Standards for Electronic Attachments

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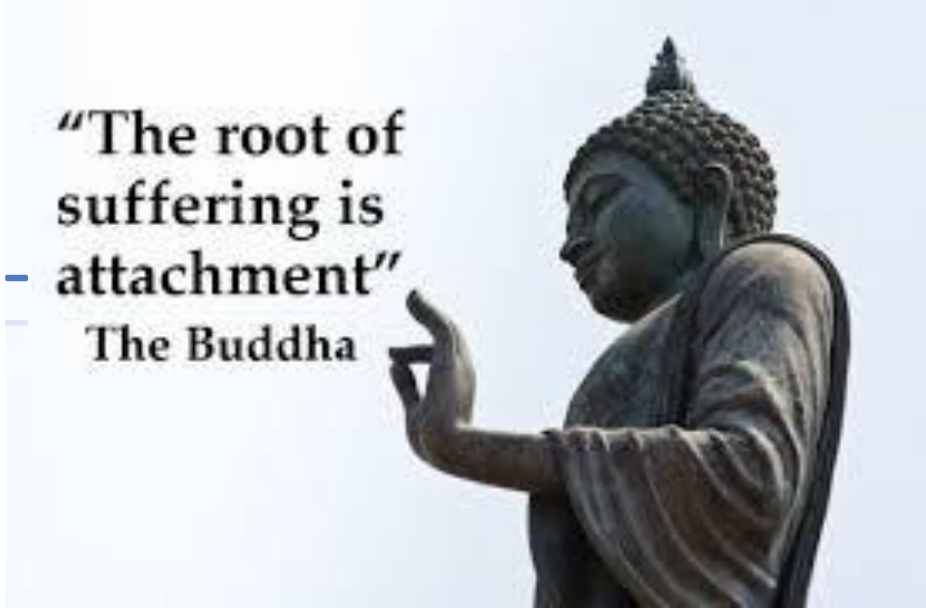
Standards for Electronic Attachments

non-



Rick Geimer

- May 2018

Speaker Information

- Rick Geimer
  - Chief Innovation Officer, Lantana Consulting Group
  - Member of HL7 CDA Management Group
  - Active member of several HL7 Work Groups:
    - FHIR Infrastructure
    - Attachments
    - Structured Documents
  - Co-editor of C-CDA and many other specifications
  - Lead on the C-CDA on FHIR project

Definition: Standard Electronic Attachment

What it is:

- Digital file
  - Human readable
  - Computer parsable
- Delivered via network
  - Manual upload to portal
  - Automated through application interface

What it is not:

