



HL7 CDA® R2 Attachment Implementation Guide:
Exchange of C-CDA Based Documents, Release 1
Release 1 (Universal Realm)
Standard for Trial Use

August 2017

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Terminology	Owner/Contact
Current Procedures Terminology (CPT) code set	American Medical Association https://www.ama-assn.org/practice-management/apply-cpt-license
SNOMED CT	SNOMED International http://www.snomed.org/snomed-ct/get-snomed-ct or info@ihtsdo.org
Logical Observation Identifiers Names & Codes (LOINC)	Regenstrief Institute
International Classification of Diseases (ICD) codes	World Health Organization (WHO)
NUCC Health Care Provider Taxonomy code set	American Medical Association. Please see www.nucc.org . AMA licensing contact: 312-464-5022 (AMA IP services)

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1 PREFACE

1.1 Revision History

The following provides a historical view of the iterations for this document and why each major revision was made.

<i>Date</i>	<i>Purpose</i>
March 27, 2016	Version 1.0
January, 2016	HL7 Attachment Supplement Specification: Exchange Implementation Guide Release 1 used as the foundation for this guide.

1.2 Acknowledgements

The writers and editors of *the HL7 Attachment Supplement Specification: Exchange Implementation Guide Release 1* want to acknowledge those who have provided years of hard work and dedicated efforts to bring forward the research and development needed to achieve the goal of information exchange amongst the healthcare industry stakeholders. This includes the current and past members of the Attachments Work Groups (formerly the Attachments Special Interest Group (ASIG)) and the Structured Documents Workgroup at HL7.

The information needs of the industry that were identified and developed over the years became key input into the foundational content found in the *HL7 Implementation Guides for CDA® Release 2: Consolidated CDA Templates*.

This Guide was Sponsored by:
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2 INTRODUCTION

This implementation guide (Guide) defines the requirements for sending and receiving standards-based electronic attachments. It does so by applying additional constraints onto standards in common use for clinical documentation and by defining requirements for sending and receiving systems for attachment request and response messages. It defines the set of attachment documents as those that contain the minimum standard metadata to support basic document management functions including identification of patients and providers, the type of document, date of creation, encounter information, and a globally unique document identifier.

This metadata set is defined in the HL7 US Realm Header published in HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm). Documents that meet this requirement at the time of publication of this Guide include those conforming to the following published HL7 implementation guides:

- Consolidated CDA (C-CDA)
- Clinical Documents for Payers (CDP1)
- Medication Therapy Management
- Clinical Oncology Treatment Plan and Summary

These implementation guides will be collectively referred to as **CDA Implementation Guides for Attachments**. The combined set of document level templates defined in the CDA Implementation Guides for Attachments will be referred to as **CDA Documents for Attachments** in this guide.

The Appendices are provided as guidance for implementers and are not required unless cited in a conformance statement in [Attachment Conformance Requirements](#).

2.1 Audience

The audience for this Guide is implementers (such as system architects and implementation developers) responsible for the exchange of Attachments between healthcare providers (hereafter known as 'providers'), and health plans/utilization management organizations and/or their business associates (hereafter known as 'payers').

2.2 Purpose

This Guide is intended to be used along with the CDA Implementation Guides for Attachments and provides guidance to implementers as they develop the means for exchanging supporting information as defined in [Section 2.3: Scope](#).

This Guide will serve to direct implementers to the appropriate HL7 implementation standard used to format the content based on the clinical document being exchanged as an Attachment. Refer to the appropriate CDA Implementation Guides for Attachments for additional information regarding levels of constraint, conformance statements, conformance verbs, cardinality, vocabulary conformance, and null flavor.

This Guide is independent of the method for exchange (e.g., transport, networking, connectivity, security/privacy).

This Guide will refer to healthcare supporting/additional information as Attachments. Additionally, a healthcare claim or encounter may be referred to as a Claim without mention of encounter and Healthcare Administrative Activities will include any or all of the activities as defined in [Section 2.3: Scope](#).

2.3 Scope

This Guide is limited in scope to those functions which support the exchange of healthcare information between providers and payers as part of the administrative business functions of both. It describes the use of CDA Documents as Attachments to exchange clinical information between payer and provider entities. Examples of that exchange using existing standards are included. However, the Guide does not limit implementations to using only those exchange standards. This Guide offers guidance for re-associating that clinical document with the healthcare administrative activity for which additional information was originally needed.

Examples of Healthcare Administrative Activities requiring this supporting information include, but are not limited to:

- healthcare claim or encounter
- healthcare services review (e.g., prior authorizations/precertifications, referrals, notifications)
- post adjudicated claim audits
- pre-payment claim audits to allow for pre-payment review

2.4 History

The Administrative Simplification provision of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 mandated the use of named healthcare electronic data interchange standards for the electronic conveyance of healthcare data that meets the business purposes specifically addressed under HIPAA. A Notice of Proposed Rule Making (NPRM) was issued in 2005 for Claims Attachments, but was withdrawn before a final rule was generated. In 2010, the Patient Protection and Affordable Care Act (ACA) re-instituted the original requirement under HIPAA for Attachments.

2.5 Approach

The HL7 Attachment Work Group (AWG) worked with payers and other industry stakeholders to identify the types of attachments needed to support claims and prior authorization of healthcare services.

The AWG collaborated with the Accredited Standards Committee (ASC) X12 Standard Development Organization (ASC X12) to define an electronic transaction that could be used to support the request for Attachments. *The ASC X12 277 Health Care Information Status Notification Transaction Set* was the most viable ASC X12 option.

The AWG determined that a proposed claims attachment standard combining the standards development efforts of ASC X12 and HL7 would be one of the possible options to support sending an Attachment. The proposed solution was the *ASC X12 275 Patient Information Transaction Set* with the HL7 Clinical Document embedded within the BDS/Binary segment.

The AWG determined it was in the best interest of providers and/or their vendors to support only one way for the exchange of the clinical information. Rather than one standard for the provider-to-provider information

exchange and another for provider-to-payer information exchange, the AWG agreed to adapt their approach to leverage and be consistent with the CDA formatting of clinical documentation.

The CDA Documents for Attachments by themselves do not fully satisfy the needs of the industry for Attachments. Additional metadata/enveloping is needed to assist in the correct pairing with a *healthcare administrative activity* and the Attachment itself. For this purpose, the Insurance Subcommittee of ASC X12 (ASC X12N) developed a suite of Technical Report Type 3 (TR3) documents for use with Attachments. Throughout this Guide, references and examples of Attachment activity may cite specific ASC X12N TR3s developed for this purpose, however there is no intent by the authors of this Guide to limit transport and messaging metadata/enveloping standards. [Refer to Appendix F: CDA Document for Attachments Transport and Payload](#)).

3 BACKGROUND

3.1 Reference Material

Before starting the development of an Attachment, there are reference materials that are needed. This section addresses the basic requirements.

3.1.1 Getting Started

The Attachment Collaboration Project (ACP) is a joint effort with WEDI, ASC X12 and HL7 that is developing a White Paper that will provide guidance on how to exchange attachments for claims and prior authorizations. The intent is to provide a single resource document for the industry to use which will identify when and where an implementer needs to obtain technical support from either HL7 or ASC X12. The ACP White Paper intends to provide information about business, operational and technical processes to support standards and implementation specifications for Attachments (ASC X12N 275, 277, 278, and 837 TR3s and the relevant HL7 attachment standards) independent of versions or regulations. The ACP Whitepaper will be located on the [WEDI Website](#).

3.1.2 HL7 Reference Materials

The following list of reference materials may be helpful to those implementing attachments and are located on the [HL7 Website](#).

- Quick Start Guide for CDA
- HL7 Consolidated Clinical Document Architecture Release 2 (C-CDA R2.1)
- HL7 C-CDA R2.1 Companion Guide¹
- HL7 Clinical Documents for Payers Set 1 (CDP1)
- HL7 Digital Signatures and Delegation of Rights Release 1
- [HL7 Implementation Guidance for Unique Object Identifiers \(OIDs\), Release 1](#)

3.1.3 Logical Observation Identifiers Names and Codes (LOINC)

[LOINC](#) is a common language (set of identifiers, names, and codes) for clinical and laboratory observations. LOINC is used in the exchange of Attachments to identify documents. For more information on the use of LOINC refer to [Section 4: LOINC](#). The current proposed specifications for attachments use LOINC codes for three main purposes:

1. To identify the specific kind of information being communicated in both a request and response (e.g., a discharge summary or diagnostic imaging report).
2. To optionally specify certain modifier variables in fulfilling the request for information (e.g., variables that indicate a modification to the default time period).
3. In structured attachment responses using HL7 CDA, LOINC codes identify the attachment (document) type, sections, and sometimes the individual entries (tests or observations).

¹ This guide is in ballot review at the time of publication of the Guid and is anticipated to be published in early 2017. The full name is HL7 CDA® R2 IG: CCDA Templates for Clinical Notes R1 Companion Guide, Release 1.

3.1.4 ASC X12N Reference Materials

The version that should be used of the ASC X12N Technical Reports 3 published for the purposes of exchanging Attachments is the version named in regulation or agreed by trading partners in the absence of regulations. The following list of ASC X12N Technical Report Type 3 reference materials and associated transactions are located in the [ASC X12 Store](#) and are important when using the ASC X12 documents to implement attachments.

- ASC X12N 277 Health Care Claim Request for Additional Information.
- ASC X12N 275 Additional Information to Support a Health Care Claim or Encounter
- ASC X12N 278 Health Care Services Review – Request for Review and Response
- ASC X12N 275 Additional Information to Support a Health Care Services Review
- ASC X12N 837 Health Care Claim: Professional (837-P)
- ASC X12N 837 Health Care Claim: Institutional (837-I)
- ASC X12N 837 Health Care Claim: Dental (837-D)

3.1.5 Additional Resources

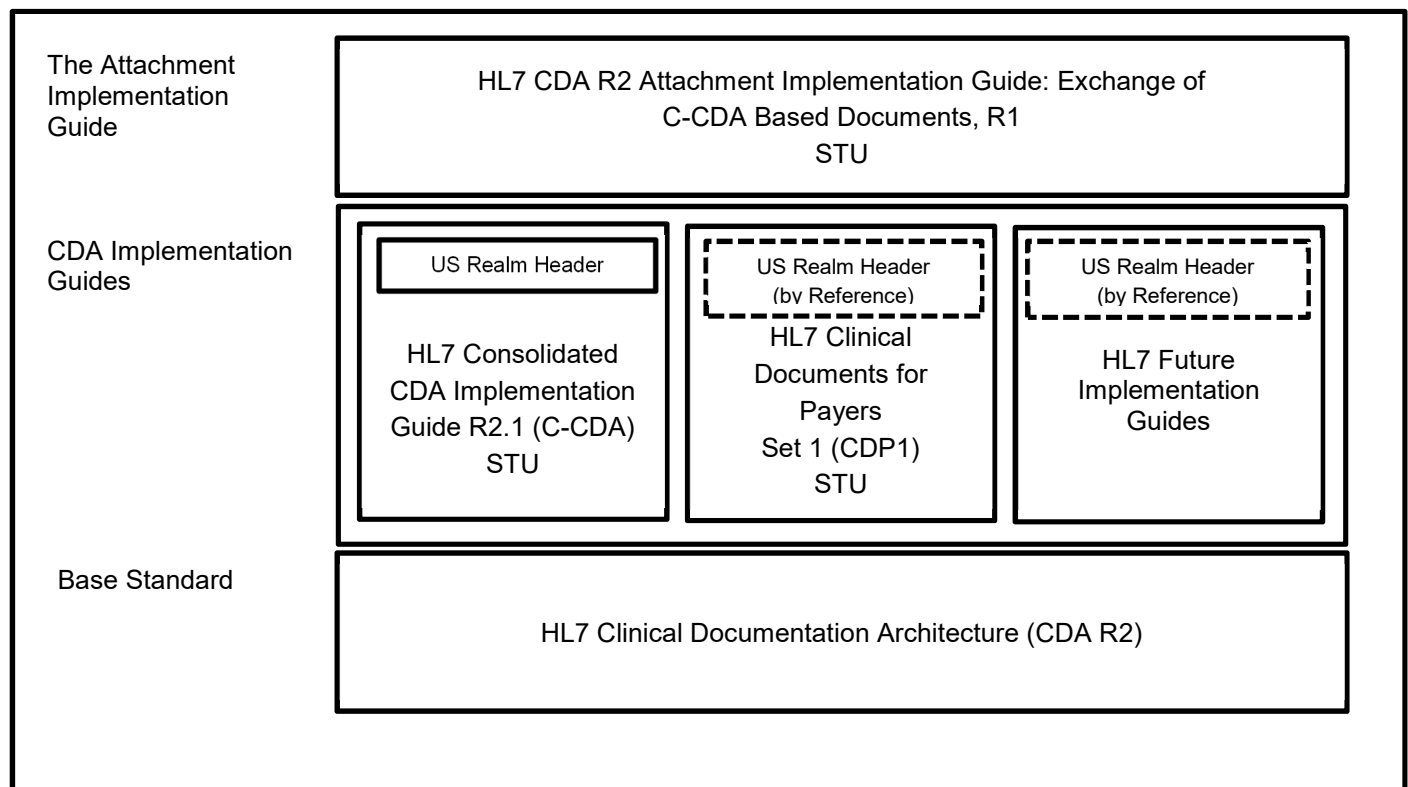
- Internet Engineering Task Force (IETF®) Requests for Comment (RFC)
 - Mime Encapsulation of Aggregate Documents ([RFC 2557](#))
 - The Base16, Base32, and Base64 Encodings ([RFC 4648](#))
- [XML in Wikipedia](#)
- [XML in 4 Minutes](#)

3.2 Relationship of Standards and Implementation Guides (IG)

3.2.1 HL7 Standards and Implementation Guides

The HL7 Clinical Document Architecture Release 2 (CDA R2) is based on the HL7 Reference Information Model and the W3C XML standard. Release 1.1 and 2.1 of the Consolidated CDA are both based on CDA R2 and are designated C-CDA R1.1 and C-CDA R2.1 respectively. This document, and the Clinical Documents for Payers – Set 1 (CDP1), incorporate, by reference, many of the C-CDA R2.1 templates.

Figure 1: HL7 Relationship of Standards and Implementation Guides



3.2.2 ASC X12 Standards and Implementation Guides

The ASC X12N Technical Reports are based on the underlying ASC X12 Standards. This document describes how a payer may request a specific attachment from a provider by using LOINC codes in the ASC X12 Standards and Technical Reports for the ASC X12N 277 or 278. The ASC X12N 275 may be used by the provider as the mechanism for submission of the C-CDA documents when responding to a request for an Attachment.

Figure 2: ASC X12 Relationship of Standards and Technical

Technical Report Type 3 (TR3)	ASC X12N 277 Health Care Claim Request for Additional Information ASC X12N 275 Additional Information to Support a Health Care Claim or Encounter ASC X12N 278 Health Care Services Review – Request for Review and Response ASC X12N 275 Additional Information to Support a Health Care Services Review
Base Standard	ASC X12 277 Health Care Information Status Notification ASC X12 275 Patient Information ASC X12 278 Health Care Services Review Information

3.3 Understanding C-CDA

This section will explain the C-CDA Implementation Guides for Attachments at a high level. Implementers should rely on the detail found in the individual guides to understand how to utilize each Standard.

3.3.1 Clinical Document Architecture (CDA)

The HL7 Version 3 Clinical Document Architecture (CDA®) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange between healthcare entities. It defines a clinical document as having the following six characteristics:

1. Persistence
2. Stewardship
3. Potential for authentication
4. Context
5. Wholeness
6. Human readability

A CDA can contain any type of clinical content -- typical CDA documents would be a Continuity of Care, Discharge Summary, Imaging Report, History & Physical, Progress Note and others. It can be transferred within a message and can exist independently, outside the transferring message.

Information about the components for CDA is being presented at a high level and is intended to convey only what is necessary for the implementer to understand the application with respect to Attachments. Refer to the CDA Implementation Guides for Attachments for technical guidance on implementation of CDA for Attachments.

A CDA document has two primary groupings of information, a **header** and a **body**:

- The header (Refer to Section 2.1 US Realm Header in the C-CDA R2.1 Volume 2 – Templates and Supporting Material for more detail)
 - Identifies and classifies the document
 - Provides information on authentication, the encounter, the patient, and the involved providers.
- The body
 - Contains the clinical report, organized into sections whose narrative content can be encoded using standard vocabularies.
 - Can be represented using a **nonXMLBody** or a **structuredBody** element.
 - **nonXMLBody** is used when the content is an external file such as a TIFF image, MS RTF document, PDF, etc. (Refer to [Table 1](#) for the complete list). The NonXMLBody class is provided for those applications that can do no more than simply wrap an existing non-XML document with the CDA Header.
 - **structuredBody** is used when the body will be XML structured content. XML structured content is always inserted into the structuredBody element, never as an external file. The StructuredBody contains one or more Section components.

For the purposes of this Guide:

- A header paired with a structuredBody element will be referred to as a “**Structured Document**”.
- A header paired with a nonXMLBody element will be referred to as an “**Unstructured Document**”².

More information about CDA can be found on the [HL7 Website](#).

3.3.2 Consolidated Clinical Documentation Architecture (C-CDA)

The C-CDA contains a library of CDA templates, incorporating and harmonizing previous efforts from Health Level Seven (HL7), Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP). It represents harmonization of the HL7 Health Story guides, HITSP C32, related components of IHE Patient Care Coordination (IHE PCC), and Continuity of Care (CCD).

3.4 ISO Object Identifiers (OID's)

OID is an acronym, used throughout HL7 specifications to mean “ISO Object Identifier”. ISO is the International Organization for Standardization (<http://www.iso.ch>), and we will see below that the International Telecommunications Union (ITU, <http://www.itu.int>) is also relevant. The HL7 OID registry, mentioned below, can be used to find or create OIDs for use in attachment implementations. The mention of ISO and ITU is for background information only.

