioritized and strives to be responsive and proactive in addressing related provider and payer priority areas. For example, in January 2011 an incidental connection developed between the CMS electronic submission of Medical Documentation (esMD) project and the HL7 EHR Records Management-Evidentiary Support (RMES) project. esMD had developed a draft CDA low level (Level 1-2) Implementation Guide, initially intended to support tasks executed by CMS Claims Review Contractors. An RMES participant was asked to contribute to discussions about future developments of more robust, CDA functions for supporting esMD incremental capabilities expansion, with special attention to RMES Profile Standard requirements for source record veracity assurance. RMES had done some pertinent work in 2009 which led to a project Scope Statement now being finalized with the HL7 Technical Steering Committee to meet

this CMS interest. The adoption of esMD as an ONC S&I Initiative demonstrates that this small initiative is likely to inform a wide range of future projects and constituencies.

4. What is the current status of common business rules (operating rules) for the requirement/submission of attachments in the industry? What are the areas where national standard business rules/operating rules for requiring /submitting attachments would be most beneficial?

Attachments vary greatly across the healthcare industry because provider types vary so widely. There are even extremes within an individual provider type. In short, a current status of common business rules (i.e., operating rules) for the requirement/submission of attachments in the industry does not now exist. However, it does exist, in multiple sectors of the industry such as O/P PT (Outpatient Physical Therapy).

- In O/P Physical Therapy it is common for the therapist to create a progress note (i.e., an attachment) for the physician every 6 weeks – typically when the patient returns for a check-up. This note contains information such as prior goals attained/ current goals/ home exercise program/ treatment program, etc.

Attachments also vary by payer and provider type, (e.g., the payer's need for attachments can be driven by an employer's group contracts).

The Attachments Work Group's outreach process establishes business rules as industry domain experts are brought together with HL7 experts to develop attachments. In general, the HL7 Work Group members do not determine content or

necessary business rules, it's rather the attachment-type domain experts working with the HL7 experts together working as one.

5. One of the responsibilities of the Committee is to identify an authoring entity for national standard operating rules for claim attachments; would you be pursuing designation as an authoring entity?

   Yes, HL7 – in collaboration with ASC X12

   - HL7 and ASC X12 have co-developed this standard by collaborating since 1996
   - Both SDO's have also jointly collaborated on many projects since that time; demonstrating a clear ability to work together toward a common outcome that satisfies industry stakeholder needs
   - Project Plans, processes, and liaisons to work together are already in place