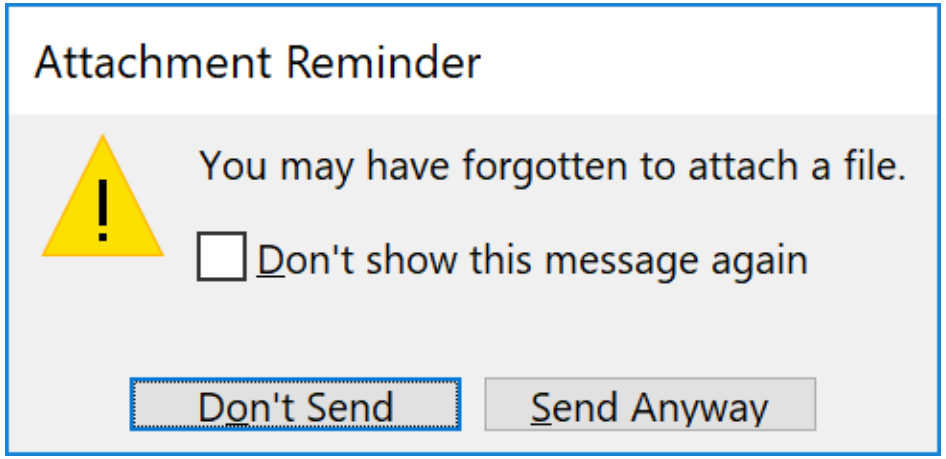
- Paper mail
- Faxes
- Physical media

Electronic Health Information

HIPAA/ACA Use Cases

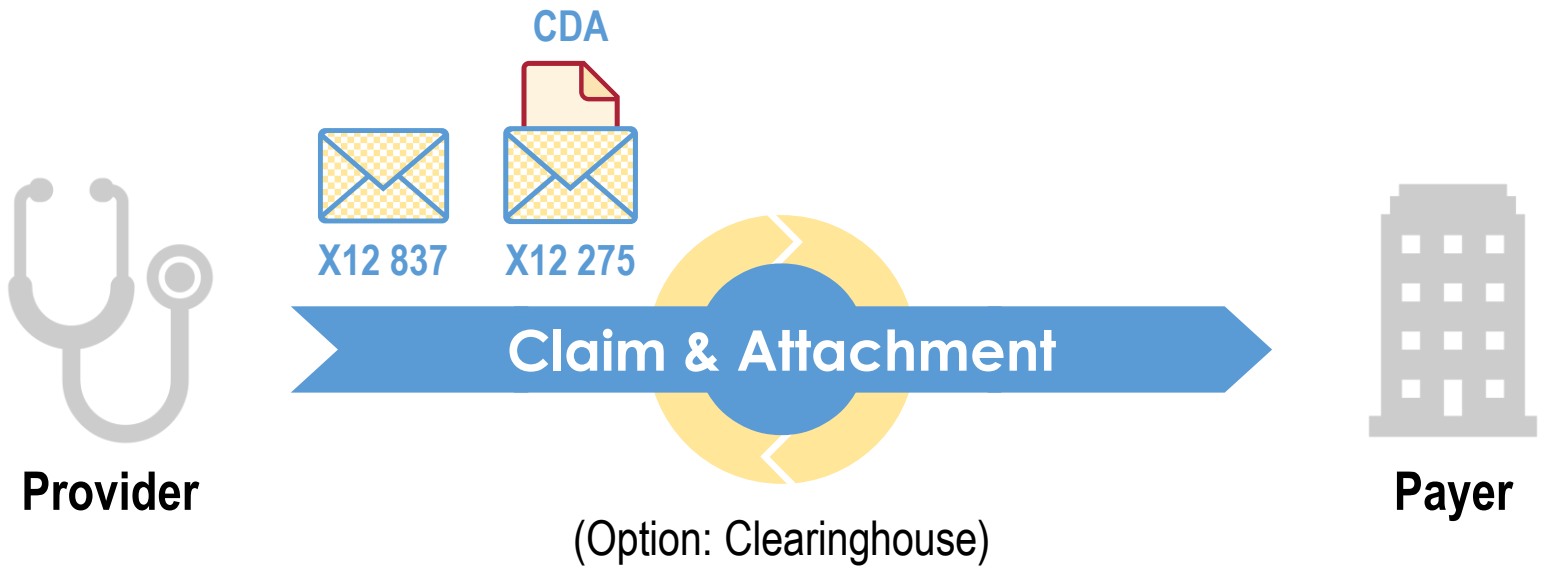
- Claims/Reimbursement
- Prior authorization
- Referral
- Audit

Not all things that are attached!