OIDs are used in CDA to identify the coding systems and identifier name spaces and in the C-CDA Templates to identify value sets. An OID is a globally unique string consisting of numbers and dots (e.g., 2.16.840.1.113883.6.90). This string expresses a tree data structure, with the left-most number representing the root and the right-most number representing a leaf.

Each branch under the root corresponds to an assigning authority. Each of these assigning authorities may, in turn, designate its own set of assigning authorities that work under its auspices, and so on down the line. Eventually, one of these authorities assigns a unique (to it as an assigning authority) number that corresponds to a leaf node on the tree.

For more information about the use of OIDs in Attachments refer to [HL7 Implementation Guidance for Unique Object Identifiers \(OIDs\), Release 1](#).

OIDS present a systematic way to identify the organization responsible for issuing a code or entity identifier (scope). HL7 is an assigning authority, and has the OID prefix “2.16.840.1.113883.” broken down as follows:

- | | |
|-------|---|
| (2) | represents that the OID was assigned by a joint ISO-ITU |
| (16) | represents assigning authority which is specific to the country |
| (840) | reflects the USA |
| (1) | is specific to the organization |

² It is important to note that the header in either structured or unstructured scenarios is always considered structured and as such, available for computer processing (parsing) to occur with its content.

(113883) represents Health Level Seven (as the assigning authority).

Any OID that begins with this is further described by a registry maintained by the HL7 organization. For example, the OID 2.16.840.1.113883.6.90 (above) was established by HL7 as a globally unique identifier for the ICD-10-CM code set for diagnoses.

Beyond that, the HL7 organization assigns any numbers - and these are maintained in a registry available on the [HL7 Website](http://www.hl7.org). HL7 uses its registry to assign OIDs within its branch for HL7 users and vendors upon their request. HL7 is also assigning OIDs to public identifier-assigning authorities both U.S. nationally (e.g., the U.S. State driver license bureaus, U.S. Social Security Administration, US National Provider Identifier (NPI) registry) and internationally (e.g., other countries' social security administrations, citizen ID registries)

Additional reference information about OIDs, including the current directory of OIDs assigned by HL7, is available at <http://www.hl7.org/oid/index.cfm>. Organizations that wish to request an OID for their own use (e.g., to be able to create identifiers within a CDA document) may also obtain one from HL7 at this site.

3.4.1 The Use of OIDs in Attachments

OIDS are used throughout the C-CDA used in Attachments. However, there are times in which an OID may not have been assigned to the information being exchanged. In this situation it is permissible to use 'UNK' as the OID. For example, Patient ID is required in C-CDA header but Patient ID is not defined nor does it state whether it is Patient ID identified by provider or the payer.

Each provider or payer should obtain an OID for their organization to establish the scope for a Patient ID.

If a provider or payer does not have an OID for their organization to establish the scope for a Patient ID, the following is a valid way to represent a Patient or Member Id:

```
<id NullFlavor='UNK'extension='MemberID'>
```

3.5 Structured/Unstructured Documents

Use of the CDA standard allows for a wide-range of implementation flexibility with respect to the implementer's technical abilities (CDA originator and recipient of the document).

For most implementers, a CDA document may simply be rendered to a common internet XML aware browser using a stylesheet³, much like one might view a PDF on a personal computer application. Even in an Unstructured Document, the Header may be partially rendered using a stylesheet. However, when exchanging information using the Unstructured Document, this mechanism may not work without additional engineering. The browser must be able to recognize the body of this document or be able to separately decode the document into its binary format.

In the instance where the body type is in an Unstructured Document and the body content contains a media type (e.g., JPEG, GIF, PDF), that content would require additional software to interpret and render the encapsulated data using an appropriate viewer for the type of document (e.g., image viewer, adobe reader).

³ A *stylesheet* is a specification used by browsers for controlling the display of the markup language (e.g., XML or HTML), describing how elements of a document should be displayed.

This requires several steps, including configuring the browser to display the non-HTML content if needed (e.g., application/pdf, application/msword or text/rtf content), linking to externally referenced content, or linking to and decoding the embedded Base64 encoded content (Refer to [Section 3.6: Base64 Encoding](#)). In addition, considerations should be given to security concerns that might be introduced by displaying content which could include scripts.

The use of a stylesheet to render a CDA document to a browser sets a low technical bar for the receiver of a CDA document. No matter what the technical level of the originator, the receiver will have the choice of leveraging the originator's highest level of technical sophistication or simply choose to render using a stylesheet and a browser. This will enable receivers of Attachments to interpret the content of a clinical document without having to be an expert on CDA.

Initially the limited capability of participants to support fully Structured Documents and the need for further development of attachment content requires the use of the unstructured content capability of the C-CDA based documents. For Attachments, even though a Structured Document template may be defined in C-CDA based Documents (attachment types where a document level template exists, excluding Unstructured Document), the use of the unstructured version of that document (e.g., nonXMLbody) is permitted.

3.5.1 Structured Content

Each CDA Implementation Guide for Attachments describes the respective document types and conformance requirements for each of the Structured Documents listed in [Appendix C: CDA R2.1](#) and [Appendix D: CDP1 R1.1](#).

Conformance criteria for each of those document types, their sections and any applicable entries are found in the appropriate section of the CDA Implementation Guides for Attachments.

3.5.2 Unstructured Content

In addition to the clinical document types described in [Appendix C: CDA R2.1](#) and [Appendix D: CDP1 R1.1](#) for Structured Documents, there is an Unstructured Document (described specifically in the C-CDA R2.1) which is available to be used for exchange of ANY clinical document type.

Unstructured documents fill an important role where structured information is inappropriate or impractical. Use of the unstructured document is intended to accommodate attachment types for which a structured format hasn't been developed (e.g., new policies) or is not supported by the sender. Clinical document types that are supported as Structured Documents may also be sent in an unstructured format (e.g., History and Physical Scanned Image, Discharge Summary PDF).

Refer to [Section 4: LOINC](#) for appropriate Document Type Codes.

3.5.3 Unstructured Document Content Types

The following table reflects the value set of the file formats supported by Unstructured Document Template in C-CDA R2.1.

Table 1: Supported File Formats

Value Set: SupportedFileFormats 2.16.840.1.113883.11.20.7.1 A value set of the file formats supported by the Unstructured Document Template.			
Code	Code System	Code System OID	Print Name
application/msword	Media Type	2.16.840.1.113883.5.79	MSWORD
application/pdf	Media Type	2.16.840.1.113883.5.79	PDF
text/plain	Media Type	2.16.840.1.113883.5.79	Plain Text
text/rtf	Media Type	2.16.840.1.113883.5.79	RTF Text
text/html	Media Type	2.16.840.1.113883.5.79	HTML Text
image/gif	Media Type	2.16.840.1.113883.5.79	GIF Image
image/tiff	Media Type	2.16.840.1.113883.5.79	TIF Image
image/jpeg	Media Type	2.16.840.1.113883.5.79	JPEG Image
image/png	Media Type	2.16.840.1.113883.5.79	PNG Image

3.6 Base64 Encoding Content

This Guide requires the use of Base64 encoding for embedding non XML documents and graphics. Also the authors acknowledge that Base64 encoding may present rendering challenges in some browsers.

3.6.1 Purpose of Base64 Encoding

The purpose of Base64 Encoding is to eliminate characters and binary representation that may interfere with the messaging standards used to exchange a specific payload (in the case of this Guide, the C-CDA). Base64 Encoding uses an algorithm that transforms the payload into a specific set of 64 characters that are both members of a subset common to most encodings, and also printable. For example, MIME's Base64 implementation uses A–Z, a–z, and 0–9 for the first 62 values. Other variations share this property but differ in the symbols chosen for the last two values.

3.6.2 Standards for Base64 Encoding

The unstructured body of an unstructured CDA must be Base64 encoded and decoded as defined in RFC 4648.

3.6.3 Base64 Encoding Examples

A quote from Thomas Hobbes' Leviathan (be aware of spaces between lines) is represented as a byte sequence of 8-bit-padded ASCII characters encoded in MIME's Base64 scheme as follows:

Quote:

“Man is distinguished, not only by his reason, but by this singular passion from other animals, which is a lust of the mind, that by a perseverance of delight in the continued and indefatigable eneration of knowledge, exceeds the short vehemence of any carnal pleasure.”

Base64 Representation:

TWFuIGlzlGRpc3Rpbmd1aXNoZWQsIG5vdCBvbmx5IGJ5IGhpcyByZWZzb24sIGJ1dCBieSB0aGlzIHNpbm
d1bGFyIHh3c3Npb24gZnJvbSBvdGhlciBhbmltYWxzLCB3aGljaCBpcyBhIGx1c3Qgb2YgdGhlIG1pbmQsIHR
oYXQgYnkgYSBwZXJzZXZlcmFuY2Ugb2YgZGVsaWdodCBpbiB0aGUgY29udGludWVkiGFuZCBpbmRlZm
F0aWdhYmxiIGdlbmVvYXRpb24gb2Yga25vd2xIZGdILCBleGNIZWRzIHRoZSBzaG9ydCB2ZWhlbWVvY2Ug
b2YgYW55IGNhcm5hbCBwbGVhc3VyZS4=

Table 2: Base64 Index

Value	Char	Value	Char	Value	Char	Value	Char
0	A	16	Q	32	g	48	w
1	B	17	R	33	h	49	x
2	C	18	S	34	i	50	y
3	D	19	T	35	j	51	z
4	E	20	U	36	k	52	0
5	F	21	V	37	l	53	1
6	G	22	W	38	m	54	2
7	H	23	X	39	n	55	3
8	I	24	Y	40	o	56	4
9	J	25	Z	41	p	57	5
10	K	26	a	42	q	58	6
11	L	27	b	43	r	59	7
12	M	28	c	44	s	60	8
13	N	29	d	45	t	61	9
14	O	30	e	46	u	62	+
15	P	31	f	47	v	63	/

Note: for more examples around Base64, see [Appendix H: Examples of Base64 Encoding](#)

3.7 Document Succession

Document succession management is required to permit a provider to supply updates to previously submitted CDA Documents for Attachments. The US Realm Header provides for two elements (setID and version) that permits the document creator to specify the document set (e.g., the Progress Note) and the version of the Progress Note for the same patient for the same visit.

The recipient of the document must recognize the setID and version in the Header and have processes in place to manage the “versioning” of the document. This version management may be accomplished by any of the following:

1. Maintain version control – keep both versions and use them appropriately (e.g., compare the documents to identify changes).
2. Supersede the prior version – replace the prior version with the new version
3. Ignore the newer version based on specific policy (e.g., decision already made based on prior submission)

4 LOINC (LOGICAL OBSERVATION IDENTIFIERS NAME AND CODES)

Logical Observation Identifiers Names and Codes ([LOINC⁴](https://loinc.org/)) is an international standard code set developed and maintained by the Regenstrief Institute for identifying clinical information. Since its inception, Regenstrief has developed LOINC as an open standard and is available at no cost. LOINC is used worldwide for the exchange and pooling of clinical results for care delivery, outcomes management, public health reporting, document management, and research. Used in conjunction with standards for messages, documents, and APIs, LOINC supports efficient processing and storage of data from disparate sources.

Attachment requests and attachment submissions use LOINC codes to identify the type of information desired and the information provided.

4.1 Overview of LOINC

LOINC is a freely available international standard for health measurements, observations, and documents. LOINC achieves these aims by creating a unique, persistent identifier – a code – which is paired with a structured name for each document or observation. Together, the code and the name(s) assigned to that concept are called a LOINC term. Each term corresponds to a single kind of document, observation, measurement, or test result. Each term is based on a formal structure that distinguishes among tests and observations that are clinically different.

The formal LOINC name is “fully-specified” in the sense that it contains the features necessary to disambiguate among similar clinically distinct observations. The fully-specified name is constructed according to a six-part semantic model that produces an aggregate or pre-coordinated expression. By design, the model does not capture all possible information about the document testing procedure or result – only enough to unambiguously identify it.

More information about the LOINC model and naming conventions can be found in the LOINC Users’ Guide along with other resources available on the [LOINC website](https://loinc.org/).

4.2 Use of LOINC in Identifying Documents

In attachment requests and responses, LOINC codes identify the kind of information being requested and the content of the response (e.g., a discharge summary or diagnostic imaging report). These LOINC codes are referred to as LOINC Document Type Codes. The electronic attachment itself, the CDA document, also uses a LOINC Document Type Code to describe the expected contents of the document. Where feasible, the document type code in the CDA document header should match the code of the corresponding submission or request and response.

This Guide restricts the set of allowable request codes to those codes identified in LOINC as codes for “HIPAA Attachments” and defines a hierarchy of preferences for the response to the request. Pre-defined subsets of codes within a controlled terminology such as LOINC are called “value sets”. The HL7 Attachments Work Group (AWG) adopted these value sets from HL7 implementation guides developed for the exchange of clinical documents, the first of which was the C-CDA. AWG extended this set through outreach to industry stakeholders who identified the types of attachments in current use. As the exchange of electronic attachments increases, new codes can be adopted without amendment to this guide because the

⁴ <https://loinc.org/>

value sets are defined here as “dynamic”, meaning, they can be extended without amendment, as long as they are published in the indicated manner by LOINC.

The LOINC website maintains an [Attachments Page](http://loinc.org/attachments) documenting three methods to identify LOINC codes that are valid for attachments⁵:

- The LOINC Table – the master database that associates codes with their component parameters (type, provider type, etc.) Useful when you want a copy of all 60,000+ LOINC codes.
- The RELMA application – a browsing and mapping application with a special form for attachment codes. Useful when you need to see a list of LOINC codes used for Attachments.
- The online LOINC search application search.loinc.org. Useful when you want to check on a specific LOINC code.

All three methods access the same sets of codes. New users should become familiar with the organization of the codes using the RELMA graphical user interface, used here to illustrate the key concepts.

This section describes how LOINC Document Type Codes for HIPAA Attachments are organized. The following sections describe how to access the codes using RELMA, the LOINC Table and the search application. The final section describes how to request additional codes.

⁵ <http://loinc.org/attachments>

4.2.1 LOINC Attachment Code Sets

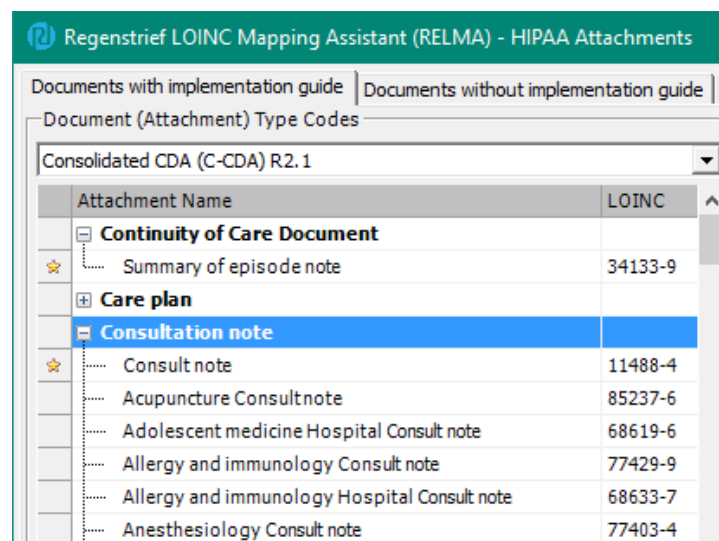
LOINC contains four sets of document type codes that apply to attachments:

- Documents with implementation guide
- Documents without implementation guide
- Valid attachment requests
- Request modifier codes

“Documents with implementation guide” lists the document type codes specified in published HL7 CDA Implementation Guides that qualify as CDA Implementation Guides for Attachments. (See the definition in [Section I: Introduction](#).) The drop-down list shows the published versions of each guide. Note that a guide may cover one type of document or a series, as is the case with the C-CDA which currently encompasses 13 types of documents.

Some implementation guides specify a single document type, as is the case for the Oncology Treatment Plan and Summary ([74156-1](#)). Within C-CDA, some documents require a single code, Continuity of Care Document ([34133-9](#)) and others, like the Consult Note, list a high-level or general document type first, and a number of more specific types following. Figure X shows the single code for CCD and general code for Consult Note ([11488-4](#)) in the RELMA HIPAA Attachments viewer. The Acupuncture Consult note ([85237-6](#)) and following are more specific Consult Note codes. The C-CDA recommends use of the high-level codes.

Figure 3: High-level and Specific Document Type Codes in RELMA



Attachment Name	LOINC
Continuity of Care Document	
Summary of episode note	34133-9
Care plan	
Consultation note	
Consult note	11488-4
Acupuncture Consult note	85237-6
Adolescent medicine Hospital Consult note	68619-6
Allergy and immunology Consult note	77429-9
Allergy and immunology Hospital Consult note	68633-7
Anesthesiology Consult note	77403-4

“Documents without implementation guides” are those that have not gone through a formal specification and publishing process under HL7. The list encompasses those clinical and administrative documents commonly required as attachments including Advanced beneficiary notice ([53243-2](#)), Explanation of Benefits ([52030-4](#)), General correspondence ([52033-8](#)), Psychiatric service attachment ([18594-2](#)) and many others⁶.

⁶ At this writing, there are 64 codes listed.

Note that the list of attachments associated with C-CDA does not include the Unstructured CDA which is defined in that guide. The reason for this is that the Unstructured CDA can carry any LOINC document type code, thus, drawing from both lists of attachment document type codes.

“Valid attachment requests” is a union of the high-level codes for documents with implementation guides plus all of the codes for documents without implementation guides.

The Request Modifier Codes are, as indicated, modifiers to the requestor codes. They come in two varieties:

- Time window modifiers related to the date of service and/or observation window
- Document template modifiers that request conformance with a particular version of a published implementation guide.

Implementation guides release new template identifiers when templates are modified. Specifying the template indicates the requestors preferred format. Submitters can then send data that is structured and coded to the most appropriate level for the recipient.

