NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS (NCVHS) SUBCOMMITTEE ON STANDARDS HEARING ON HIPAA AND ACA ADMINISTRATIVE SIMPLIFICATION —ATTACHMENT STANDARD — CHARLES JAFFE MD PHD, HL7 CEO

Hubert Humphrey Building
200 Independence Avenue, SW – Room 705-A
Washington, DC 20024
Tuesday, February 16, 2016

HL7 Attachment Development

- HL7 Attachment Work Group established in '97
  - Focus on clinical data for additional information to support a claim
    - ASC X12 provided the existing Provider/Payer EDI Communication Channel
    - HL7 provided the Clinical Data Architecture
      - Human Readable
      - Machine Interpretable
    - Industry Outreach to Payers and Providers to identify types of request
    - Industry Domain Experts defined data content for each type of request
    - LOINC codes were used to 'tag' each type of request
- *Additional Information Specifications CDA R1* – May 2004
  - Ambulance, Rehab Services, Clinical Reports, Medications, Lab Results
  - Pilot by Medicare Carriers; Adminstar Federal, Empire Medicare Services, Health Care Services Corporation, UHC Government Operations, Xact (Highmark)
- Proposed in 2005 NPRM
- Rescinded in 2007

HL7 Attachment Development

- Meaningful Use (MU) EHRs
  - Align Attachments with MU EHRs – gap analysis with AIS Booklets
    - Continue to incent providers with consistent documents types for sending the same clinical documents to either Payers or other Providers (Op Note is an Op Note)
  - ***HL7 CDA R2 IHE Health Story Consolidation R.1.1* – July 2012**

- 2012-2016
  - **Expand Use Cases beyond support for claim payment using the same Attachment Types found in C-CDA**
    - Claim, Prior Authorization, Referrals, Notification, Post Pay Audits, Eligibility
  - *HL7 CDA R2 Consolidated CDA Templates for Clinical Notes R.2.1* – May 2014
  - *HL7 Attachment Supplement Specifications Request and Response Implementation Guide R1 – March 2016*
  - *HL7 Implementation Guide for CDA® Release 2: Additional CDA R2 Templates -- Clinical Documents for Payers – Set 1 - Dec 2015*
- 2016 –
  - Payers participating in FHIR Connectathons
  - Developing FHIR Resources (API); C-CDA on FHIR, Blue Button +EOB

- HL7 Standards are FREE to download.

Recommendations

- Consistent use of clinical documents and alignment with other use cases on clinical information exchange
  - ***HL7 CDA R2 Consolidated CDA Templates for Clinical Notes R.2.1***
- Guidance specifically for Payers and Providers on how to use HL7 C-CDA for Attachments
  - ***HL7 Attachment Supplement Specifications Request and Response Implementation Guide R1***
- For optional use –
  - ***HL7 Implementation Guide for CDA® Release 2: Additional CDA R2 Templates -- Clinical Documents for Payers – Set 1***
- LOINC – defined set of codes to the request Attachments
  - ***HIPAA Panel Solicited and Unsolicited lists***

Considerations for Adoption

- Industry initially supported the exchange of *unstructured documents*
- Adopt any *structured document* defined by an HL7 CDA Standard require the C-CDA R2.1 Header and the narrative block text for each populated section.
  - Provides the human readable text of all entry level templates for each section. Payers must support receiving the header and narrative, if received from any provider.
  - Support for structured CDA documents with entry level templates should be based on individual trading partner decision.

FHIR Maturity

- Pilot FHIR Resources and Profiles for exchanging Attachments
  - Independence Blue Cross
    - using FHIR to allow front end applications to access back end data
  - Cambia
    - using FHIR to request and receive ADT messages
- C-CDA on FHIR project
  - Start with key document types like CCD and Discharge Summary
  - Winter 2017 HL7 Ballot
    - Complete C-CDA on FHIR profiles for C-CDA R2.1 (used for Attachments)