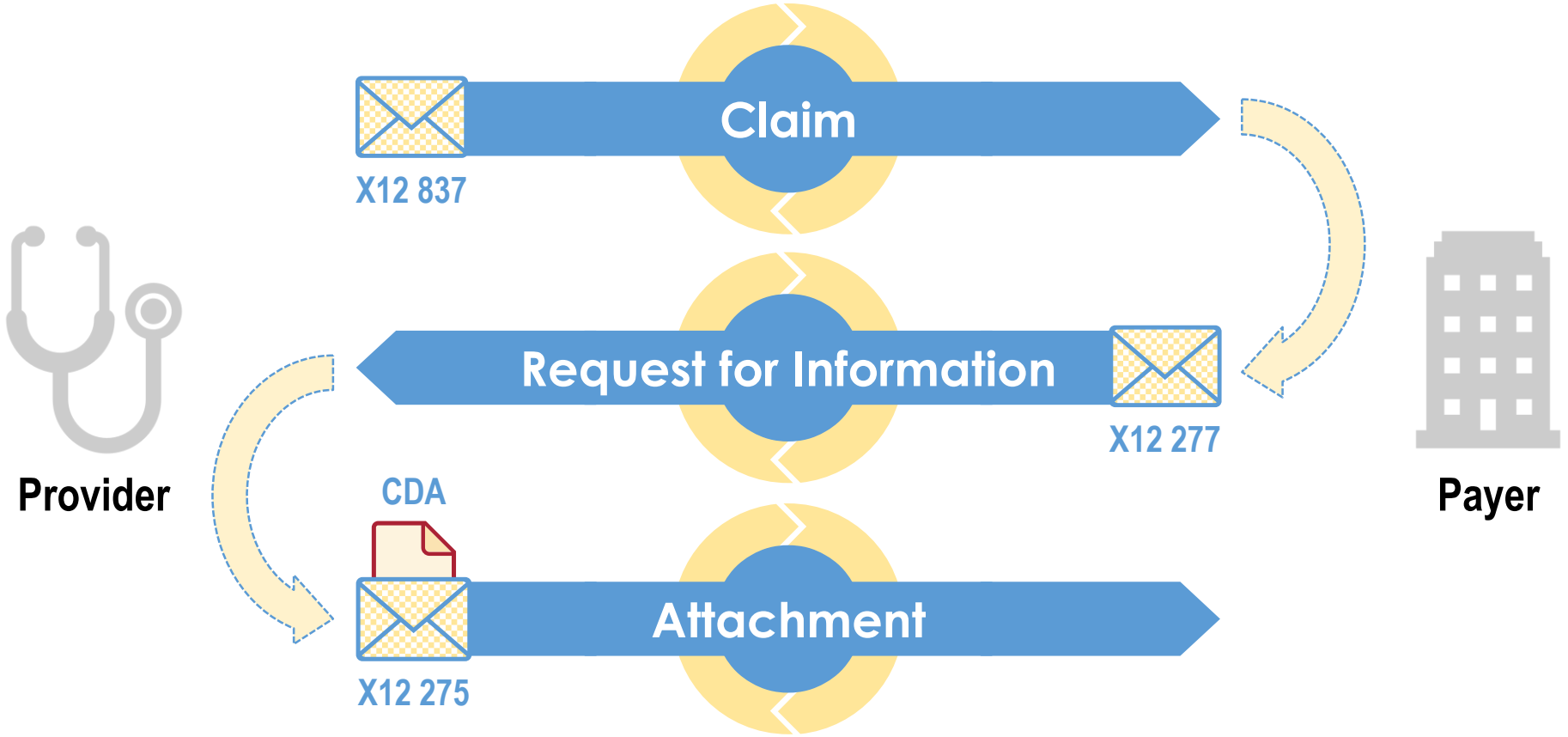
Claims Attachments: Basic Orchestration

- Unsolicited Claims Attachment



Claims Attachments: Basic Orchestration

- Idealized orchestration: Solicited Claims Attachment



Standard Electronic Attachments

- Minimum Requirements:
  - A wrapper:
    - Default: X12
    - Alternatives: FHIR, other
  - An attachment:
    - CDA, can be a Consolidated CDA (C-CDA)
    - Shallow layer of additional requirements
    - ***Vastly*** lower minimum requirement than for Meaningful Use
  - Transport: not addressed, and can vary
    - SFTP
    - SOAP
    - other

X12 275

Base 64 Encoded CDA Document

```
ST*275*1001*006020
BGN*11*0001*201201
NM1*PR*2*ABC INSUR
NM1*41*2*XYZ SERVI
NM1*1P*HOLY HILLS
NX1*1P~
N3*2345 WINTER BLVD~
N4*MIAMI*FL*33132~
NM1*QC*1*JACKSON*JACK*J***MI*98765432~
REF*EJ*JACKSON123~
REF*EA*STHHL12345~
DTP*472*D8*20111229~
LX*1~
TRN*2*1822634840~
STC*R4:11490-0:20120103:LOI*20120103~
DTP*368*D8*20120110~
CAT*AE*MB~
OOI*1*47*ATTACHMENT~
BDS*ASC*6289*…… <BASE 64 ENCODED CDA
SE*27*1001~
```

```
TWFuIGlzIGRpc3Rpbmd1aXNoZWQsIG5vdCBvbmx5IGJ5IGhpcyByZWFzb24sIGJ1dCBieSB0aGlzIHN
pbmd1bGFyIHBhc3Npb24gZnJvbSBvdGhlciBhbmltYWxzLCB3aGljaCBpcyBhIGx1c3Qgb2YgdGhlIG
1pbmQsIHRoYXQgYnkgYSBwZXJzZXZlcmFuY2Ugb2YgZGVsaWdodCBpbiB0aGUgY29udGludWVkIGFuZ
CBpbmRlZmF0aWdhYmxlIGdlbmVyYXRpb24gb2Yga25vd2xlZGdlLCBleGNlZWRzIHRoZSBzaG9ydCB2
ZWhlbWVuY2Ugb2YgYW55IGNhcm5hbCBwbGVhc3VyZS4=
……
```

Unencoded CDA XML Document

```
<ClinicalDocument xmlns="urn:hl7-org:v3">
    <realmCode code="US"/>
    <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
    <templateId root="2.16.840.1.113883.10.20.22.1.2" extension="2015-08-01"/>
    <templateId root="2.16.840.1.113883.10.20.22.1.2"/>
    <templateId root="2.16.840.1.113883.10.20.22.1.1"/>
    <id extension="TT988" root="2.16.840.1.113883.19.5.99999.1"/>
    <code code="34133-9" displayName="Summarization of Episode Note"
     codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <title>Patient Chart Summary</title>
    <effectiveTime value="201308151030-0800"/>
    <confidentialityCode code="N" displayName="normal"
     codeSystem="2.16.840.1.113883.5.25"
     codeSystemName="Confidentiality"/>
    <languageCode code="en-US"/>
    ...
</ClinicalDocument>
```