Consistent with the use of LOINC allowed by the LOINC License, the HL7 Attachment Supplement Specification requires that LOINC codes be used as published in the LOINC database, without leading zeroes and with the hyphen that precedes the check digit (e.g., "8709-8" and "10154-3"). Along with the LOINC Document Type code, this Guide strongly recommends that one of the published LOINC names also be transmitted in the message. For most purposes, the LOINC Long Common Name is the best name to include in electronic messages. Note that the LOINC Long Common Name is the human readable label for the concept that the LOINC code represents. It may differ from the name used in practice or the title on on the document itself. Thus, for a summary note you have:

- Name of the specification Continuity of Care Document (CCD)
- LOINC Long Common Name Summarization of episode note
- Document title, as displayed ABC Hospital Summary

A local document management system might classify it using yet again a different text string, according to local usage. For this reason, the codes themselves are the authoritative classification and the code name is a useful guide to content.

4.2.2 Use of LOINC in CDA Documents:

As stated, all CDA documents with a US Realm Header carry a LOINC document type code.

In addition to document type, LOINC codes identify the sections, and sometimes the individual entries (tests or observations) in structured CDA documents. Note that for documents with published implementation guides, RELMA lists the required and optional sections for each type of document listed, as defined by the corresponding HL7 implementation guide. These section codes are used where the body of the document is structured.

Any document listed as having an associated implementation guide may be either structured or unstructured. Documents for which there is no associated implementation guide, by default, are unstructured. Structured documents may contain data coded using any number of coding systems as required and allowed by the individual implementation guides, including SNOMED, ICD, CPT, and others. In a structured document, the section/entry coded entries may be helpful to the recipient in extracting/parsing information within the document.

4.2.3 Requesting an Attachment

When requesting documents for Attachments, the following guidelines should be observed.

1. Use only LOINC codes from the “Valid HL7 Attachment Request” list to specify the kind of attachment being requested.
2. Include LOINC codes from the “Request Modifier Codes” list to request a document coded to a particular implementation guide release or to specify a time window to be covered by the attachment.

While a LOINC code can identify information at the section and sometimes the entry level, a request for additional information should always be at the document level (i.e., specifying a LOINC Document Type Code).

In summary, attachment requests use LOINC codes in three ways:

- LOINC Document Type: Identify an electronic Attachment in its entirety (e.g., Discharge Summary Report)
- LOINC Document Template Modifier code: Identify the specific implementation guide version of a document being requested (e.g., C-CDA R2.1 Operative Note versus the CDP1 Enhanced Operative Note)
- LOINC Time Window Modifier code: Identify the explicit scope of a requested activity (e.g., to modify a request for information to a period 30 days prior to treatment).

Table 3: Example Care Plan Request and Modifier Codes

Request	LOINC Name	Doc Type Code	Modifier Code	Modifier Code
Care Plan (any)	Plan of Care note	18776-5	--	--
Care Plan (C-CDA R2.1)	Plan of Care note	18776-5	81237-0	--
Care Plan (3 months or less before date of service)	Plan of Care note	18776-5	--	18804-5
Care Plan (C-CDA R2.1, 3 months or less before date of service)	Plan of Care note	18776-5	81237-0	18804-5

Request modifier codes can be used singly or in combination, up to one modifier of each type.

4.2.4 Submitting an Attachment:

If an attachment is unsolicited, the submitter can send any valid attachment type. Best practice indicates that unsolicited submissions should be as highly structured and coded as possible to encourage greater hands-off processing which benefits all stakeholders. The document type code for those types that have a published implementation guide should be the preferred code, but may be any of the valid codes.

If the attachment is solicited, the following guidelines should be observed. The list below is in priority order.

1. Where a published implementation guide applies, the response should be a structured document, where possible. It may be an unstructured document.
2. Whether structured or unstructured, the response should use the same LOINC document type code as requested.
3. The response may use a more specific document type code (e.g., request is for a Consult Note (11488-4). The response should use that code and may use any of the subordinate codes e.g., Cardiology Consult Note (34099-2)).
4. If no document meets the request specifically, then the respondent may provide any applicable document and should use the appropriate LOINC document type code to describe its contents.

Table 4: Example Request and Response Codes in Priority Order

Request Document Type	Requestor Doc Type Code	Response Document Type	Response Doc Type Code	Document level	Same/different document type
Referral Note	57133-1	Referral Note	57133-1	Structured	Same, generic code
		Cardiology Referral Note	57170-3	Structured	More specific: Cardiology Referral Note
		Referral Note	57133-1	Unstructured	Same, generic code
		Cardiology Referral Note	57170-3	Unstructured	More specific: Cardiology Referral Note
		Discharge Summary	18842-5	Structured or unstructured	Different document type: e.g., Discharge Summary

(See Table 8: C-CDA R2.1 Clinical Document Types with Recommended LOINC Code for Requests or Table 9: CDP1 R1.1 Clinical Document Types with Recommended LOINC Code for Requests).

4.3 Navigating LOINC to Identify Valid Attachment Types

As noted above, LOINC provides three methods to access and navigate codes: the RELMA application with a graphical user interface and the LOINC Table, both of which are downloads, and an online search via search.loinc.org, which provides a structured export of terms.

The best method to become familiar with each and to stay up to date is to make use of the documentation for valid attachment codes on <http://loinc.org/attachments>. In addition, any single code can be looked up using this syntax: <http://loinc.org/XXXXX-X> where “XXXXX-X” is replaced with a valid code, such as 53243-2.

The LOINC Manual and online documentation describe how to use the LOINC query syntax. Queries against the online search or RELMA can yield, for example, all valid attachment codes where an IG does (or does not) exist or more specialized queries, including keyword search terms. For example, the query term “consent HL7AttachmentStructure:NoIGexists” yields a list of three terms for different types of consent documents. The query term “cardiac HL7AttachmentStructure:IGexists” returns a large number of results including the term “cardiac” in the Long Name which are specializations of procedure notes, operative reports, consult notes, plans of care, and several other types of notes.

4.4 Updating LOINC and the Attachment Document Type Codes

The LOINC database, maintained and managed by the Regenstrief Institute, will maintain the content of the external value set of LOINC codes available for usage in the exchange of Attachments , and is further described below.

To request a new Attachment Type, initial contact should be made to the HL7 Attachments WG via any of the work group Co-Chairs found at the following link: [Attachment Workgroup Leaders](#).

Regenstrief welcomes requests for new LOINC terms. It is because of submissions from the LOINC community that the vocabulary has been able to grow and adapt so quickly. Regenstrief is also always happy to receive specific suggestions about revisions or enhancements to existing content like synonyms and term descriptions as well. The general process for how to request these enhancements to LOINC are described on the [LOINC website](#).

With each release (semi-annually), the LOINC database contains additional new terms and some edits to existing terms. LOINC development follows best practices for terminology system development by never reusing or deleting codes. If a LOINC term is identified as erroneous or a duplicate of a previous term it is flagged as “deprecated” in the database, but the record is not removed. Changes in concept status are made very judiciously.

There are various mechanisms for staying abreast of LOINC updates that are available from the LOINC website. You can join the LOINC announcement email list (<http://loinc.org/mailling-lists>), subscribe to the LOINC news RSS feed (<http://feeds.feedburner.com/LOINCNews>), follow on Twitter (@LOINC), or check the website for other new features.

5 BUSINESS OVERVIEW FOR ATTACHMENTS

5.1 Attachment Exchange

This Guide will touch on the business overview for additional information. For a more detailed explanation refer to the “*Guidance on Implementation of Attachments for Healthcare Transactions*” developed by the Attachment Collaboration Project.

In the course of doing business, payers may need additional information from a provider to determine if the service being billed or requested (prior authorization) is consistent with:

- patient’s insurance benefits
- patient’s demographics (i.e., age, sex)
- general medical policies
- level of service being performed
- specific condition/diagnosis to include past history and/or treatment that has already been completed, but was not effective

5.1.1 Claims Attachment Exchange

Upon receipt of a claim, the claims adjudication area within a payer organization may perform a review to determine if additional information is required. The payer may communicate a list of procedures and/or services that would require additional information or in some situations the process may be automated based on predefined rules. The request for information is systematically generated and sent to the provider.

A payer, after adjudicating a claim, may decide to perform post-adjudication review. The payer may initiate a request for additional information.

5.1.2 Prior Authorization

Upon receipt of a request for prior authorization the utilization area within a payer organization may perform a review to determine if additional information is required. The payer may communicate a list of procedures and/or services that would require additional information for a prior authorization or in some situations the process may be automated based on predefined rules. The request for information is systematically generated and sent to the provider.

5.1.3 Referral

The Attachment may also be used in provider to provider exchange when a patient is referred for consultations, services, evaluations, etc. The referral is usually initiated by a primary care provider, but may be initiated by a payer or other entity. When information is not sent and additional information is needed, the “referred to” provider may request that pertinent information be sent.

Provider “A” is caring for a patient and refers that patient to a specialist (Provider “B”) for further assessment. Provider “A” sends a referral to Provider “B”. Provider “B” receives the referral and, upon review, determines they need additional information from Provider “A” and sends them a request. Provider “A” responds with the Attachment.

5.1.4 Notification

A Notification can be used to send unsolicited information among providers, payers, delegated UMO entities and/or other providers. This information can take the form of copies of health service reviews or notification of scheduled treatment, or the beginning and end of treatment. A participant who is the recipient of the information may acknowledge they received the data, or reject the data due to specific application layer processing, but may not respond with any review decision outcome. Notification falls into four categories:

Advance Notification used to communicate scheduled admissions or services.

Completion Notification used to communicate patient facility admission or discharge and services completion for any specific episode of care.

Information Copy used for any Health Services Review information sent to primary care provider(s), service provider(s), or other healthcare entities requiring the information for specific purposes.

Change Notification used to report changes to the detail of a previously sent notification or information copy.

The information source is the entity that knows the outcome of the service review request, and can be either a UMO or a provider. For example, in a situation where the primary care provider can authorize specialty referrals that do not require review for medical necessity, appropriateness, or level of care, the primary care provider is the information source and may have responsibility for notifying both the UMO and the service provider of the specialty referral. In cases where the UMO is the decision maker, the UMO would send a notice of certification to the requesting provider and the service provider.

5.2 Solicited and Unsolicited Attachments

For the purposes of this Guide, we will use the terms “solicited” and “unsolicited” to help clarify the scenarios for which one or more standards are to be used. The response, whether solicited or unsolicited, refers to the act of providing Attachments needed.

Solicited and unsolicited scenarios are tied closely to the response side of the attachment activity without regard to the mode of the request. They are also aligned closely with the entity establishing the Attachment Control Number that is used to match the attachment itself with either the claim, referral, or prior authorization attachment activity. For more about Attachment re-association ID see [Section 5.3.3: Attachment Control Number](#).

5.2.1 Solicited Attachments

A solicited Attachment refers to the act of requesting and/or responding with information which was requested after a healthcare entity determines a need for additional information to complete the *healthcare administrative activity*.

In the **solicited scenario**, the entity creating the request for additional information would assign an Attachment Control Number used to re-associate the Attachment response to the original Attachment request. This Attachment Control Number must be returned with the Attachment response.

5.2.2 Unsolicited Attachments

An unsolicited Attachment refers to the act of providing additional information that conforms to a set of rules-based criteria. These guidelines are defined by the payer through trading partner agreements or published criteria (i.e., policies, websites). The criteria may be for a certain type of claim, for a specific health care provider, procedure, or service is known in advance to the provider. This Guide takes no position with respect to the business reasons that initiate unsolicited attachments.

In the **unsolicited scenario**, the provider would assign an Attachment Control Number. This identifier must be provided with the Attachment to be re-associated with the healthcare administrative activity.

5.3 Attachment Activity

This Guide addresses the processes used in requesting additional information and responding with Attachments. [Table 3: ASC X12N Location of Attachment Control Numbers](#) and [Table 4: Request Attachment Activity Table](#) are used to help illustrate these activities, since the actor's role will vary depending on the activity type. Each row in the tables represent an Attachment Activity based on a unique business flow.

Attachment information, by default, is considered to be at the clinical document level. In some cases, the requestor of attachment information may need information at the sub-document level (section or entry). In this case, development of guidance based on scenarios may be helpful to identify the most appropriate document type to request the needed information. Absent that guidance, it would be up to the requestor of attachment information to determine the most appropriate document type to use for the response.

5.3.1 Attachment Request Activity

A request for additional information can originate in numerous ways and may be initiated by unique business events depending on the originating actor. These events are referred to as “triggering events” that are not specifically addressed in this Guide.

The Mode, method of requesting additional information, and Timing of the request is triggered by a request from the payer or based on pre-defined rules. The Attachment Control Number is assigned to the Attachment either by the provider or the payer based on the Mode of the request.

5.3.2 Attachment Response Activity

The act of submitting additional information electronically is a response activity. A response may be as a result of a request or based on predefined rules.

5.3.3 Attachment Control Number

An essential component of an attachment activity is the ability to re-associate the Attachment with the request through the use of an Attachment Control Number. Depending on the attachment activity, the entity responsible for assigning an Attachment Control Number will vary. When the Attachment is unsolicited, the Attachment Control Number shall be used in both the Attachment and the enveloping metadata. When the Attachment is solicited, the Attachment Control Number shall be used only in the enveloping metadata (for more information on enveloping metadata, see [Appendix F: CDA Document for Attachments Transport and Payload.](#))

5.3.4 Attachment Control Number in ASC X12 Transactions

Table 5: ASC X12N Location of Attachment Control Number below provides the location of the Attachment Control Number in the ASC X12 transactions used in the request for and response to Attachments. At the time of this publication the names used within the transactions are not always consistent. The ACP Workgroup will be working with ASC X12 to align all of the Attachment Control Numbers in future versions.

Table 5: ASC X12N Location of Attachment Control Numbers

Transactions	Location	Industry Name
Version 5010		
X222 Professional Claim (837) X223 Institutional Claim (837) X224 Dental Claim (837)	Loop 2300 & 2400 PWK05	Code AC Attachment Control Number
	Loop 2300 & 2400 PWK06	Attachment Control Number
X217 Services Review (278)	Loop 2000E & 2000F PWK05	Code AC Attachment Control Number
	Loop 2000E & 2000F PWK06	Attachment Control Number
Version 6020 (Recommended for adoption under HIPAA)		
X313 Request for Additional Information (277)	2200D TRN02	Payer Claim Control Number
X314 Additional Information to Support a Claim (275)	2000A TRN02	Payer Claim Control Number or Provider Attachment Control Number
X315 Healthcare Services Review (278)	Loop 2000E & 2000F PWK05	Code AC Attachment Control Number
X316 Additional Information to Support Health Services Review (275)	2000A TRN02	Attachment Control Trace Number

5.3.5 Attachment Activity

Table 6: Request Attachment Activity highlights how the Attachment Control Number will be integrated into the attachment activity processes and reflects some of the more common scenarios for illustrative purposes.

Table 6: Request Attachment Activity

Healthcare Administrative Activity	Request		Attachment Control Number		Attachment Activity Basis
	Mode	Timing	Assigning Actor	Reassociation	
Claim	Request for additional information	After Claim is received and reviewed by Payer	Payer	Payer Request and provider Attachment	Solicited
	Pre-defined Rules	In advance of Claim submittal	Provider	Provider Claim and Attachment	Unsolicited
Prior Authorization	Request for additional information	After Prior Authorization is received and reviewed by Payer	Payer	Payer Request and provider Attachment	Solicited
	Pre-defined Rules	In advance of Prior Authorization Request submittal	Provider	Provider Prior Authorization request and Attachment	Unsolicited
Referral	Request for additional information	After Referral is received and reviewed by Payer	Payer	Payer request and provider Attachment	Solicited
	Pre-defined Rules	In advance of Referral	Provider	Provider referral request and Attachment	Unsolicited

5.3.6 Attachments ASC X12N Activity

There are multiple standards available in the industry to accomplish the exchange of information for attachment purposes (e.g., request, response, acknowledgement).

[Table 7: ASC X12N Attachment Activity](#) describes the scenarios addressed for Attachment exchange purposes and shows the correlation to each of the Activity ID's with an ASC X12N Transaction Set. The version that should be used of the ASC X12N Technical Reports published for the purposes of exchanging Attachments is the version named in regulation or agreed by trading partners in the absence of regulations.

To better understand the relationship of the row values for each attachment activity, a “table interpretation template” was developed.

Descriptions of the Column headings and table values are:

Healthcare Administrative Activity

The type of healthcare administrative activity of the originating actor for the 'request' activity type.

Activity ID

A symbolic ID used to express, in abbreviated form, the attachment activity. (NOTE: This ID will be used to uniquely determine the standard(s) necessary to accomplish the attachment exchange activity described in the row of the table)

Originator Activity Type

Describes the type of activity of the originating actor.

- Request – explicitly requested additional information.
- Response – Attachment provided electronically in response to an explicit request.
- Attachment Submission – indicates the Attachment was sent without a request.

Attachment Activity Basis

- Solicited
 - an explicit request for additional information
 - the response to an explicit request.
- Unsolicited
 - Attachment from the Originator Actor to the Receiver Actor based ONLY on a “rules based” request and in the absence of an explicit request.

Actor

- Originator – the actor originating or initiating the attachment activity.
- Receiver – the actor receiving the attachment activity.

Example Figure ID

Identifies specific Figures/Illustrations that depict the specific Healthcare Administrative Activity.

Envelope/Transaction Standard Example

Identifies examples of electronic standards available to accomplish the specific attachment activity for that table row.