HL7 Responses to Questions

Development Timeline

- HL7 Attachment Work Group established in '97
  - Originally a Special Interest Group under Structured Documents
    - Focus on clinical data for additional information to support a claim
  - Led by CMS Pilot to reduce paper
    - Change Paper Letter Requests for Additional Information to Electronic
    - Collaboration with ASC X12 to Bridge for Administrative and Clinical Data
      - **Use existing Provider/Payer Communication Channel (EDI X12)**
    - Allows for flexibility in technical adoption
      - ✓ **Human Readable**
      - ✓ **Machine Interpretable**
    - Industry Outreach to Payers and Providers to identify Types of Request Industry Domain Experts define Data Content for each type of request
    - LOINC codes to 'tag' each type of request
- Additional Information Specifications CDA R1 – May 2004
  - Ambulance, Rehab Services, Clinical Reports, Medications, Lab Results
  - Pilot by Medicare Carriers; Adminstar Federal, Empire Medicare Services, Health Care Services Corporation, UHC Government Operations, Xact (Highmark)

Development Timeline

- **2005 NPRM on Attachments - Recommended**
  - ***HL7 AIS Booklets in CDA R1***
    - **Ambulance, Rehab Services, Clinical Reports, Medications, Lab Results and Emergency Department**
  - X12 277 Request and X12 275 Additional Information to Support a Claim
  - LOINC code tables for HIPAA
  - Implementations
    - Empire Medicare Services, Mayo Clinic. Montefiore, NextGen and Sloan Kettering
      - Unsolicited 275 and Unstructured Attachment
    - Arizona Medicaid – 275 with Unstructured Attachment
    - Availity, HCSC – Unsolicited 275 with Unstructured Attachment
  - **Rescinded in 2007**
- **Meaningful Use (MU) EHRs**
  - Align Attachments with MU EHRs – gap analysis with AIS Booklets
    - Continue to incent providers with consistent documents types for sending the same clinical documents to either Payers or other Providers (Op Note is an Op Note)
  - ***HL7 CDA R2 IHE Health Story Consolidation R.1.1*** **– July 2012**
    - Conformance with MU Stage 1

Development Timeline

- 2012-2016
  - Expand Use Cases using the same Attachment Types found in C-CDA
    - Claim, Prior Authorization, Referrals, Notification, Post Pay Audits, Eligibility
  - **HL7 CDA R2 Consolidated CDA Templates for Clinical Notes R.2.1 – May 2014**
  - HL7 Attachment Supplement Specifications Request and Response Implementation Guide R1
  - HL7 Implementation Guide for CDA® Release 2: Additional CDA R2 Templates -- Clinical Documents for Payers – Set 1
- 2016 –
  - Payers participating in FHIR Connectathons
  - Developing FHIR Resources (API); C-CDA on FHIR, Blue Button +EOB
- HL7 Standards are FREE to download.

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 - Established Attachment Special Interest Group under Structured Documents Work Group
CMS Pilot – Attachment Information Specification Booklets CDA R1

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

‘05 - WPS, Mayo Clinic - Unsolicited, Unstructured 275
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
277 Request, 275 Unstructured

‘13 - esMD, 275 Unstructured

’14 - NGS Anthem, Mayo Clinic
277 Request, 275 Unstructured

‘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)?

- Same HL7 standard identified for Meaningful Use Stage 2 is proposed for adoption for Attachments.
  - HL7 CDA R2 Consolidated CDA Templates for Clinical Notes R.2.1 – May 2014
    - Conformance with MU Stage 2
- HL7 CDA R2 C-CDA Templates for Clinical Notes 2.1
  - Implementation specification for 12 structured document types and Unstructured documents (listed in LOINC Panel for Attachments)
    - 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
- This will make it easy for providers to send the same clinical document to payers that 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 12 structured document types and Unstructured documents (listed in LOINC Panel for Attachments)
  - 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.

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 be an impact to payers
- Providers perspective
  - Providers will need to link their EHR system with their Practice Management
  - Providers would like to have one standard to create, not multiple standards that would require them to create different 'version' of a clinical document depending on different 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.

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.

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.

HL7 has a Help Desk that can assist with inquiries from the industry on implementation questions.

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

Yes, any providers or payers that have not implemented these transactions will have to update their systems.

There are new standards and codes to implement that have not be used by most payers.

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.

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

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

No, HL7 not developed strategies to measure the impact of implementation.

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?

This will be on ongoing process, as 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.

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

HL7 is not aware that any metrics exist.

Does the proposed standard incorporate privacy, security and confidentiality?

HL7 CDA allows for authentication of the author of the document.

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

The standards for exchange of clinical information, 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 validation of compliance with conformance statements defined in HL7 C-CDA templates.

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

- To get the industry using 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.
- The industry needs direction on the standards and codes for Attachments to ensure that we are all working together and not moving in different directions.