Health Level Seven (HL7)

- Clinical Document Architecture, R2 (2005)
  - Generic rules for any ***clinical document***
  - Many type of implementation guides
    - Continuity of Care
    - Public Health
    - Quality Reporting
- Implementation guide defines attachments
  - Restricts types of CDA documents to those with common metadata sufficient for medical records management (US Realm Header)
  - Defines code sets for requests, submissions

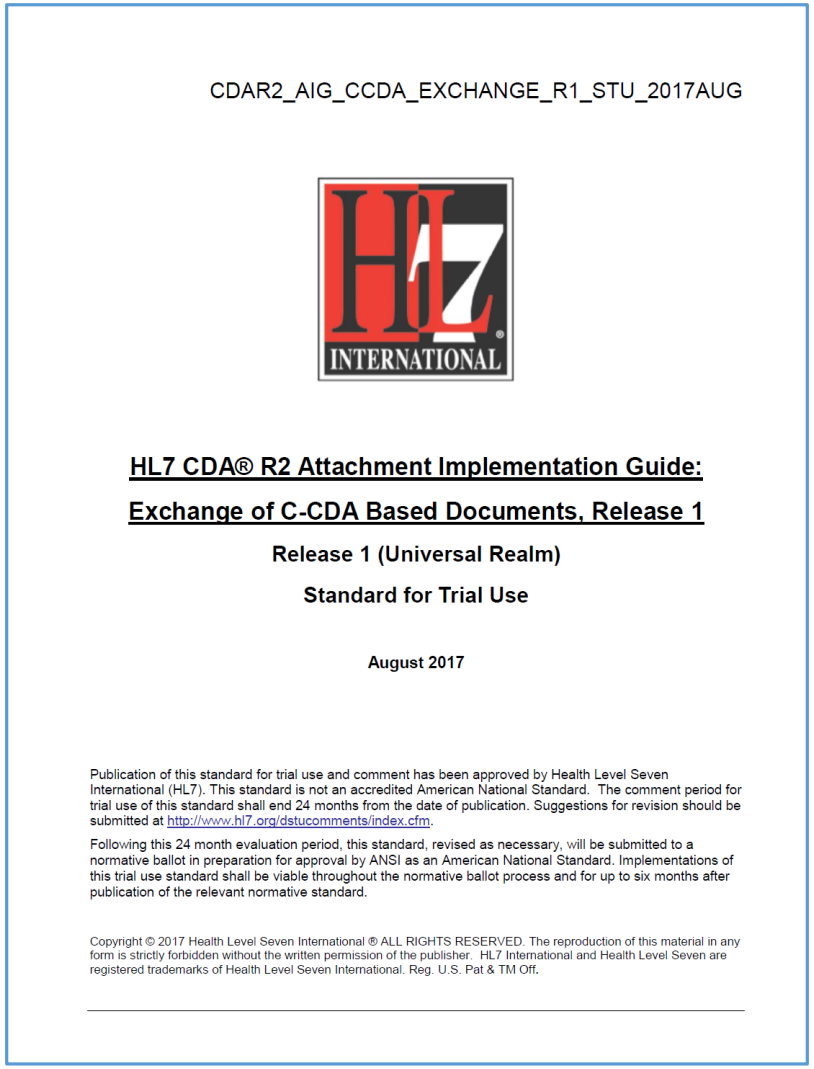
Attachments Implementation Guide

HL7 CDA Attachment Implementation Guide (IG):

- Exchange of C-CDA Based Documents, Release 1
- Standard for Trial Use (STU)
- ***Released August 2017***

The IG Documents:

- Approach
- Background
  - Structured/unstructured
  - ISO Object Identifiers (OIDs)
  - Base64 Encoding
  - Document Succession
- Classification using LOINC
- Business requirements
- Rules (conformance requirements)



CDAR2_AIG_CCDA_EXCHANGE_R1_STU_2017AUG

HL7 CDA® R2 Attachment Implementation Guide:

Exchange of C-CDA Based Documents, Release 1

Release 1 (Universal Realm)

Standard for Trial Use

August 2017

Publication of this standard for trial use and comment has been approved by Health Level Seven International (HL7). This standard is not an accredited American National Standard. The comment period for trial use of this standard shall end 24 months from the date of publication. Suggestions for revision should be submitted at http://www.hl7.org/dstucomments/index.cfm.

Following this 24 month evaluation period, this standard, revised as necessary, will be submitted to a normative ballot in preparation for approval by ANSI as an American National Standard. Implementations of this trial use standard shall be viable throughout the normative ballot process and for up to six months after publication of the relevant normative standard.