Table 7: ASC X12N Attachment Activity

Healthcare Administrative Activity	Activity ID	Originator Activity Type	Attachment Activity Basis		Actor		Example Figure ID	ASC X12N Envelope/ Transaction Standard Example
			Solicited	Unsolicited	Originator	Receiver		
Claims Attachment	#1	Request	X		Payer	Provider	<u>1</u>	277 ¹
	#2	Response	X		Provider	Payer		275 ²
	#3	Attachment Submission		X	Provider	Payer	<u>2</u>	275 ²
Prior Auth Attachment	#4	Request	X		Payer	Provider	<u>3</u>	278 ³
	#5	Response	X		Provider	Payer		275 ⁴
	#6	Attachment Submission		X	Provider	Payer	<u>4</u>	275 ⁴
Referral Attachment	#7	Request	X		Payer/ Referring Provider	Referred To Provider	<u>5</u>	278 ³
	#8	Response	X		Referred To Provider	Payer/ Referring Provider		275 ⁴
	#9	Attachment Submission		X	Referred To Provider	Payer/ Referring Provider	<u>6</u>	275 ⁴
Post Adjudicated Claim Attachment	#10	Request	X		Payer	Provider	<u>7</u>	277 ¹
	#11	Response	X		Provider	Payer		275 ²
Notification Attachment	#12	Attachment Submission		X	Facility provider	Primary care provider	<u>8</u>	275 ⁴

¹ ASC X12N 277 – Health Care Information Status Notification - Technical Report Type 3 for Health Care Claim Request for Additional Information

² ASC X12N 275 – Patient Information – Technical Report 3 for Additional Information to Support a Health Care Claim or Encounter

³ ASC X12N 278 – Health Care Services Review Information Technical Report 3 for Health Care Services Request for Review and Response

⁴ ASC X12N 275 – Patient Information – Technical Report 3 for Additional Information to Support a Health Care Service Review

5.4 Attachment Scenarios

The following examples are derived from [Table 7: ASC X12N Attachment Activity](#):

Refer to [Section 8: Attachment Business Flows](#) for each of the scenarios below.

5.4.1 Claim Attachment Scenarios

[Activity #1](#) represents the information exchange for the Claims Attachment solicited request for additional information from the payer to the provider. [\(Example\)](#)

[Activity #2](#) represents the information exchange for the Claims Attachment solicited Attachment response from the provider to the payer. [\(Example\)](#)

[Activity #3](#) represents the information exchange for the Claims Attachment unsolicited Attachment submission from the provider to the payer. [\(Example\)](#)

5.4.2 Prior Authorization Attachment Scenarios

[Activity #4](#) represents the information exchange for the Prior Authorization Attachment solicited request for additional information from the payer to the provider. [\(Example\)](#)

[Activity #5](#) represents the information exchange for the Prior Authorization solicited Attachment response from the provider to the payer. [\(Example\)](#)

[Activity #6](#) represents the information exchange for the Prior Authorization Attachment unsolicited Attachment submission from the provider to the payer. [\(Example\)](#)

5.4.3 Referral Attachment Scenarios

[Activity #7](#) represents the information exchange for the Referral Attachment solicited request for additional information from the payer/referred to provider to the referring provider. [\(Example\)](#)

[Activity #8](#) represents the information exchange for the Referral Attachment solicited Attachment response from the referring provider to the payer/referred to provider. [\(Example\)](#)

[Activity #9](#) represents the information exchange for the Referral Attachment unsolicited Attachment submission from the referring provider to the payer/referred to provider. [\(Example\)](#)

5.4.4 Post Adjudicated Claims Attachment Scenarios

[Activity #10](#) represents the information exchange for the Post Adjudicated Claim Attachment solicited request for additional information from the payer to the provider. [\(Example\)](#)

[Activity #11](#) represents the information exchange for the Post Adjudicated Claim Attachment solicited Attachment response from the provider to the payer. [\(Example\)](#)

5.4.5 Notification Attachment Scenarios

Activity #12 represents the information exchange for the notification unsolicited Attachment submissions from the facility provider to the primary care provider. ([Example](#))

6 ATTACHMENT BUSINESS FLOWS

The examples in this Guide will provide typical business flows for each of the attachment activities consistent with [Table 7: ASC X12N Attachment Activity](#). Each specific activity will be identified and correlated back to an entry in the table using the “Attachment Activity ID #”. Some of the examples may include information exchanges that are not covered in this Guide but necessary to reflect the complete business flow. These activities will be clearly marked.

As previously noted, where the ASC X12 Transaction Sets are shown it should not be construed to be limited to these standards.

The examples in this section are intended for illustrative purposes only and are not all inclusive.

For use of LOINC codes in Attachments refer to [Section 4.2: Use of LOINC in Identifying Attachment Documents](#).

6.1 Solicited Attachment Exchange

When requesting additional information, a single LOINC is used to codify the specific document type being requested. In CDA Documents for Attachments, there could be multiple LOINC codes which represent a single document type (e.g., Operative Note) in general or that are further specialized (depending on “setting” and “Specialty/Training/Professional Level”). The LOINC Document Codes that are valid for each CDA Document for Attachments type are defined in the respective CDA Implementation Guide for Attachments.

Examples of these clinical document types and their recommended LOINC Document Type Codes are found in [Appendix C: C-CDA R2.1](#) and [Appendix D: CDP1 R1.1](#).

As mentioned in C-CDA, use of the “requested” LOINC Document Type Code is preferred but not required for the response. For the purposes of Attachments, the use of the “requested” LOINC Document Type Code is preferred as the single LOINC code used in the response to the request for additional information. However, other LOINC codes in the response may also be permitted if the responder deems it appropriate for their business purposes.

To accommodate both Payer/UMO needs for additional information and the flexibility afforded by C-CDA, special rules for requesting and responding have been developed for Attachments as described in [Section 4.2: Use of LOINC in Identifying Attachment Documents](#).

6.1.1 Claim Attachment – Solicited Scenario

When a provider submits a claim for payment (triggering event), a payer may determine that additional information is needed to complete the adjudication. The payer initiates a request for that additional information. The provider receives that request, and responds to the payer with the Attachment requested.

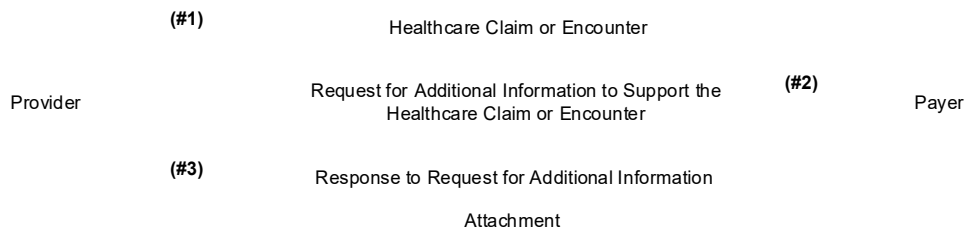
The diagram below depicts the business flow of the examples on [Table 7: ASC X12N Attachment Activity](#) for a solicited claim attachment.

Arrow #1 The claim submitted by provider to a payer is the triggering event.

Arrow #2 The request for additional information by payer to provider using ASC X12N 277. ([Activity #1](#))

Arrow #3 The provider's response with an Attachment using ASC X12N 275. ([Activity #2](#))

Figure 4: Example - Claims Attachment (Solicited)



6.1.2 Prior Authorization Attachment – Solicited Scenario

When a provider submits a request for prior authorization (triggering event), a payer may determine that additional information is needed to complete review. The payer initiates a request for that additional information. The provider receives that request, and responds to the payer with the Attachment requested. For the purposes of the scenario below it is assumed that the Prior Authorization Request (triggering event) would be submitted using the ASC X12N 278.

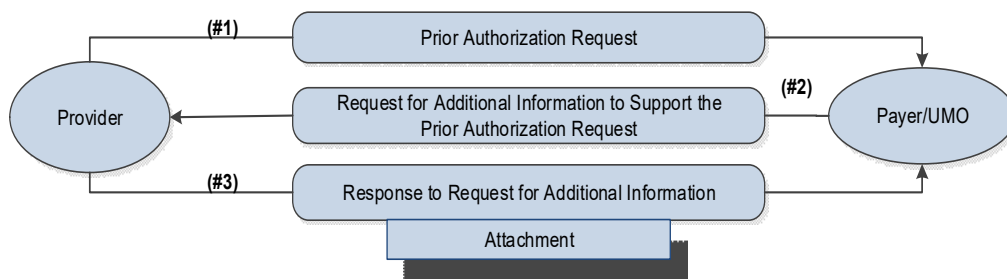
The diagram below depicts the business flow of the example on [Table 7: ASC X12N Attachment Activity](#) for solicited Prior Authorization Attachment.

Arrow #1 The Prior Authorization Request by a provider to a payer is the triggering event.

Arrow #2 A Request for Additional Information in support of a Prior Authorization requested by payer to the provider using ASC X12N 278. [\(Activity #4\)](#)

Arrow #3 The provider's response with an Attachment using ASC X12N 275. [\(Activity #5\)](#)

Figure 5: Example - Prior Authorization (Solicited)



6.1.3 Referral Attachment – Solicited Scenario

When a provider submits a Referral to another provider or the payer (triggering event), additional information may be needed. A request for that additional information is sent to the referring provider. The referring provider receives that request, and responds with the Attachment requested.

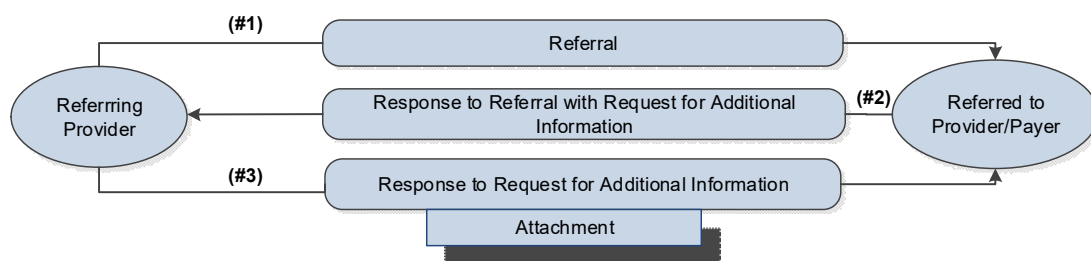
The diagram below depicts the business flow of the examples on [Table 7: ASC X12N Attachment Activity](#) for an Solicited Referral Attachment.

Arrow #1 The Referral Request from referring provider to another provider or a payer is the triggering event.

Arrow #2 A Request for Additional Information in support of a Referral by the provider or payer to referring provider using ASC X12N 278. [\(Activity #7\)](#)

Arrow #3 The referring provider's response with an Attachment using ASC X12N 275. [\(Activity #8\)](#)

Figure 6: Example Referral Attachment (Solicited)



6.1.4 Post Adjudicated Claim Attachment – Solicited Scenario

A payer, after adjudicating a claim, may decide to perform post-adjudication review. The payer may initiate a request for additional information. Both the claim and the remittance advice are the triggering events.

The diagram below depicts the business flow of the examples on [Table 7: ASC X12N Attachment Activity](#) for a solicited claim Attachment.

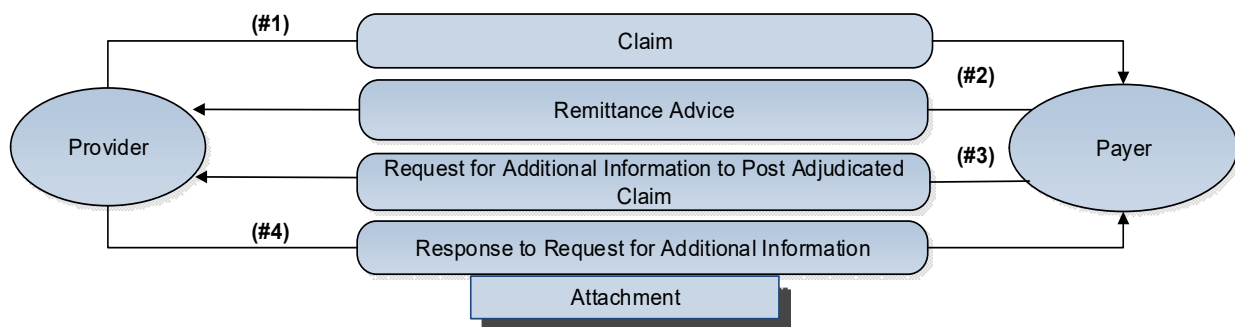
Arrow #1 The claim is submitted by a provider to a payer and is the triggering event.

Arrow #2 The Remittance Advice is returned by the payer to the provider and is the triggering event.

Arrow #3 A Request for Additional Information by the payer to the provider. This may occur anytime following the adjudication of the claim using ASC X12N 277. [\(Activity #10\)](#)

Arrow #4 The provider's response with an Attachment using ASC X12N 275. [\(Activity #11\)](#)

Figure 7: Example - Post Adjudicated Claim Attachment (Solicited)



6.2 Unsolicited Attachment Exchange

When the conditions for submitting additional information are of a consistent and recurring nature, the payer may make these conditions known in advance to the provider so that the provider may submit the Attachment without waiting for a request.

When submitting an Attachment in the unsolicited model, the specific LOINC code to be used as the Document Type ID follows these rules:

- In the CDA Implementation Guides for Attachments there are LOINC codes specified as “Recommended” and “Value Sets”. For Structured Documents and their unstructured counterparts, the “LOINC Document Type Code” for unsolicited attachments should always be a member of the appropriate “Value Set”.
- For Unstructured Documents that do not have a structured counterpart, refer to Using the LOINC Database to Identify Valid Attachment Types for determining valid LOINC Document Type Codes for unstructured Attachments.

6.2.1 Claim Attachment – Unsolicited

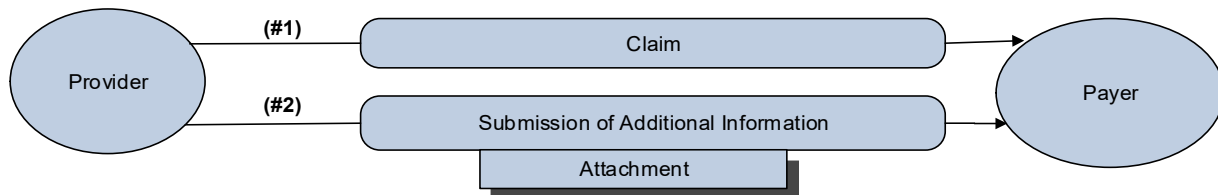
When a provider submits a claim to a payer and knows in advance that additional information is needed to complete the adjudication, the provider may submit the Attachment without waiting for the request.

The diagram below depicts the business flow of the examples on [Table 7: ASC X12N Attachment Activity](#) for an unsolicited claim Attachment.

Arrow #1 The claim submitted by provider to a payer.

Arrow #2 Provider submits additional information previously agreed to between payer and provider as an Attachment using ASC X12N 275. ([Activity #3](#))

Figure 8: Example - Claims Attachment (Unsolicited)



6.2.2 Prior Authorization Attachment – Unsolicited Scenario

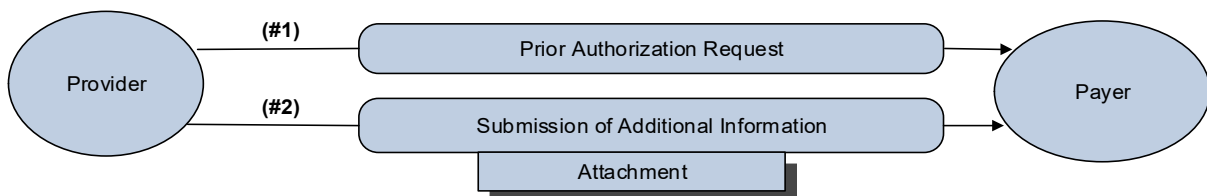
When a provider submits a request for prior authorization to a payer and knows in advance that additional information is needed to complete the approval, the provider may submit the Attachment without waiting for the request.

The diagram below depicts the business flow of the examples on [Table 7: ASC X12N Attachment Activity](#) for an unsolicited Prior Authorization Attachment.

Arrow #1 Prior Authorization Request from a provider to a payer using ASC X12N 278.

Arrow #2 Provider submits additional information previously agreed to between payer and provider as an Attachment using ASC X12N 275. ([Activity #6](#))

Figure 9: Example – Prior Authorization (Unsolicited)



6.2.3 Referral Attachment – Unsolicited Scenario

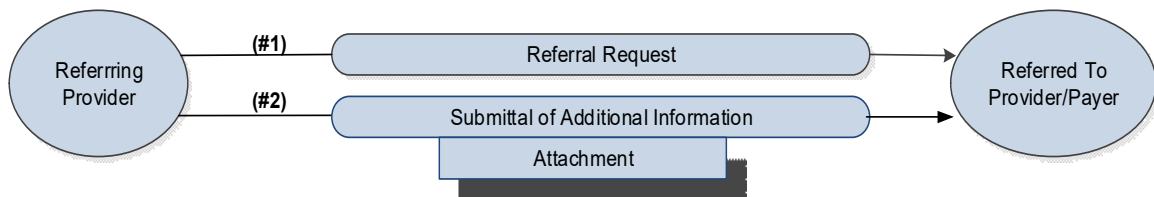
When a provider submits a referral to another provider or a payer and knows in advance that additional information is needed, the provider may submit the Attachment without waiting for the request.

The diagram below depicts the business flow of the examples on [Table 7: ASC X12N Attachment Activity](#) for an unsolicited Referral Attachment.

Arrow #1 Referral is submitted from a provider to another provider or payer using ASC X12N 278.

Arrow #2 Provider submits additional information previously agreed to between payer and provider as an Attachment using ASC X12N 275. ([Activity #9](#))

Figure 10: Example - Referral Attachment (Unsolicited)



6.2.4 Notification Attachment – Unsolicited Scenario

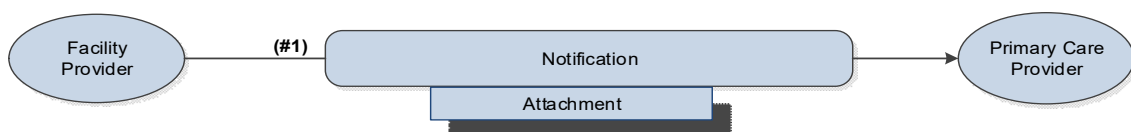
A provider submits a notification to another provider along with additional information as needed.

In the example below, a facility provider discharges a patient of a primary care provider, and forwards a notification to that effect.

The diagram below depicts the business flow of the examples on [Table 7: ASC X12N Attachment Activity](#) for a Notification Attachment.