Minimum Requirements for CDA

- Header + Body = metadata + clinical report
- Header is simple XML
- Required for all CDA:
  - Document metadata (document id, type, title, date, confidentiality, language)
  - Patient
  - Author, Provider organization, System Used
  - Custodian (Document Steward)
- Required for all CDA attachments:
  - US Realm Header from Consolidated CDA (C-CDA)
  - Legal authenticator
  - Document type code is from LOINC
  - Note: Some attachment types may require additional information on participants.
- Body may be unstructured or structured

Attachment Types in LOINC

Clinical Document types (Structured)

Documents with implementation guide | Documents without implementation guide | Valid attachment requests | Request Modifier Codes

Document (Attachment) Type Codes

Consolidated CDA (C-CDA) R2.1

Attachment Name	LOINC
Continuity of Care Document	
Summary of episode note	34133-9
Care plan	
Consultation note	
Diagnostic imaging report	
Discharge summary	
History and physical note	
Procedure note	
Progress note	
Referral note	
Surgical operation note	
Transfer summary	

Wrapped Text | Expand | Collapse | Print Preview

Clinical & Administrative Document Types (Unstructured & Structured)

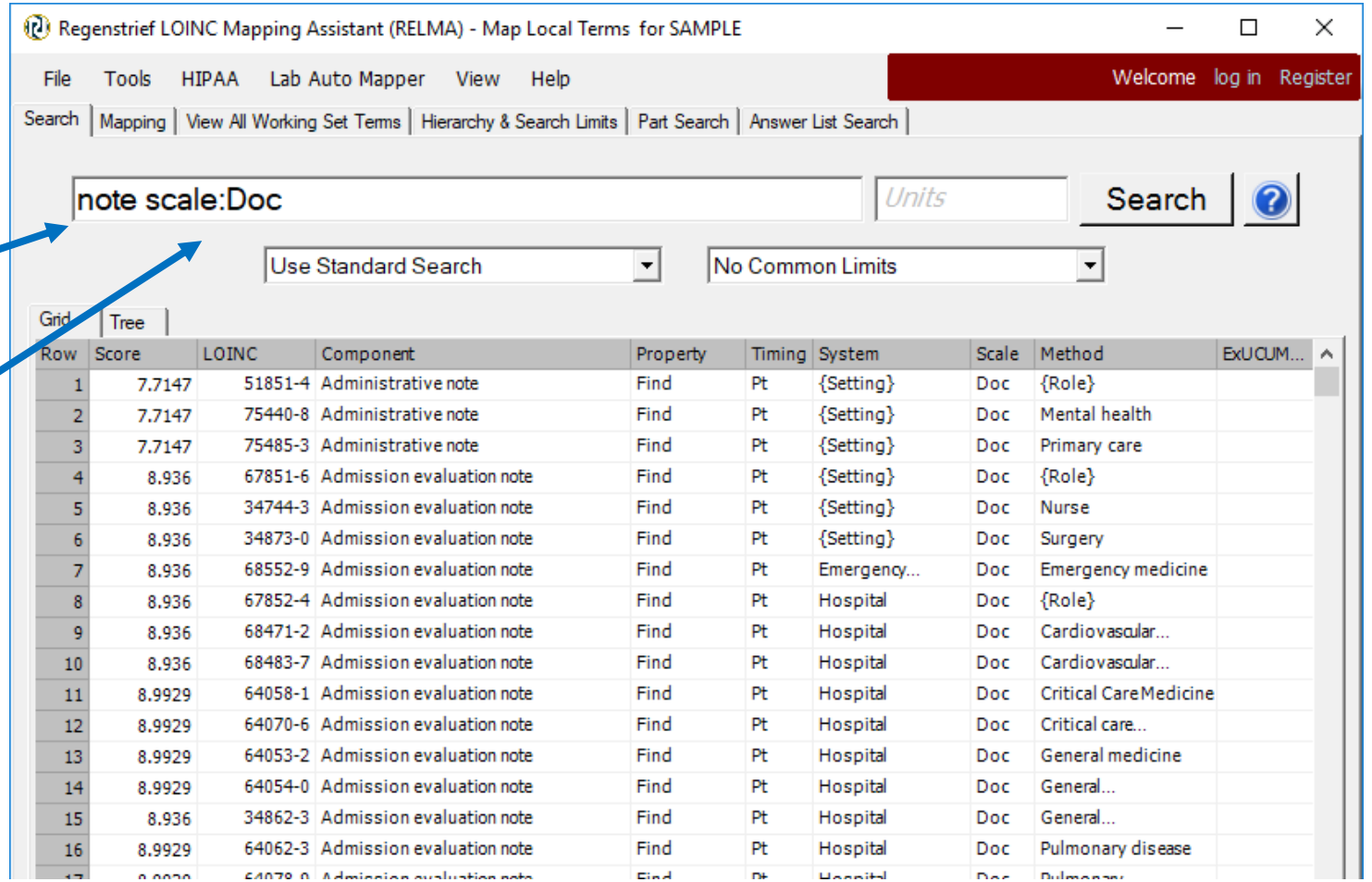
Documents with implementation guide | Documents without implementation guide | Valid attachment requests | Request Modifier Codes

Row	Attachment Name	LOINC
1	Advanced beneficiary notice	53243-2
2	Appeal denial letter	52032-0
3	Automobile liability	52065-0
4	Blood glucose monitors	52041-1
5	Charge ticket or encounter form	53242-4
6	Continuous positive airway pressure (CPAP)	52042-9
7	Dental X-rays and other images (not DICOM)	52040-3
8	Eligibility acknowledgement	53247-3
9	Employee assistance program	52071-8
10	Enteral nutrition	52043-7
11	Explanation of benefits	52030-4
12	Explanation of benefits to subscriber	52031-2
13	External infusion pump	52044-5
14	First report of injury	52064-3
15	Gait trainers	52045-2
16	General correspondence	52033-8
17	Home health claims	52035-3
18	Home health prior authorization	52036-1
19	Hospital beds	52046-0
20	Immunosuppressive drugs	52047-8
21	Lymphedema pumps	52048-6
22	Manual wheelchair	52049-4

Wrapped Text | Print Preview

Finding Response Attachment Types in RELMA

- Using the search tab in RELMA
  - Add search term (Ex.: “note”)
  - Add scale: Doc after search term to limit to document type codes



Row	Score	LOINC	Component	Property	Timing	System	Scale	Method	ExUCUM...
1	7.7147	51851-4	Administrative note	Find	Pt	{Setting}	Doc	{Role}	
2	7.7147	75440-8	Administrative note	Find	Pt	{Setting}	Doc	Mental health	
3	7.7147	75485-3	Administrative note	Find	Pt	{Setting}	Doc	Primary care	
4	8.936	67851-6	Admission evaluation note	Find	Pt	{Setting}	Doc	{Role}	
5	8.936	34744-3	Admission evaluation note	Find	Pt	{Setting}	Doc	Nurse	
6	8.936	34873-0	Admission evaluation note	Find	Pt	{Setting}	Doc	Surgery	
7	8.936	68552-9	Admission evaluation note	Find	Pt	Emergency...	Doc	Emergency medicine	
8	8.936	67852-4	Admission evaluation note	Find	Pt	Hospital	Doc	{Role}	
9	8.936	68471-2	Admission evaluation note	Find	Pt	Hospital	Doc	Cardiovascular...	
10	8.936	68483-7	Admission evaluation note	Find	Pt	Hospital	Doc	Cardiovascular...	
11	8.9929	64058-1	Admission evaluation note	Find	Pt	Hospital	Doc	Critical CareMedicine	
12	8.9929	64070-6	Admission evaluation note	Find	Pt	Hospital	Doc	Critical care...	
13	8.9929	64053-2	Admission evaluation note	Find	Pt	Hospital	Doc	General medicine	
14	8.9929	64054-0	Admission evaluation note	Find	Pt	Hospital	Doc	General...	
15	8.936	34862-3	Admission evaluation note	Find	Pt	Hospital	Doc	General...	
16	8.9929	64062-3	Admission evaluation note	Find	Pt	Hospital	Doc	Pulmonary disease	

Body Types

- Non-XML Body:
  - PDF, Microsoft Word, etc.
- XML Body:
  - CDA documents conforming to Implementation Guides (IGs) such as C-CDA
  - May include large amounts of coded data
- Simple XML Body (Proposed):
  - CDA XML
  - Limited or no coded data

- All body types are human readable and can be attested to.

Non-XML Body

- Use cases:
  - Existing electronic documents such as Microsoft Word, HTML, etc.
  - Scanned paper data
  - Systems that only export in PDF
  - Documents without a CDA implementation guide

- Non-XML body CDA documents are expected to be common for attachments.

80% of clinical information is unstructured.

"Eighty percent of clinical data is locked away in unstructured physician notes that can't be read by an EHR…"
Peter Embi, MD, President & CEO
Regenstrief Institute [9]

28 BUSINESS

www.HealthcareITNews.com | Healthcare IT News | April 2017

Health Catalyst, Regenstrief partner to commercialize natural language processing technology

The companies say they intend to put the artificial intelligence-powered text analytics technology to work accelerating advances in patient care.

BERNIE MONEGAIN, *Editor-at-Large*

HEALTH CATALYST and t he Regenstrief Institute are working together to commercialize nDepth, Regenstrief's natural language processing technology.

nDepth is an acronym for NLP Data Extraction Providing Targeted Healthcare. Indianapolis-based Regenstrief developed the technology to harness unstructured data.