Arrow #1 Attachment information from the facility provider to the Primary Care Provider using ASC X12N 275. ([Activity #12](#))

Figure 11: Example - Notification Attachment (Unsolicited)



7 ATTACHMENTS CONFORMANCE REQUIREMENTS

This section, in conjunction with the HL7 CDA Release 2 (CDA R2) standard, addresses conformance requirements when using CDA documents for attachments. The numbered notes at the beginning of each subsection are concepts meant to provide guidance. Conformance statements (prefaced with AIGEX) are used to ensure that the documents are used in a consistent manner and provide guidance on how to construct, exchange or consume a valid document. Conformance statements that have 'SHALL' must always be adhered to while 'SHOULD' or 'MAY' indicate best practice. For an explanation regarding the use of nullFlavors the reader should consult the relevant implementation guide or the base standard (CDA R2).

The AIGEX conformance identifiers in front of each conformance statements are unique error codes and should be used, where appropriate, in the validator when the document fails to meet the requirements of the conformance statement.

7.1 US Realm Header Requirements

- 1.) All documents (both structured and unstructured) must have a valid US Realm Header for consistent description of the following document attributes:
 - **Patient**
The patient is recorded in `ClinicalDocument.recordTarget`. The `recordTarget` represents the medical record that this document belongs to. A clinical document typically has exactly one `recordTarget` participant. In the uncommon case where a clinical document (such as a group encounter note) is placed into more than one patient chart, more than one `recordTarget` participants can be stated.
 - **Provider organization**
The provider organization responsible for maintaining the document is recorded in `ClinicalDocument.custodian`. Represents the organization that is in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document. Every CDA document has exactly one custodian.
 - **Author(s)**
Represents the humans and/or machines that authored the document.
 - **Legal authenticator and Authenticators**
The `legalAuthenticator` is recorded in `ClinicalDocument.legalAuthenticator`, and represents a participant who has legally authenticated the document. Authenticators are recorded in `ClinicalDocument.authenticator`, and each authenticator represents a participant who has attested to the accuracy of the document, but who does not have privileges to legally authenticate the document. An example would be a resident physician who sees a patient and dictates a note, then later signs it.
 - **Other relevant participants**
Other participants are recorded in `ClinicalDocument.participant`. Used to represent other participants not explicitly mentioned by other classes, that were somehow involved in the documented acts.
 - **Encounter date(s)**
The encounter dates are recorded in `ClinicalDocument.componentOf.encompassingEncounter`. This optional class represents the setting of the clinical encounter during which the documented act(s) or `ServiceEvent` occurred. Documents are not necessarily generated during an

encounter, such as when a clinician, in response to an abnormal lab result, attempts to contact the patient but can't, and writes a Progress Note.

- **Purpose (inFulfillmentOf and documentation of)**
Orders are recorded in `ClinicalDocument.inFulfillmentOf.order`, and represents orders that are fulfilled by this document. Service events are recorded in `ClinicalDocument.documentationOf.serviceEvent` and represents the main act, such as a colonoscopy or an appendectomy, being documented.
- **Authorization**
Authorization info is recorded in `ClinicalDocumentation/authorization`, and references the consents associated with the document.
- **Document SetId and Version Number**
CDA documents may contain a `ClinicalDocument.setId` and a `ClinicalDocument.versionNumber`, which together support a document identification and versioning scheme used in some document management systems. In this scheme, all documents in a chain of replacements have the same `ClinicalDocument.setId` and are distinguished by an incrementing `ClinicalDocument.versionNumber`. The initial version of a document gets, in addition to a new unique value for `ClinicalDocument.id`, a new value for `ClinicalDocument.setId`, and has the value of `ClinicalDocument.versionNumber` set to equal "1". A replacement document gets a new globally unique `ClinicalDocument.id` value, and uses the same value for `ClinicalDocument.setId` as the parent report being replaced, and increments the value of `ClinicalDocument.versionNumber` by 1. (Note that version number must be incremented by one when a report is replaced, but can also be incremented more often to meet local requirements.)

AIGEX-HD1: All documents SHALL have a Header that conforms to the HL7 US Realm Header, *templateId* 2.16.840.1.113883.10.20.22.1.1, with no extension or with a valid *extension*.

AIGEX-HD2: All document recipients SHALL support all required elements (those with SHALL verbs) defined in the HL7 US Realm Header, *templateId* 2.16.840.1.113883.10.20.22.1.1 with no extension or with a valid *extension*.

AIGEX-HD3: Document recipients SHALL NOT reject a document because optional (SHOULD OR MAY) element(s) are populated in the HL7 US Realm Header, *templateId* 2.16.840.1.113883.10.20.22.1.1 with no extension or with a valid *extension*.

AIGEX-HD4: All documents SHALL have a *legalAuthenticator*.
In the case of generated summary documents, institutions may meet the requirement for a Legal Authenticator by extending the practice of maintaining a "Signature on File". The person/entity indicated is responsible for the contents of the note where it is understood that this Legal Authenticator is not an author of the document. Policy for determining who is responsible for legal authentication of the summary document rests with the originating organization.

AIGEX-HD5: All documents SHALL have one or more *author(s)*.

AIGEX-HD6: All documents SHOULD have a valid *setId* and *versionNumber*.

AIGEX-HD7: All documents that contain *sdhc:signatureText*, SHALL conform to the HL7 Digital Signatures and Delegation of Rights Implementation Guide R1.

7.2 Structured Document Requirements

- 1.) All structured documents must fully conform to the specification of the associated published HL7 implementation guide containing the specific template(s) (by *templateId*) in the structured document.
- 2.) CDA Release 2.0 states: “There must be a deterministic way for a recipient of an arbitrary CDA document to render the attested content” (See Section 1.2.3 in CDA R2, Human Readability and Rendering CDA Documents). C-CDA R2.1 expands on the requirements of CDA, defining rendering best practice to the document metadata in the CDA Header which then apply to all attachments. Note that due to the variability of rendering systems which may be EMRs, web browsers, or any number of claims review/processing systems, there is no requirement to render this information directly from the document, simply to ensure that the viewer has the appropriate contextual information when reading the document.

AIGEX-SD1: All document templates in structured documents SHALL conform to the implementation guide specifications for the specific document template (e.g., for the specific *templateId* and, if present, extension).

AIGEX-SD2: All structured documents SHALL have a name, title, for each populated section that describes in human-readable text the purpose/content of the section.

AIGEX-SD3: Document recipients SHALL NOT reject a document because optional (SHOULD OR MAY) element(s) are populated in the structured body of the document.

AIGEX-SD4: All structured documents SHALL have a narrative block (text) for each populated section that includes the content of the section in human-readable text; including at a minimum, all clinically relevant information contained in all entry level templates in that section.

AIGEX-SD5: All document recipients SHALL provide a mechanism to recognize, and display to a user the narrative block (text) for each populated section.

AIGEX-SD6: All section templates in structured documents SHALL conform to the implementation guide specifications for the specific section template (e.g., for the specific *templateId* and *extension*).

AIGEX-SD7: All entry templates in structured documents SHALL conform to the implementation guide specifications for the specific entry template (e.g., for the specific *templateId* and *extension*).

7.3 Unstructured Document Requirements

- 1.) All unstructured documents must fully conform to the specification of the associated published HL7 implementation guide containing the HL7 Unstructured Document, *templateId* 2.16.840.1.113883.10.20.22.1.10 with no extension or with a valid extension.
- 2.) All unstructured documents must fully conform to the specification for use of specific HIPAA LOINC codes for unstructured documents.
- 3.) All unstructured content must conform to the allowed *mediaType*, compression (optional), and Base64 Encoding.

AIGEX-UD1: All unstructured documents SHALL conform to the HL7 Unstructured Document, *templateId* 2.16.840.1.113883.10.20.22.1.10 with no extension or with a valid *extension*.

AIGEX-UD2: The US Realm Header for all unstructured documents SHALL contain exactly one LOINC *code* where the *@code* SHALL be selected from LOINC document type codes (scale = DOC) and accurately represents the content of the unstructured body.

AIGEX-UD3: If the unstructured content is the same as content for a defined structured document (e.g., both are a Discharge Summary), then the LOINC code for the equivalent structured document **SHOULD** be used.

AIGEX-UD4: An unstructured document **SHALL NOT** contain a reference to a document file unless there is a trading partner agreement.

Example: A reference to a document is a URL or URI that points to a document either in the same directory or, potentially, on a site that must be accessed via the Internet. Since the document is not contained in the CDA, it is subject to modification without tracking and if it is on a remote site, there may be security issues.

AIGEX-UD5: An unstructured document **SHALL** contain exactly one `@mediaType` (e.g., MIME type) selected from the value set defined in [Table 1: Supported File Formats](#).

Example: if the unstructured document is a PDF, then the value of `@mediaType` will be `application/pdf`.

AIGEX-UD6: The unstructured content **SHALL** be Base64 Encoded using the method defined in RFC 4648.

AIGEX-UD7: If unstructured content is “compressed”, it **SHALL** be compressed using the method in RFC 1951 prior to being Base64 Encoded and the *compression* attribute **SHALL** be present and it **SHALL** have the value of “DF”.

7.4 Validation Requirements

- 1.) All CDA Documents for Attachments must meet the conformance requirements for CDA R2, the specific CDA Implementation Guide in which the document is defined (specific *templateId* and *extension*).
- 2.) Conformance against the requirements of CDA and CDA templates must be validated. HL7 publishes an informative XML schema for CDA R2 and informative Schematron rules for many of the CDA-based implementation guides. Several tools that validate conformance requirements against these rules are also available.

AIGEX-VR1: All documents **SHALL** conform to the CDA R2 schema for CDA (XSD) with `sdte` extensions included.

AIGEX-VR2: All documents **SHALL** conform to the published HL7 implementation guide conformance specifications for the specific document template (including incorporated section and entry templates) as defined for the specific *templateId* and *extension*.

AIGEX-VR3: All documents **SHALL** pass defined as no errors the validation requirements in VR1 and VR2.

AIGEX-VR4: Documents that do not meet the validation criteria **SHALL NOT** be considered a valid attachment for the purpose of this Guide.

7.5 Document Succession Requirements

- 1.) Document senders and recipients must use `setId` and `version` to manage document succession.
- 2.) A document recipient must associate and maintain all versions of a document and make them appropriately available to their users.
- 3.) Documentation retention requirements apply to all versions of a document.

- AIGEX-DS1: Document creators SHOULD use the setId and version in the US Realm Header to identify a specific document (document type, patient and visit) the initial version and any successor documents shall use the same setId and increment the version.
- AIGEX-DS2: Document recipients SHOULD recognize, associate, and make available versions of documents as defined by the setId and version in the US Realm Header.
- AIGEX-DS3: Document recipients SHOULD apply any document retention policies to all versions of a document as defined by setId and version.

7.6 C-CDA R1.1 and R2.1 Structured Document Requirements (Request and Response)

- 1.) The following conformance statements apply only to C-CDA R1.1 and R2.1 Structured Documents. Structured documents shall be requested using the appropriate LOINC codes defined in [Table 8: C-CDA R2.1 Clinical Document Types with Recommended LOINC Code for Requests](#) of this Guide.
 - 2.) Document senders should respond with the corresponding documents when possible. Refer to [Section 4](#) for more details on use of LOINC Codes.
- AIGEX-CC1: Document requester SHALL use the LOINC code from [Table 8: C-CDA R2.1 Clinical Document Types with Recommended LOINC Code for Requests](#) when requesting a structured document defined in the C-CDA R1.1 or R2.1 implementation guide.
- AIGEX-CC2: Responder to the request SHOULD send the document template from [Table 8: C-CDA R2.1 Clinical Document Types with Recommended LOINC Code for Requests](#) associated with the requested LOINC code.
- AIGEX-CC3: Document requester SHALL use the LOINC IG Modifier Code for C-CDA R1.1 or R2.1 to request a document that meets their respective conformance requirements.
- AIGEX-CC4: Responder to the request SHOULD send a document that conforms to requirements defined in the implementation guide specified by LOINC IG Modifier Code, if sent with the request.

7.7 CDP1 R1.1 Documents Requirements (Request and Response)

- 1.) At the time of the document publication, CDP1 is optional. However, if used, the following conformance statements must be adhered to.
- 2.) Structured documents shall be requested using the appropriate LOINC codes defined in [Table 9: CDP1 R1.1 Clinical Document Types with Recommended LOINC Code for Requests](#).
- 3.) Document senders should respond with the corresponding documents when possible.

AIGEX-CD1: Document requester SHALL use the LOINC code from [Table 9: CDP1 R1.1 Clinical Document Types with Recommended LOINC Code for Requests](#) when requesting a structured document defined in the CDP1 R1.1 implementation guide.

AIGEX-CD2: Responder to the request SHOULD send the document template from [Table 9: CDP1 R1.1 Clinical Document Types with Recommended LOINC Code for Requests](#) associated with the requested LOINC code.

AIGEX-CD3: Document requester SHALL use the LOINC IG Modifier Code for CDP1 R1.1 to request a document that meets their respective conformance requirements.

AIGEX-CD4: Responder to the request SHOULD send a document that conforms to requirements defined in the implementation guide specified in the LOINC IG Modifier Code, if sent with the request.

7.8 Other Structured CDA Documents for Attachments Requirements (Request and Response)

- 1.) Structured documents shall be requested using the appropriate LOINC codes defined in the HIPAA tab in the Regenstrief RELMA database.
- 2.) Document senders should respond with the corresponding documents when possible.

AIGEX-CD1: Document requester SHALL use the LOINC Document Type Code defined for structured documents on the “Documents with Implementation Guide” tab in the HIPAA Attachment tab of the Regenstrief RELMA database when requesting a structured document not defined in [Table 8: C-CADA R2.1 Clinical Document Types with Recommended LOINC Code for Requests](#) or [Table 9: CDP1 R1.1 Clinical Document Types with Recommended LOINC Code for Requests](#) of this Guide.

AIGEX-CD2: Responder to the request SHOULD return the requested document using the requested LOINC Document Type Code or a LOINC code associated with the requested LOINC code for the document template from the “Documents with Implementation Guide” tab in the HIPAA Attachment tab of the Regenstrief RELMA database.

7.9 Unstructured Document (Request and Response)

- 1.) Unstructured documents (e.g., Documents for which no implementation guide exists) shall be requested using the appropriate LOINC codes defined for Unstructured Documents in the Documents without Implementation Guide tab in the HIPAA Attachment tab of the Regenstrief RELMA database.
- 2.) Document senders should respond with the corresponding documents when possible.

AIGEX-CU1: When requesting unstructured information, the document requester SHALL use the LOINC Document Type Code defined for the corresponding unstructured document from the Documents without Implementation Guide tab in the HIPAA Attachment Tab of the Regenstrief RELMA database.

AIGEX-CU2: Responder to the request SHOULD return the requested unstructured information corresponding to the unstructured document in the Documents without Implementation Guide tab in the HIPAA Attachment tab of the Regenstrief RELMA database in an unstructured document type as defined in the Unstructured Documents section of this Guide.

7.10 LOINC Range Modifier Code Requirements

- 1.) LOINC Range Modifier Codes are used to modify the request for information. All valid LOINC Range Modifier Codes are defined in the Request Modifier tab HIPAA Attachment tab of the Regenstrief RELMA database and should be used by the requester and responder to limit the scope of the response.

AIGEX-MC1: When requesting documents using a LOINC Range Modifier Code, the document requester SHALL send only LOINC Range Modifier Codes defined in the HIPAA Attachment tab in the Regenstrief RELMA database.

AIGEX-MC2: When responding to a request that includes a LOINC Range Modifier Code defined in the HIPAA Attachment tab in the Regenstrief RELMA database, the responder SHOULD only send information that corresponds to the scope defined by the LOINC Range Modifier Code for the requested LOINC Document Type.

7.11 Attachment Control Number Requirements

- 1.) An Attachment Control Number is used to associate the Attachment with the request for an Attachment or with a claim, referral, or request for prior-authorization.
- 2.) When the Attachment is unsolicited, the Attachment Control Number for the claim, referral, or request for prior-authorization shall be included in the enveloping metadata. When the Attachment is solicited, the Attachment Control Number from the Attachment request shall be returned with the Attachment in the enveloping metadata.

AIGEX-AC1: When requesting an Attachment, the requester SHALL send an Attachment Control Number with the request.

AIGEX-AC2: When responding to a request, the sender SHALL return the Attachment Control Number with the Attachment response in the enveloping metadata.

AIGEX-AC3: When sending an unsolicited Attachment, the sender SHALL include the Attachment Control Number corresponding to the related transaction (claim, referral, or request for prior authorization) in the enveloping metadata.

7.12 Transport and Metadata Requirement

- 1.) To ensure that Attachment requests and responses are associated with the appropriate payer, provider, patient, visit and service, specific information must be included in the Attachment request, a solicited Attachment response and an unsolicited Attachment submission.

AIGEX-TM1: Each exchange of Attachment information (request, response or unsolicited submission) SHALL include, in the enveloping metadata all of the information defined in [Appendix F: CDA Document for Attachments Transport and Payload](#) as “must accompany”.

AIGEX-TM2: Each exchange of Attachment information (request, response or unsolicited submission) MAY include, in the enveloping metadata all of the information defined in [Appendix F: CDA Document for Attachments Transport and Payload](#) as “MAY be included”.

APPENDIX A ABBREVIATIONS, ACRONYMS, AND DEFINITIONS

AIS – Additional Information Specification

ANSI – American National Standards Institute is the organization that accredits U.S. Standards Development Organizations, ensuring that their methods for creating standards are open and follow due process.

ASC X12 - ANSI accredited standards development organization, and one of the six Designated Standards Maintenance Organizations (DSMO) tasked to develop, update and maintain the administrative and financial transactions standards.

ASC X12N – Insurance Sub-Committee within ASC X12 responsible for developing standards and related technical reports for the insurance industry.

ASC X12N 277 – Health Care Information Status Notification - Technical Report Type 3 for Health Care Claim Request for Additional Information

ASC X12N 275 – Patient Information – Technical Report 3 for Additional Information to Support a Health Care Claim or Encounter

ASC X12N 278 – Health Care Services Review Information Technical Report 3 for Health Care Services Request for Review and Response

ASC X12N 275 – Patient Information – Technical Report 3 for Additional Information to Support a Health Care Service Review

Attachments - The additional information needed in support of a healthcare administrative activity

Attachment Submission - Refers to additional information submitted to a payer either as a result of a request or based on advance knowledge of this information need (e.g., rules based on medical policy).