Salt-Lake City-based Health Catalyst, a data warehousing and analytics company, has been in the business of extracting data to boost care quality since it launched in 2008.

Regenstrief's nDepth is artificial intelligence-powered text analytics technology. It was developed within the Indiana Health Information Exchange, the largest and oldest HIE in the country.

Regenstrief fine-tuned nDepth through extensive and repeated use, searching more than 230 million text records from more than 17 million patients.

The goal of the partnership is to speed improvements in patient care by unlocking the unstructured data within electronic health records.

Health Catalyst will incorporate nDepth into its data analytics platform in use by health systems that together serve 85 million patients across the country.

"Eighty percent of clinical data is locked away in unstructured physician notes that can't be read by an EHR and so can't be accessed by advanced decision support and quality improvement applications," Peter Embi, MD, president and CEO of Regenstrief Institute, said in a statement. "We will help millions of patients benefit from the untapped potential hidden within unstructured data."

Memorial Hospital at Gulfport, in Gulfport, Miss., served as the co-development partner and first deployment site for Health Catalyst's integration of nDepth. The 445-bed not-for-profit health system deployed the Health Catalyst data and analytics platform in 2014.

nDepth analyzes any document type to mine the unstructured data for insights for clinicians and quality improvement professionals. The technology employs Natural Language Processing – a combination of linguistics, pattern recognition, and machine learning – to derive meaning from text.

nDepth enhances these foundational technologies with clinical domain expertise and phenotype libraries built and curated by clinicians.

Some recent applications of nDepth include finding patients with metastatic melanoma, identifying pre-diabetic patients for clinical trials, and capturing hypoglycemic events.

Health Catalyst and Regenstrief announced the partnership at HIMSS17 in February in Orlando. ▪

Regenstrief CEO
Peter Embi, MD

Non-XML Body Details

- Two options for including files (e.g., PDFs):
  - Embed via Base64 encoding
    - Consolidates all content in a single file
    - Requires decoding before content can be displayed with standard CDA stylesheets
  - Reference via URI
    - Render with standard CDA stylesheets
    - Splits content in multiple files
    - Can include a hash for security

- The *HL7 Attachments Implementation Guide* requires Base64 encoding, barring prior arrangements between trading partners.

Non-XML Body Examples

- Base64 Encoded

```
<nonXMLBody>
 <text
  mediaType="application/pdf"
  representation="B64">
  JVBERi0xLjQNJeLjz9MNCjE2IDAgb2Jq...
 </text>
</nonXMLBody>
```

- Referenced File

```
<nonXMLBody>
 <text mediaType="application/pdf" >
  <reference
   value="UD_sample.pdf"/>
 </text>
</nonXMLBody>
```

XML Body

- Also known as a **Structured Body**
- Summary documents with XML Body are exported by Meaningful Use certified EHRs
- Includes both human-readable content and coded data
- Some document types allow narrative only
- Conforms to CDA implementation guides
- Examples of clinical content:
  - Problems
  - Allergies
  - Medications
  - Procedures

Structured Body Example (Narrative)

```
<section>
  <templateId root="2.16.840.1.113883.10.20.22.2.6"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.6.1"/>
  <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"/>
  <title>ALLERGIES, ADVERSE REACTIONS, ALERTS</title>
  <text>
    <table border="1" width="100%">
      <thead>  <tr>
         <th>Substance</th>  <th>Overall Severity</th> <th>Reaction</th>
         <th>Reaction Severity</th> <th>Status</th>
       </tr>  </thead>
      <tbody>  <tr>
         <td>ALLERGENIC EXTRACT, PENICILLIN</td>  <td>Moderate to Severe</td>  <td>Nausea</td>
         <td>Mild</td> <td>Inactive</td>
       </tr>  </tbody>
    </table>
  </text>
</section>
```

Rendered View

ALLERGIES, ADVERSE REACTIONS, ALERTS

Substance	Overall Severity	Reaction	Reaction Severity	Status
ALLERGENIC EXTRACT, PENICILLIN	Moderate to Severe	Nausea	Mild	Inactive

Structured Body Example (Coded Data)

```
<observation classCode="OBS" moodCode="EVN">
  <id root="80a6c740-67a5-11db-bd13-0800200c9a66"/>
  <code
    code="26515-7"
    codeSystem="2.16.840.1.113883.6.1"
    displayName="PLT"/>
  <statusCode code="completed"/>
  <effectiveTime value="200003231430-0400"/>
  <value xsi:type="PQ"
    value="123"
    unit="10+3/ul"/>
  <interpretationCode
    code="L"
    codeSystem="2.16.840.1.113883.5.83"/>
  <referenceRange>
    <observationRange>
      <value xsi:type="IVL_PQ">
        <low value="150" unit="10+3/ul"/>
        <high value="350" unit="10+3/ul"/>
      </value>
    </observationRange>
  </referenceRange>
</observation>
```

- Lab Result
  - LOINC code for Platelets
  - Observation made on March 23, 2000 at 14:30
  - The measured value: 123
  - Interpretation is “low”
  - The measured value is less than the low value of the reference range (why the interpretation is low)

Simple XML Body

- CDA documents with narrative, in which coded data are allowed but not required
- Incremental improvement over non-XML Body
  - CDA Narrative (single format vs. CDA + PDF or other format)
  - Incremental coded data where there is ROI
- Sections have titles and LOINC codes are optional
- January 2018 HL7 ballot
  - http://www.hl7.org/documentcenter/public/ballots/2018JAN/downloads/CDAR2_IG_XDOC_R1_D1_2018JAN.zip
  - Must be an HL7 voting member to access while under ballot
  - Will be freely available to anyone a few months after final publication
  - Full name : C-CDA R2.1 Supplemental Templates for Minimally Structured Document (XDoc), Release 1 (US Realm)

Simple XML Body Example

```
<structuredBody>
    <component>
        <section>
            <code code="48765-2"
             codeSystem="2.16.840.1.113883.6.1"
             codeSystemName="LOINC"/>
            <title>Allergies</title>
            <text>
                <list listType="unordered">
                    <item>Penicillin: Hives</item> </list>
            </text>
        </section>
    </component>
    <component>
        <section>
            <title>Problems</title>
            <text>
                <list listType="unordered">
                    <item>Hypertension</item> </list>
            </text>
        </section>
    </component>
</structuredBody>
```

HL7 CDA: How do you make one?

- Scan-to-CDA:
  - CDA Header in XML, demographics required by Meaningful Use
  - Any type of note, clinical or administrative
  - Imaged body
- Speak-to-CDA
  - Same Header
  - Typically Discharge Summary, Op Note, Path or Diagnostic Imaging
  - Unstructured body (PDF, txt, DOC, RTF)
  - Coded structured body (coded per C-CDA, HL7 IG)
  - Simple structured body (CDA R2 XML, coding optional)
- EMR-to-CDA
  - Same Header
  - Typically “summary” notes (Continuity of Care Document)
  - Structured body coded to Meaningful Use

Challenges

- For the industry as a whole
  - Uncertainty around regulation
  - Limits to consensus
    - Wrapper (FHIR, other alternatives to X12)
    - Attachments (how much required coding)
  - Define impact on workflow (prior authorization especially)
  - Inclusion/exclusion of audit use case
  - Adapting to new workflow
  - Competing priorities
  - Standards timelines, flexibility
- Regulators
  - Balancing flexibility with stability
  - Low barrier to entry with room to grow

Challenges

- Providers
  - Comprehensive, indexed electronic record
  - Administrative and clinical system integration
- Payers & clearinghouses
  - Claim/attachment cross-walk
  - X12: New transactions
  - CDA: New syntax (XML), data types, code systems
  - Criteria for unsolicited attachments
- Vendors
  - Indexing by document type code
  - Validating against the standards
  - X12 / HL7 translations

Opportunities

- One method across the industry
- Cost savings:
  - Reduced time to payment
  - Reduced number of claim denials
  - Reduced cost of:
    - Physical storage (e.g., secure rooms, file cabinets, boxes)
    - Materials (e.g., paper, envelopers, postage)
    - Scanner/Fax machines usage
  - Reduced time to:
    - Locate and submit information
    - Coordinate mail room
    - Monitor claims status
    - Training requirements
- Distributed savings across all stakeholders

Matchings Costs to Benefits

IMPLEMENTATION PHASE	PROVIDER COST	PAYER COST	BENEFIT	ROI
Simple CDA, unsolicited	Retrieve, create CDA; package & send	EDI gateway to document manager	Turnaround, materials, labor	SHARED
Simple CDA, solicited	Interpret 277	Claim triggers EDI gateway	+ Volume	SHARED
Integrate administrative & clinical systems	System integration	----	Labor (PROVIDER)	**PROVIDER ONLY**
Increase structured data	Standard codes	Rules & rules engine	Labor (PAYER)	**PAYER ONLY**

Investing in Information: Phased Approach

- Lay groundwork
  - Header metadata
  - Human readable sections or unstructured documents
- Build
  - Consensus on requirements
  - Vocabulary glossary
- Understand
  - Relationship of vocabulary to model
- Introduce interoperable semantic content as requirements and business drivers dictate

Electronic Attachments Tell a Comprehensive Story

Q&A