Attachment Control Number – A unique identifier assigned to the Request for Attachment and/or the Attachment used for linking the request to the response.

AWG – HL7 Attachment Work Group

CAQH CORE - Council for Affordable Quality Health Care Committee on Operating Rules for Information Exchange is a group organized to develop operating rules that align with adopted administrative health care standards transactions to encourage adoption. The goal is to improve the quality of healthcare and reduce administrative burdens for physicians and payers.

C-CDA - Consolidated Clinical Document Architecture

CDA Documents for Attachments – Document level templates defined in the CDA Implementation Guides for Attachments.

CDA Implementation Guides for Attachments – Published HL7 Implementation guides that define documents that conform to the requirements of the HL7 US Realm Header which is specified in HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm).

CDA R2 - The HL7 Version 3 Clinical Document Architecture (CDA®) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange between healthcare providers and patients. It defines a clinical document as having the following six characteristics: 1) Persistence, 2) Stewardship, 3) Potential for authentication, 4) Context, 5) Wholeness and 6) Human readability.

C-CDA R1.1 – HL7 Implementation Guides for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1

C-CDA R2.1 - HL7 Implementation Guides for CDA Release 2: Consolidated CDA Templates for Clinical Notes Volume 1 Introductory Material and Volume 2 Templates and Supporting Material

CDA – Clinical Document Architecture

CDP1 - HL7 Implementation Guides for CDA Release 2: Additional CDA R2 Documentation Templates -- Clinical Documents for Payers – Set 1

Claim – A bill for healthcare services or healthcare encounter.

CMS – Center for Medicare & Medicaid Services.

Compression - File compression is commonly used when sending a file from one computer to another over a connection that has limited bandwidth. The compression basically makes the file smaller and, therefore, the sending of the file is faster. For the purposes of Attachments compression using RFC 1951 is recommended.

DSTU – Draft Standard for Trial Use – an HL7 designation for a standard or implementation guide that is on a path to become a normative standard. In mid-2016 HL7 changed the title of publications for trial use from 'Draft Standard for Trial Use (DSTU)' to 'Standard for Trial Use (STU)'. Existing publications have maintained the original designation. Functionality, the two status designations are identical.

esMD - Electronic Submission of Medical Documentation – a CMS and ONC S&I initiative to identify specific standards to support the electronic exchange of medical documentation for administrative purposes.

GIF – Graphics Interchange Format is a digital bitmap image format

Healthcare Administrative Activity - Healthcare activities where the need for Attachments may be required (e.g., Claims, Referrals, Prior Authorizations, etc). This includes but is not limited to establishing coverage, conforming with treatment protocols, providing historical documentation for future treatment or other administrative functions

HL7 – Health Level 7 International is an ANSI-accredited standards development organization that develops data definitions and message formats that allow for the integration of healthcare information systems. Its protocol has been proposed as a means to put electronic documents into the ASC X12N 275 standard for electronic claims attachment transmission.

HTML -- Hypertext Markup Language, a standardized system for tagging text files to achieve font, color, graphic, and hyperlink effects on World Wide Web pages.

IETF® - Internet Engineering Task Force - The mission of the IETF is to make the Internet work better by producing high quality, relevant technical documents that influence the way people design, use, and manage the Internet.

JPEG – Joint Photographic Experts Group is a compressed digital photography Image compressed using the Joint Photographic Experts Group method

LOINC – Logical Observation Identifiers, Names and Codes (<http://loinc.org>). Logical Observation Identifiers Names and Codes is a database and universal standard for identifying medical laboratory observations. First developed in 1994, it was created and is maintained by the Regenstrief Institute, a US nonprofit medical research organization.

LOINC Document Type Code - Refers to the LOINC code for a specific type of document (i.e., CCD, History and Physical, Discharge Summary) to be exchanged

LOINC Document Type - Refers to a specific document type (i.e., CCD, History and Physical, Discharge Summary) to be exchanged

LOINC Implementation Guide Modifier Code – Requests that the LOINC Document Type use the corresponding template as defined in the specified implementation guide (including the specific version).

LOINC Range Modifier Code -- A modifier that refers to the “Item Selection” or “Time Window” value used to further constrain a LOINC Document Type Code request.

MIME – Multipurpose Internet Mail Extensions - is an extension of the original Internet e-mail protocol that lets people use the protocol to exchange different kinds of data files on the Internet: audio, video, images, application programs, and other kinds, as well as the ASCII text handled in the original protocol, the Simple Mail Transport Protocol (SMTP).

Mod-10 – Algorithm applied to a series of numbers to arrive at a single (0-9) digit (check digit). When used in LOINC codes, the algorithm is applied to the digits to left of the hyphen to compute the check digit to the right of the hyphen

MSWORD – Microsoft Word file format

OID - An ISO Object Identifier is a globally unique string consisting of numbers and dots (e.g., 2.16.840.1.113883.3.1). This string expresses a tree data structure, with the left-most number representing the root and the right-most number representing a leaf

ONC – Office of the National Coordinator

S&I – Standards and Interoperability – initiatives supported by ONC to identify and promote standards for interoperability

Solicited Attachment - Refers to additional information submitted to a payer in response to a near-term request from the payer

STU –Standard for Trial Use – an HL7 designation for a standard or implementation guide that is on a path to become a normative standard.

Payer - Refers to a healthcare entity, such as a health insurance company or UMO, that receives and process claims, prior authorizations and referrals

PDF – Portable Document Format is a file format developed by Adobe as a means of distributing compact, platform-independent documents

Plain Text – text with no embedded formatting codes

PNG – Portable Network Graphics is a bitmapped image format that employs lossless data compression.

RFC – Request for Comments in the context of this document refers to Internet Engineering Task Force tools.

RTF – Rich Text Format -- a proprietary document file format with published specification developed by Microsoft Corporation

Style sheet - Specification used by browsers for controlling the display of the markup language (e.g., XML or HTML), describing how elements of a document should be displayed.

Structured Document – a CDA header paired with a structuredBody element.

TIFF – Tagged Image Format used for scanned images

Triggering Event – an event such as a claim submission or request for prior authorization that may result in a request for additional information. Triggering Events in this document are for reference only and out of scope.

UMO – Utilization Management Organization

Unsolicited Attachment - Refers to additional information submitted to a payer but done so based on advance knowledge of this information need (e.g., rules based on medical policy) rather than in response to a near-term request from the payer.

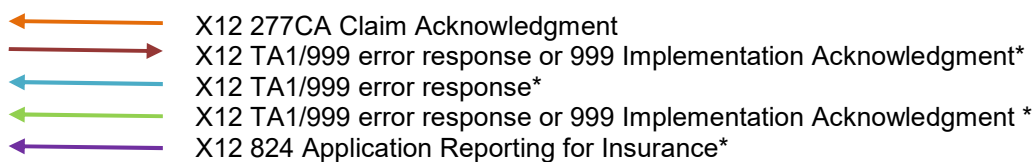
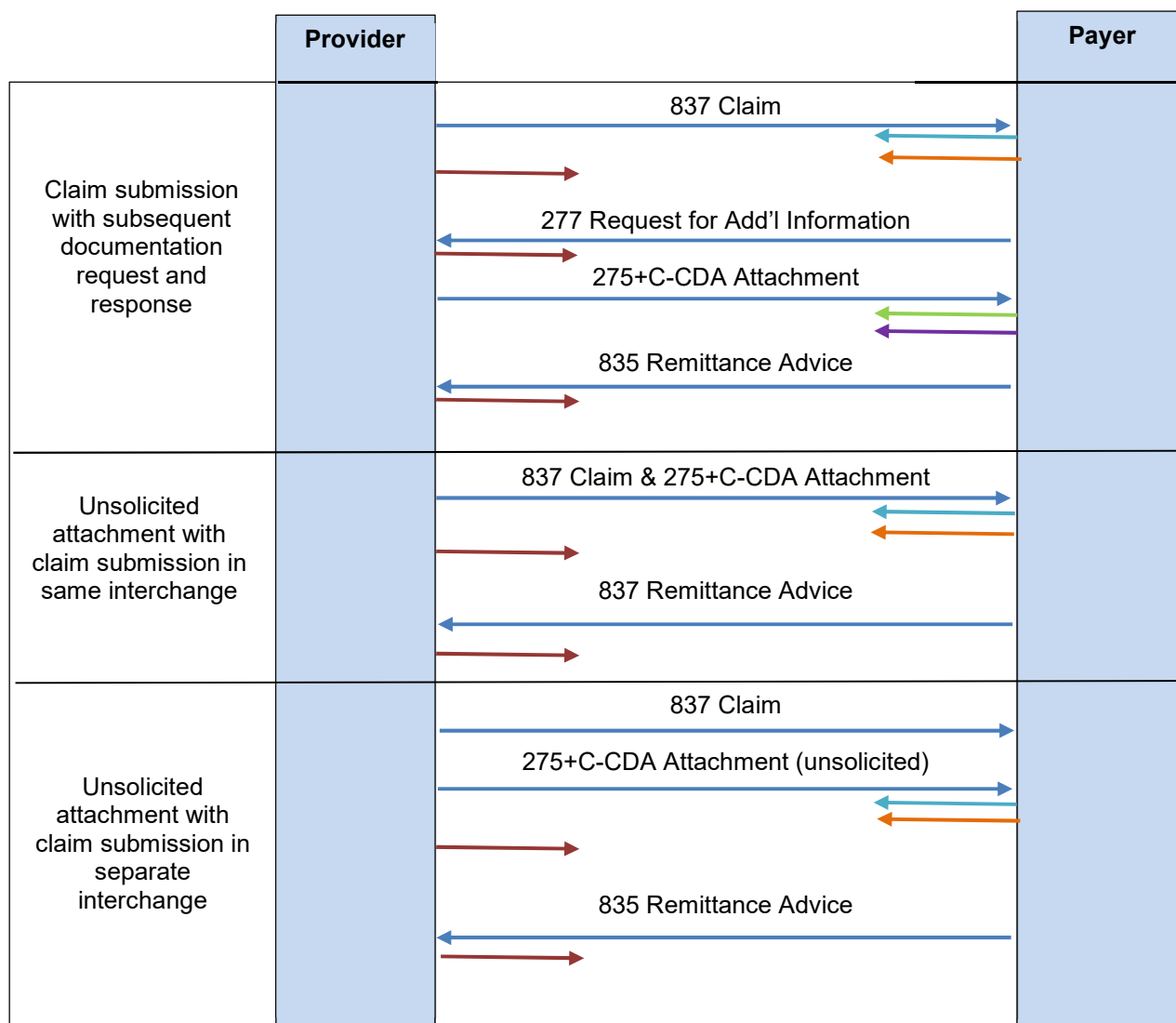
Unstructured Document – a CDA header paired with a nonXMLbody element

APPENDIX B

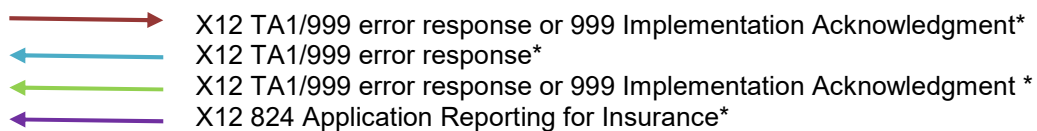
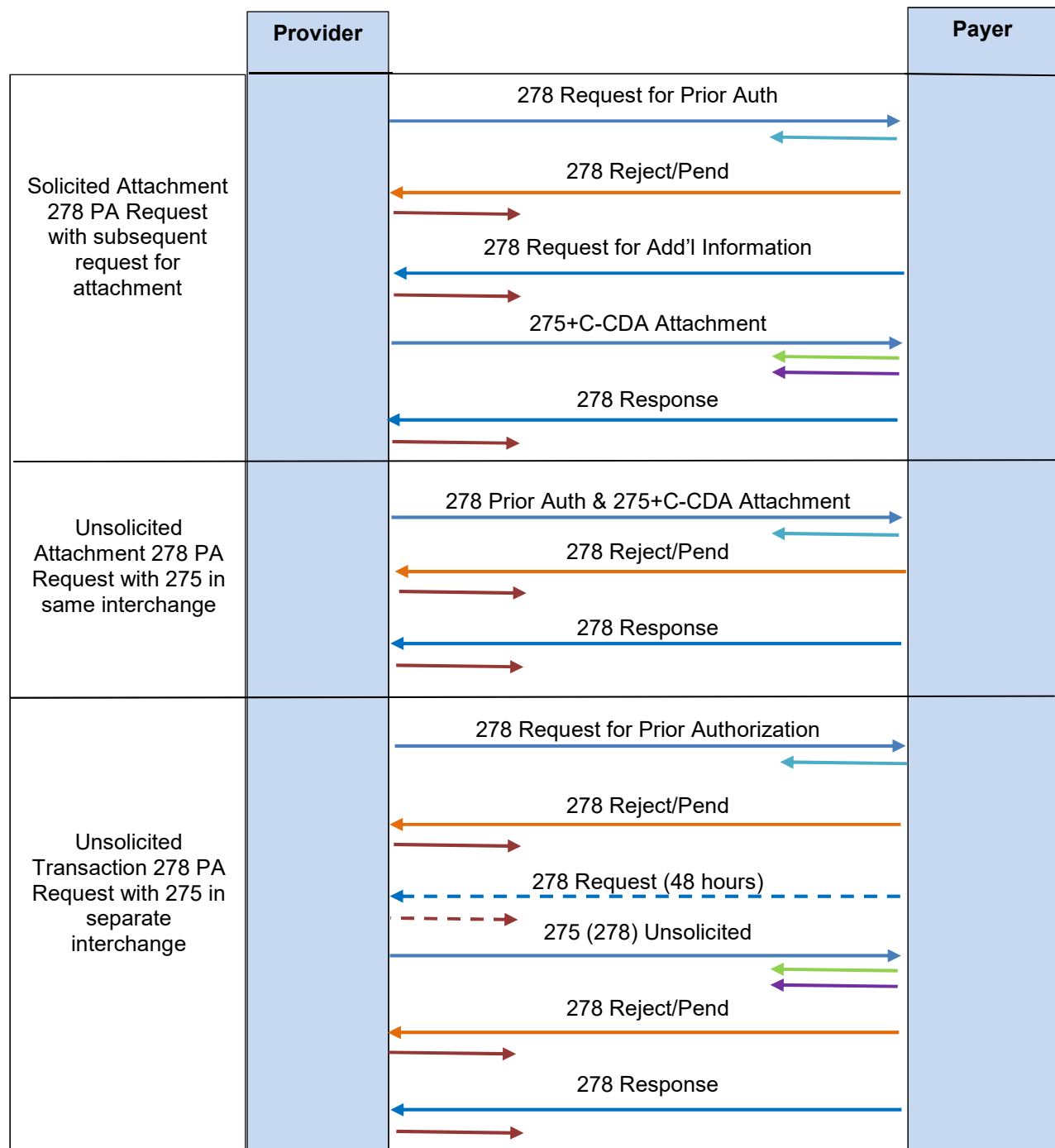
ASC X12 TRANSACTION STANDARDS AND ERROR FLOWS

ASC X12N has created several standards for enveloping the Attachment and providing acknowledgments for each transaction exchange.

Figure 12: ASC X12 Claim Transaction Flows



*Required when mutually agreed to between trading partners



*Required when mutually agreed to between trading partners

APPENDIX C

CONSOLIDATED CLINICAL DOCUMENTATION ARCHITECTURE R2.1

C.1 Overview of Implementation Guide

The current release of the C-CDA named C-CDA R2.1 was split into two volumes. This two-volume implementation guide (IG) contains an overview of Clinical Document Architecture (CDA) markup standards, design, and use (Volume 1) and a consolidated library of CDA templates for clinical notes applicable to the US Realm (Volume 2). These two volumes comprise a Draft Standard for Trial Use (DSTU). The C-CDA R2.1 replaces the HL7 Implementation Guides for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1.

C.2 Document Templates

C-CDA Implementation Guides define clinical information in a format based on CDA and constrained by conformance statements consistent with industry best practices for specific types of summary clinical documents. Some broadly used clinical document types have been more fully developed in CDA than others. These structured clinical document types are:

- Care Plan
- Consultation Note
- Continuity of Care Document (CCD)
- Diagnostic Imaging Report (DIR)
- Discharge Summary
- History and Physical
- Operative Note
- Procedure Note
- Progress Note
- Referral Note
- Transfer Summary

Other clinical information not listed above may also be exchanged using C-CDA R2.1 by taking advantage of the “Unstructured Document”, as described in Section 1.1.24 of the C-CDA R2.1: Volume 1 Introductory Material.

Throughout the C-CDA R2.1 implementers will see references to sending and receiving EHR systems. This is because the C-CDA R2.1 was written from the perspective of exchange between EHR systems. For the purposes of this Guide there is no assumption that exchange will occur between two EHR systems. Instead, as you will see in the use case portion of this document ([Attachment Business Flows](#)), the additional information a payer is seeking may exist in a provider’s electronic repository, such as an EHR system.

Section 1 of the C-CDA R2.1: Volume 1 Introductory Material describes at a high level how templates are used to represent the organization of CDA structure in a document. Metadata found in the Header as well as specific clinical information found in the Body components as Documents Sections within those documents, and entries within those sections are explained as described in Sections 1-4 of the C-CDA R2.1: Volume 2 Templates and Supporting Material.

C.3 LOINC Document Type Codes

The following table shows the recommended LOINC codes for the C-CDA R2.1 structured documents current at the time of this publication. These codes should be used to request a “clinical” document and to identify such a document when it is submitted.

Table 8: C-CDA R2.1 Clinical Document Types with Recommended LOINC Code for Requests

Clinical Document Type	"Recommended" LOINC	LOINC Long Description	C-CDA R2.1 Table Reference	ValueSet
Care Plan	18776-5	Plan of care note	–	No value set
Consultation Note	11488-4	Consult note	Table #28	ConsultDocumentType
Continuity of Care (CCD)	34133-9	Summary of episode note	–	No value set
Diagnostic Imaging Report	18748-4	Diagnostic imaging study	–	LOINC Imaging Document Codes
Discharge Summary	18842-5	Discharge summary	Table #37	DischargeSummaryTypeCode
History and Physical	34117-2	History and physical note	Table #41	HPDocumentType
Operative Note	11504-8	Surgical operation note	Table #44	SurgicalOperationNoteDocumentTypeCode
Procedure Note	28570-0	procedure note	Table #48	ProcedureNoteDocumentTypeCodes
Progress Note	11506-3	Progress note	Table# 51	ProgressNoteDocumentTypeCode
Referral Note	57133-1	Referral note	Table# 54	ReferralDocumentType
Transfer Summary	18761-7	Transfer summary note	Table# 57	TransferDocumentType

The requester may request a document that conforms to a specific implementation guide (e.g., C-CDA R2.1 or C-CDA R1.1) by specifying the appropriate LOINC Implementation Guide Modifier code for that implementation guide. See [Section 4.2.3 Requesting an Attachment](#) for guidance.

APPENDIX D

CLINICAL DOCUMENTS FOR PAYERS – SET 1 R1.1

D.1 Overview of Implementation Guide

Electronic Submission of Medial Documentation (esMD) Initiative mapped existing CMS Medicare Fee For Service (FFS) and other use cases requiring an enhanced set of information to the proposed C-CDA R2.1 templates. The resulting analysis revealed the need for additional, highly constrained document templates to augment those defined by the C-CDA R2.1. This work resulted in the creation of documents defined in the Clinical Documents for Payers – Set 1 (CDP1).

D.2 Document Templates

CDP1 Implementation Guide defines five additional document templates that are compliant with and based on the C-CDA R2.1 standard. These templates are highly constrained and ensure that the supporting EHR must be capable of including the defined information for a section or declare that it is not available or appropriate for the purpose of the document. The new templates are:

- Enhanced Encounter Document
- Enhanced Discharge Document
- Enhanced Operative Note Document
- Enhanced Procedure Document
- Interval Document

Other clinical information not listed above may also be exchanged using any of the C-CDA R2.1 documents or the “Unstructured Document”, as described in Section 1.1.24 of the C-CDA R2.1: Volume 1 Introductory Material.

D.3 LOINC Document Type Codes

The following table shows the recommended LOINC Document Type Codes for the CDP1 structured documents current at the time of this publication. These codes should be used to request a “clinical” document and to identify such a document when it is submitted.

Table 9: CDP1 R1.1 Clinical Document Types with Recommended LOINC Code for Requests

Clinical Document Type	"Recommended" LOINC	LOINC Name	CDP1 Table Reference	ValueSet
Discharge Summary	18842-5	Discharge summary	-	DischargeSummaryTypeCode
Enhanced Encounter	77601-3	Enhanced note	-	ConsultDocumentType and
Interval	77600-5	Interval note	-	No value set
Operative Note	11504-8	Surgical Operation note	Table #44	SurgicalOperationNoteDocumentTypeCode
Procedure Note	28570-0	Procedure note	Table #48	ProcedureNoteDocumentTypeCodes

The requester may request a document that conforms to the CDP1 implementation guide by specifying the appropriate LOINC Implementation Guide Modifier Code for the Clinical Documents for Payers Set 1 Release 1.1. See [Section 4.2.3 Requesting an Attachment](#) for guidance.

APPENDIX E

DIGITAL SIGNATURES ON ATTACHMENTS

The HL7 standard “Digital Signatures and Delegation of Rights DSTU R1” provides the information required for one or more persons to digitally sign any C-CDA based document supporting the US Realm Header defined in C-CDA R2 or C-CDA R2.1. The digital signature provides for:

- a non-repudiation signature that attests to the role and signature purpose of each Authorized Signer to the document
- a delegation of rights where the signer is a Delegated Signer and not the Authorized Signer responsible individual or organization (e.g., the signer is acting as an authorized agent)
- medical/legal attestation for administrative and clinical purposes such as documenting transfer of clinical care (e.g., the Longitudinal Coordination of Care initiative)
- both digital co-signatures and counter signatures

For example, an Authorized Signer may play a role in the document, such as an author, and would therefore be represented in the author participation declared in the header. As an Authorized Signer, the person will be represented as an authenticator in the header. In the `sdct:signatureText` for the authenticator, the Authorized Signer will have a `signerRole`. If this Authorized Signer claims to be an anesthesiologist, signing as an author, then this information would be represented in the `signerRole` as the `claimedRole` and `signaturePurpose`. Through appropriate use of both `signerRole` and `signaturePurpose`, digital signatures can accommodate co-signatures on any C-CDA (e.g., multiple Authorized Signers can indicate that they are co-authors). In addition, since the XAdES-X-L standard use by this guide supports counter signatures, any digital signature may be countersigned.

The standard provides:

- a method of incorporating digital signatures and delegation of right assertions into the header of a CDA Document for Attachments in the `sdct:signatureText` element.
- a digital signature standard for a CDA Document for Attachments that supports the exchange of a signed:
 - digest of the message
 - timestamp
 - role of the signer
 - purpose of signature
- a digital signature standard for:
 - the public certificate of the signer
 - long term validation data, including Online Certificate Status Protocol (OCSP) response and/or Certificate Revocation List (CRL)
- a standard to assert a delegation of rights that supports the exchange of:
 - the certificate ID of both parties
 - the purpose of the delegation
 - the effective date range of the assertion
- a method to validate an existing delegation of rights assertion

The ability to provide Digital Signatures and Delegation of Rights Assertion artifacts can be achieved with existing standards. The capability may be provided as a service by third parties or incorporated directly into or provided in conjunction with EHRs and payer systems.

E.1 User Story– Digital Signature by Authorized Signer

The Authorized Signer digitally signs the document establishing the signer's role and purpose of signature. The Authorized Signer sends the signed document to the Recipient. The Recipient receives the Signed Document and authenticates the Authorized Signer's digital certificate, the signature artifact, and validates the data integrity of the document.

In order to participate in digital signing, the Authorized Signer obtains and maintains an X.509v3 digital signing certificate. Entities approved by a Registration Authority will receive the X.509v3 certificate from a Certificate Authority to incorporate into their business process.

The Authorized Signer creates a Digital Signature artifact incorporating their role, purpose of signature, and date/time of the signature and inserts it into the `sdhc:signatureText` element. The Authorized Signer, who has satisfied any requirements for a specific exchange of documentation with a Recipient, sends (directly or through a delegated agent) the digitally signed CDA document in a secure transaction to the Recipient using appropriate transmission methods.

E.2 Creating a Digital Signature

The standard used to sign a CDA Document for Attachments is XAdES-X-L, an extension to the W3C XML Digital Signature (XML-DSIG) standard that adds support for long term signature verification via timestamps, certificates, revocation lists, and additional features.

E.2.1 Computation of the Digest

When digitally signing a CDA document, the Digest of the Signed Data Object is the entire document **excluding** all occurrences of (and elements contained within) `<authenticator>` and `<legalAuthenticator>`. By excluding `legalAuthenticator` and `authenticator` participant occurrences from the calculation of the Digest, the information signed by each Authorized Signer and Delegated Signer will not be altered by subsequent signing events. This allows for multiple Authorized Signers and Delegated Signers on any C-CDA. It should be noted that excluding the `legalAuthenticator` and `authenticator` participant occurrences from the calculation of the Digest does not remove them from the C-CDA.

E.2.2 Signature Process

The signer creates the XAdES-X-L Digital Signature and populates it with all required elements including:

1. The signer's public X.509v3 signing certificate
2. The Digest of the CDA
3. The Signed Digest
4. The following signed elements:
 - a. Coordinated Universal Time (UTC)
 - b. Role
 - c. Signature Purpose
5. A signed OCSP or CRL in the `RevocationValues` element

E.2.3 Specifications for the Encapsulated Data (ED) Data Type

The `sdct:signatureText` element used to store the digital signature has an ED data type and is to be specified with the following values:

representation = "B64"
mediaType = "application"

E.2.4 Specifications for Thumbnail

The `sdct:signatureText` element is an ED data type permits the definition of a thumbnail to provide a human readable version of the Digital Signature:

`<thumbnail mediaType="text/plain" representation="TXT">`

The thumbnail text string SHOULD contain the following elements for an Authorized Signer:

1. "Digitally Signed by Authorized Signer"
2. Signers name
3. Date and time of signature
4. Role
5. Purpose

Example (Authorized Signer):

Digitally signed by Authorized Signer John Doe on 4/21/2013 at 15:30 EDT as Physician for the purpose of Author's signature.

E.3 Verifying an XAdES-based Signature

A Recipient is the receiver of the signed CDA Document for Attachments and should verify the Digital Signatures using the following steps to verify the identity of the Authorize Signer(s) and the integrity of the CDA document.

The following steps provide technical verification of the signer's signature and do not discuss the requirements that policy may place on verification of Certificate content, CDA Document for Attachments types, delegation, etc. XAdES-X-L is used to encapsulate all validation artifacts (such as path to issuer and revocation list) to avoid any dependency on availability of such resources at the time of validation.

1. Verify the X.509v3 Certificate was:
 - a. current at the time of signature
 - b. issued for an acceptable purpose
 - c. trust anchor is acceptable by verifying the complete chain to the issuing CA's root certificate
 - d. issued with the `altName` field including the required identification (NPI within the US realm) or an Alternative ID.
 - e. The CRL or OCSP included in the XAdES-X-L was signed by the issuing CA at a date and time, acceptable by policy, relative to the date of the Digital Signature.
 - f. The signing certificate is not on the signed CRL or is indicated as valid on the signed OSCP response included in the XAdES-X-L `RevocationValues` element.
2. Inspect signature date/time for constancy with signature and timestamp policy.
3. Verify that the role of the signer is appropriate

4. Inspect the signature purpose is reasonable and appropriate given the document content and the signer identity
5. Decrypt the signed Digest with the public key from the X.509v3 public digital certificate.
6. Compute the Digest of the CDA Document for Attachments using the serialization and algorithm specified in the signature
7. Verify that the signed Digest matches the computed Digest.

If any of these steps fails, the Signature cannot be verified.

APPENDIX F

CDA DOCUMENT FOR ATTACHMENTS TRANSPORT AND PAYLOAD

This Appendix covers standards based approaches to sending a CDA Document for Attachments using electronic transactions. This Appendix will use the term CDA to represent any CDA Document for Attachments. Any reference to existing standards are based on information at the time of publication of this guide.

F.1 Transport Options

There are a variety of transport options for exchanging any CDA. These include the use of the public Internet using SOAP message envelope specifications Council for Affordable Quality Healthcare Committee on Operating Rules for Information Exchange (CAQH CORE) Connectivity Operating Rules or the IHE XDR profile or via email (SMTP) using the DIRECT specifications.

CONNECT,⁷ which implements the Nationwide Health Information Network (NwHIN) standards and specifications, including the NwHIN CAQH CORE X12 Document Submission Service Interface Specification v1.0⁸ using the Phase II CAQH CORE 270 Connectivity Rule v2.2.0 and Direct project specifications, is an open source software code platform designed to enable the secure, effective exchange of information. While CONNECT was initially developed by federal agencies to support their health-related missions, it is now available to all organizations and can be used to set up health information exchanges and share data using nationally-recognized interoperability standards. Any CDA Document for Attachments can be embedded (wrapped) into an ASC X12N 275 transaction and then transported via SOAP or SMTP.

The current version of CONNECT includes only the NwHIN CAQH CORE X12 Document Submission Service Interface Specification v1.0. The NwHIN CAQH CORE X12 Document Submission Service Interface Specification v1.0 supports both synchronous and deferred modes for exchanging an ASC X12 275 transaction.

Table 10: Transport Options

Transport	Message/Metadata	Clinical Payload
SOAP Real Time	ASC X12N 275 with CAQH CORE	CDA
SOAP Batch	ASC X12N 275 with CAQH CORE	CDA
CONNECT (SOAP)	ASC X12N 275 with CAQH CORE	CDA
CONNECT (SOAP)	XDR	CDA
Direct (SMTP)	ASC X12N 275 (X12 MIME)	CDA
Direct (SMTP)	XML MIME	CDA

F.2 Metadata Requirements

When an EHR or other patient record system creates any clinical document (Attachment) consistent with the CDA Implementation Guide for Attachments Standards, it does so without regard to the recipient or

⁷ <http://www.connectopensource.org/>

⁸ <http://exchange-specifications.wikispaces.com/file/detail/CAQH+CORE+X12+DocumentSubmissionServiceSpecification+v1.0.doc>

that recipient's purpose for obtaining that Attachment. Because of this, the recipient may need additional information (metadata) to better understand which healthcare attachment activity for which the Attachment is intended.

The following metadata must accompany the attachment information being exchanged:

- Requestor (Payer/UMO) Name and Identifier
- Request receiver Name and ID (ETIN, etc)
- Provider of Service Name and ID (NPI)
- Attachment Control Number (payer or provider assigned, depending on solicited/unsolicited)
- Attachment Information ID needed (LOINC Code), both in request and response
- Date Requested and Response Due Date
- Payer Contact Information
- Date of Service/Encounter

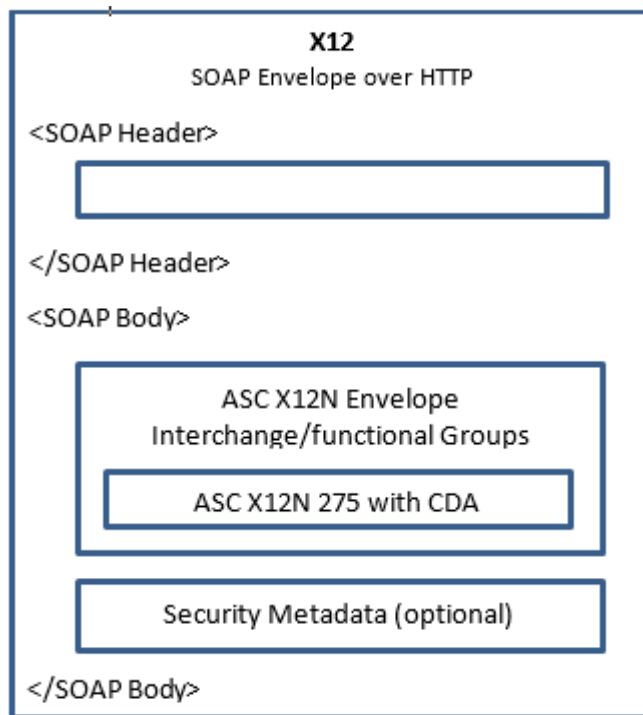
In addition to the metadata above, the following MAY be included if the situation indicates:

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

F.3 Overview of X12 (Synchronous or Real Time)

This section defines how a transaction may be submitted with the ASC X12N 275. Submission under this mechanism is constrained to synchronous (real-time) transmissions (deferred or batch transmissions are out of scope):

Figure 13: ASC X12N Real-time



F.3.1 Security Metadata

When using the Phase II CAQH CORE Rule 270: Connectivity Rule 2.2.0 or the Phase IV CAQH CORE 470 Connectivity Rule or the NwHIN CAQH CORE X12 Document Submission Service Interface Specification v1.0, the Security Metadata must be placed in the Body element of the SOAP envelope, as illustrated below (example is for using standards defined by the HL7 Digital Signature and Delegation of Rights DSTU and applied to transaction as specified in the S&I PPA Implementation Guide):

```
<securityMetadata>
  <digitalSignature>...</digitalSignature>
  <delegationofRights>...</delegationofRights >
</securityMetadata>
```

F.3.2 Error Handling

Envelope level errors shall be handled in accordance with Phase II CAQH CORE Rule 270: Connectivity Rule Version 2.2.0 or Phase IV CAQH CORE 470 Connectivity Rule. To handle CORE-compliant envelope processing status and error codes, two fields called `errorCode` and `errorMessage` are included in the CORE-compliant Envelope. `errorMessage` is a free form text field that describes the error for the purpose of troubleshooting/logging. When an error occurs, `PayloadType` is set to *CoreEnvelopeError*.

X12 Interchange Envelope Conformance errors in the transaction may be communicated in an X12 TA1 response. The possible TA1 error codes are located in the ASC X12N TA1 Implementation Specification.

X12 Standard Conformance & Implementation Guide Conformance errors in the transaction may be communicated in an X12 999 response. The possible 999 error codes are located in the ASC X12N 999 Implementation Specification.

Application processing errors in the transaction may be communicated in an X12 824 response. The possible 824 error codes are located in the ASC X12N 824 Implementation Specification. When the error has been caused by a specific segment or segments, the response should identify the segment or segments that caused the error. It is the responsibility of the responder to select an appropriate error code from the *Insurance Business Process Application Error Codes*.

The relevant ASC X12N Implementation Guides for error and acknowledgment handling and the ASC X12 Acknowledgment Reference Model are available at <http://store.x12.org/store/healthcare-5010-original-guides>.

The Insurance Business Process Application Error Codes are maintained by the Washington Publishing Company and are available at <http://www.wpc-edi.com/reference/codelists/healthcare/insurance-business-process-application-error-codes/>.

F.4 Overview of a payload over eHealth Exchange with ASC X12N Message

This section defines how a CDA document may be sent over eHealth Exchange with the NwHIN CAQH CORE ASC X12N Document Submission Service Interface Specification v.1.0.

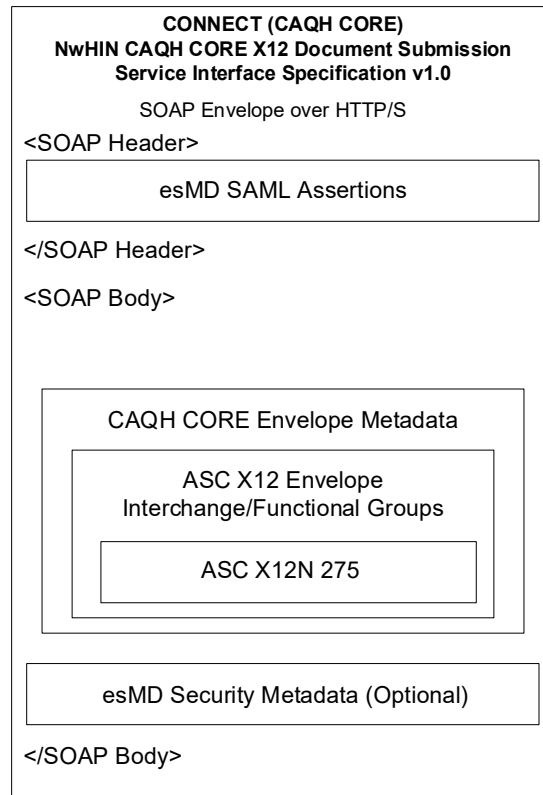
F.4.1 ASC X12N 275 over eHealth Exchange (CORE)

Sequoia (previously Healthway and the Nationwide Health Information Network (NHIN)) adopted the Phase II CAQH CORE Rule 270: Connectivity Rule Version 2.2.0 to exchange ASC X12N Administrative Transactions between one or more Health Information Exchanges via the Internet. CONNECT is the open source software code platform used by CMS supporting Exchange participants. The “CAQH CORE X12 Document Submission Service Interface Specification v1.0”⁹ defines specific constraints on the use of the CAQH CORE Connectivity Rule. Figure 12 presents the components of a request or response message using ASC X12N 275 and CONNECT with the NwHIN CAQH CORE X12 Document Submission Service Interface Specification v1.0.

⁹ <http://sequoiaproject.org/ehealth-exchange/testing-overview/specifications/>

Specific CONNECT implementations may provide support for X12 transactions as a payload within a CAQH CORE SOAP message envelope or within an XDR SOAP message envelope. Implementations of CONNECT should be capable of sending and receiving an ASC X12 transaction either as a payload in a CAQH CORE SOAP message envelope or optionally as a payload in an XDR SOAP message envelope based on trading partner agreements.

Figure 14: CONNECT with ASC X12N Specification



Note: Per the NwHIN CAQH CORE X12 Document Submission Service Interface Specification v1.0 for Real-time using the SOAP envelope, the payload must be Base64 encoded.¹⁰

¹⁰ NwHIN CAQH CORE X12 Document Submission Service Interface Specification v1.0s

F.4.2 CONNECT SAML Assertions

SAML assertions for transactions with CMS must conform to the “Implementation Guide for Health Information Handlers for Electronic Submission of Medical Documentation Project,” Section 5.3.5.5: *esMD SAML Assertions Details*, which states:

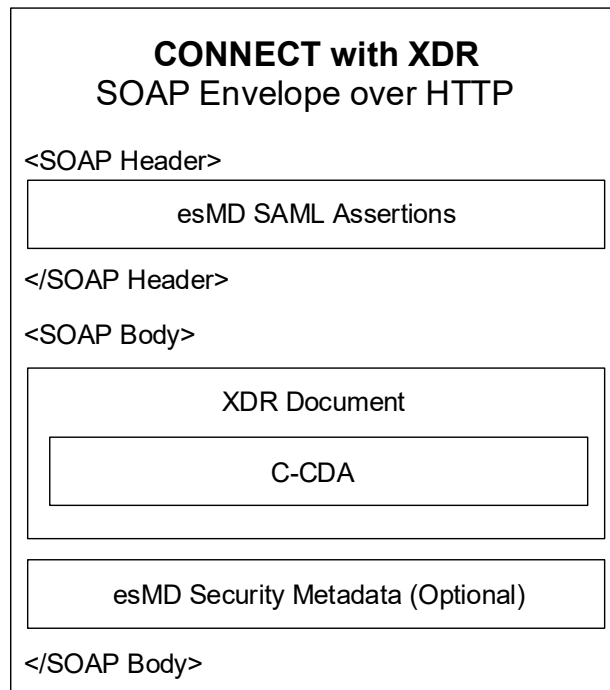
The CONNECT SAML Assertions define the exchange of metadata used to characterize the initiator of a request so that it may be evaluated by the Payer Gateway in local authorization decisions. The purpose of this SAML Assertion exchange is to provide the Payer Gateway with the information needed to make an authorization decision using the policy enforcement point for the requested esMD function. Each initiating SOAP message must convey information regarding the Registration Requestor’s attributes and authentication using SAML 2.0 Assertions.

SAML assertions for transactions with Commercial Payers must conform to the eHealth Exchange Authorization Framework Specification v3.0.

F.5 Overview of a Payload Over CONNECT with XDR

This section defines how a transaction may be sent over CONNECT with the eHealth Exchange CAQH CORE X12 Document Submission Service Interface Specification.

Figure 15: CONNECT w/ ASC X12N 275



Note: Per specifications, encoding for XDR may be indicated in the metadata, and encoding must be Base64.¹¹

¹¹ Nationwide Health Information Network Electronic Submission of Medical Documentation: esMD XDR Production Specification, Version 1.0

Table 11: XD* Submission Set Metadata

S.No	Existing or Extension	XD* Metadata Attribute	Definition ¹²	Data Type	Required ¹³
1	Existing	Author	Represents the humans and/or machines that authored the document. This attribute contains the following sub-attributes: authorInstitution, authorPerson, authorRole, authorSpecialty, authorTelecommunication		R2
1.1	Existing	authorInstitution (sub-attribute of author)	XON.1 - Name of the Provider or Agent sending the request XON.10 - ID of the Provider or Agent sending the request	XON	R2
1.2	Existing	authorPerson (sub-attribute of author)	Contact person for administrative questions XCN.2 - Last Name XCN.3 - First Name XCN.4 - Middle Name XCN.5 - Suffix XCN.6 - Prefix	XCN	O
1.3	Existing	authorTelecomm unication	Telephone/fax/email for esMD administrative questions XTN.1 - [NNN] [(999)]999-9999 [X99999] [B99999] [C any text] XTN.4 - Email Address XTN.6 - area code XTN.7 - phone number XTN.8 - extension	XTN	O
2	Existing	Comments	Description of reason for the replacement, follow up, or termination for a prior request		O
3	Existing	contentTypeCode	The code specifying the type of clinical activity that resulted in placing these XDS Documents in this XDS-Submission Set. These values are to be drawn for a vocabulary defined by the XDS Affinity Domain.		R2
4	Existing	contentTypeCode DisplayName			R2
5	Existing	entryUUID	A unique ID or a globally unique identifier within the document submission request for the SubmissionSet. Intervening portal generates this as part of generating the XDR/XDM message	UUID	R
6	Existing	intendedRecipient	Intended Recipient represents the organization(s) or person(s) for whom the Document Submission set is intended.	XON/XCN	R2

¹² Where appropriate, constraints or detail specific to esMD is indicated separately within this column

¹³ R=Required; R2=Required if known; O=Optional

S.No	Existing or Extension	XD* Metadata Attribute	Definition ¹²	Data Type	Required ¹³
			<p>The Intended Recipient for the Registration Request will be a Payer or Payer Contractor to whom the Provider or Agent sends the message. This Intended Recipient will be identified by the Unique Payer ID.</p> <p>For Payer, use XON datatype: XON.1 - Organization Name XON.10 - Organization NPI or Alternate ID</p>		
7	Existing	patientID	The patientId represents the subject of care of the document.		R2
8	Existing	sourceID	Globally unique identifier, in OID format		R
9	Existing	submissionTime	<p>Point in Time at the Document Source when the Submission Set was created and issued for registration to the Document Registry. Shall have a single value.</p> <p>This shall be provided by the Document Source (in case of e-mail with significant delay).</p> <p>Timestamp should be to at least the second</p>	DTM	R
10	Existing	title	Represents the title of the Submission Set.		O
11	Existing	uniqueID	A globally unique identifier, in OID format, assigned by the Sender to the submission set in the transmission. The length of this Unique Identifier shall not exceed 128 bytes.		R

Table 12: XD* Document Entry Metadata

S.No	Existing or Extension	XD* Metadata Attribute	Definition	Data Type	Required ¹⁴
1	Existing	author	Represents the humans and/or machines that authored the document. This attribute contains the following sub-attributes: authorInstitution, authorPerson, authorRole, authorSpecialty. Note that the sender information is carried in the Submission Set author attribute, not necessarily this one.		R2
1.1	Existing	authorInstitution (sub-attribute of author)	XON.1 - Name of the Provider or Agent XON.10 - ID of the Provider or Agent	XON	R2
1.2	Existing	authorPerson (sub-attribute of author)	Contact person for esMD administrative questions XCN.2 - Last Name XCN.3 - First Name XCN.4 - Middle Name XCN.5 - Suffix XCN.6 - Prefix	XCN	O
2	Existing	classCode	The code specifying the particular kind of document. Supports environments where content is provided without context, for example a PDF document or a patient's document as patients do not understanding coding systems. Could consider a well-known class code which identifies the entry as a "directed" entry.		XDR/XDM - R2
3	Existing	classCodeDisplay	The name to be displayed for communicating to a human the meaning of the classCode. Shall have a single value for each value of classCode.		XDR/XDM - R2
4	Existing	comments	Description of reason for the replacement, follow up, or termination for a prior request		O
5	Existing	confidentialityCode	The code specifying the level of confidentiality of the Document.		XDR/XDM - R2
6	Existing	creationTime	Represents the time the author created the document in the Document Source. Shall have a single value. If the creation time of the document is unknown it is better to specify nothing than use a value that is misleading.	DTM	XDR/XDM - R2

¹⁴ R=Required; R2=Required if known; O=Optional

S.No	Existing or Extension	XD* Metadata Attribute	Definition	Data Type	Required ¹⁴
7	Existing	entryUUID	A unique ID or a globally unique identifier within the document submission request for the SubmissionSet. Intervening portal generates this as part of generating the XDR/XDM message	UUID	R
8	Existing	formatCode	Globally unique code for specifying the format of the document.		XDR/XDM - R2
9	Existing	formatCodeDisplayName	The name to be displayed for communicating to human readers the meaning of the formatCode.		XDR/XDM - R2
10	Existing	hash	Hash key of the request/response XML document.	SHA1	XDR - O XDM - R
11	Existing	healthcareFacilityTypeCode	This code represents the type of organizational setting of the clinical encounter during which the documented act occurred.		XDR/XDM - R2
12	Existing	healthcareFacilityTypeCodeDisplayName	The name to be displayed for communicating to a human the meaning of the healthcareFacilityTypeCode. Shall have a single value corresponding to the healthcareFacilityTypeCode.		XDR/XDM - R2
13	Existing	languageCode	Specifies the human language of character data in the document. The values of the attribute are language identifiers as described by the IETF (Internet Engineering Task Force) RFC 3066.		XDR/XDM - R2
14	Existing	mimeType	MIME type of the document in the Repository. Shall have a single value.		R
15	Existing	patientID	The patientId represents the subject of care of the document.		XDR/XDM - R2
16	Existing	practiceSettingCode	The code specifying the clinical specialty where the act that resulted in the document was performed.		XDR/XDM - R2
17	Existing	practiceSettingCodeDisplayName	The name to be displayed for communicating to a human the meaning of the practiceSettingCode. Shall have a single value corresponding to the practiceSettingCode.		XDR/XDM - R2
18	Existing	sourcePatientId	The sourcePatientId represents the subject of care medical record Identifier (e.g., Patient Id) in the local patient Identifier Domain of the Document Source. It shall contain two parts: Authority Domain Id An Id in the above domain (e.g., Patient Id).		XDR/XDM - R2
19	Existing	title	Represents the title of the document. Max length shall be 128 bytes in UTF-8 format.		O
20	Existing	typeCode	The code specifying the precise kind of document		R2
21	Existing	typeCodeDisplayName	The name to be displayed for communicating to a human the meaning of the typeCode. Shall have a single value corresponding to the typeCode.		R2

S.No	Existing or Extension	XD* Metadata Attribute	Definition	Data Type	Required ¹⁴
22	Existing	uniqueID	<p>Globally unique identifier for the document in submission-set assigned by the Document Source in OID format. Shall have a single value.</p> <p>A globally unique identifier assigned to each document in the SubmissionSet. The length of the Unique Identifier shall not exceed 128 bytes. The structure and format of this ID shall be consistent with the specification corresponding to the format attribute. This ID will be generated based on the UUID.</p> <p>Generated based on the UUID. The same ID will be returned with the response message.</p>		R
23	Existing	URI	Required in XDM to address the location in the zip package of the document		XDR - O XDM - R

F.5.1 esMD Security Metadata

When using CONNECT, the Security Metadata must be placed in the Body element of the SOAP envelope.

F.5.2 Error Handling

XD* error codes are defined in Section 4 of Integrating the Healthcare Enterprise's (IHE's) Information Technology Industry (ITI) Technical Framework, Volume 3. For errors related to processing the XD* metadata, the esMD Response to a Registration Request will use the XD* error codes.

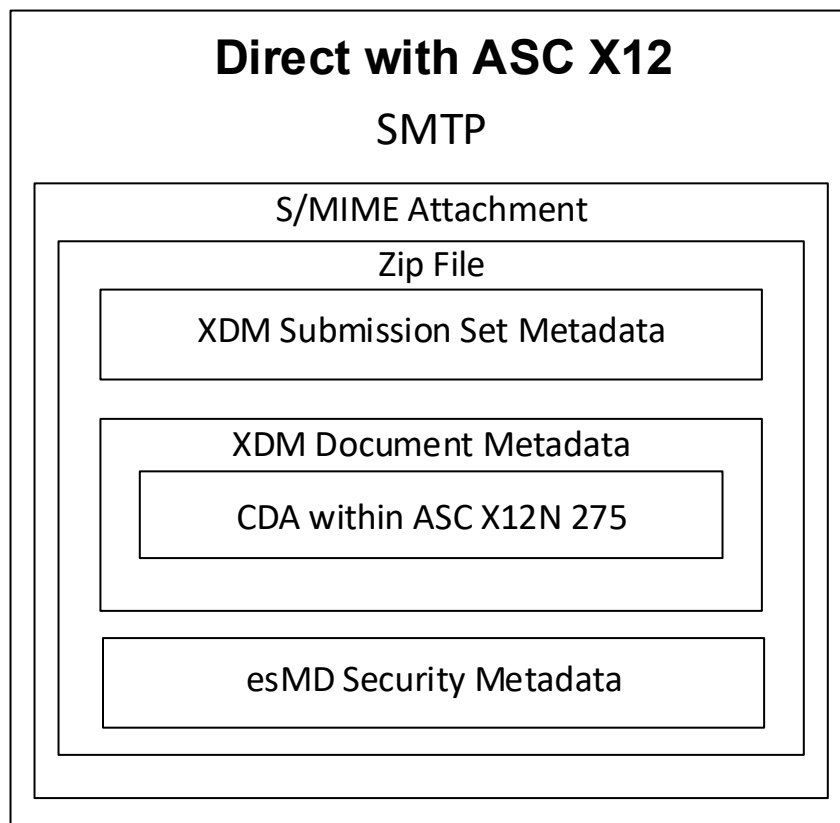
Application processing errors shall be communicated in an *ebRS RegistryResponse* using the *Insurance Business Process Application Error Codes*. It is the responsibility of the responder to select an appropriate error code from the *Insurance Business Process Application Error Codes*.

The *ebRS RegistryResponse* *errorCode* field must contain the selected esMD error or *Insurance Business Process Application Error Codes*. When the error has been caused by a specific HPD Plus attribute, the *ebRS RegistryResponse* *location* field should identify the Object Class and Attribute that caused the error.

F.6 Overview of Payload Over Direct (ASC X12 Message)

This section defines how a transaction may be sent using Direct. The figure below presents the components of a transaction over Direct:

Figure 16: Direct Message with ASC X12N Payload



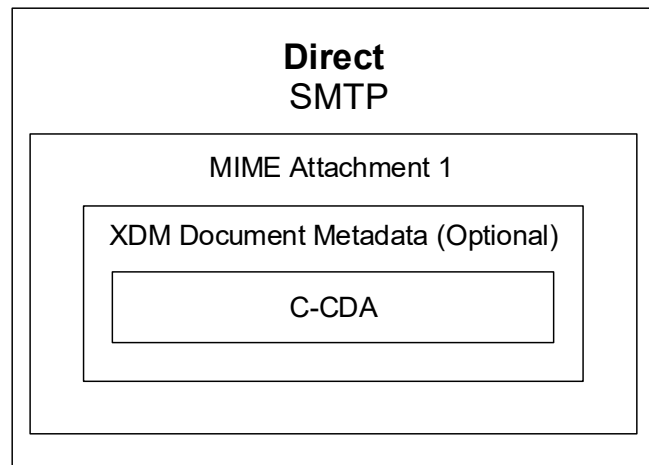
Note: XDM and XDR metadata allow for indication of encoding method. This method must be Base64.¹⁵ XDM is optional in cases where more than one clinical document is included in Attachment 1.

¹⁵ XDR and XDM for Direct Messaging Specification, Version 1, finalized 9 March 2011. Refer to Section 6.0: Metadata

F.7 Overview of Payload Over Direct

This section defines how a transaction may be sent Direct. The figure below presents the components of a transaction over Direct:

Figure 17: Direct Message with CDA XDM Payload



Note: XDM and XDR metadata allow for indication of encoding method. This method must be Base64.¹⁶ XDM is optional in cases where more than one clinical document is included in Attachment 1.

¹⁶ XDR and XDM for Direct Messaging Specification, Version 1, finalized 9 March 2011. Refer to Section 6.0: Metadata

APPENDIX G

FAST HEALTHCARE INTEROPERABILITY RESOURCES (FHIR)

FHIR is an emerging HL7 standard for interoperability. It defines the representation of information for an exchange between two organizations or internally between applications using Application Program Interfaces (API). The specification is evolving via ongoing testing and implementation providing feedback to the standards process. There is a reasonable expectation that this standard will be used to exchange attachments information in the future and provide for a more flexible real-time query and response to allow providers and payers to communicate clinical and administrative information using one of several internet based protocols (e.g., Rest).

G.1 What is FHIR

FHIR® – Fast Healthcare Interoperability Resources (hl7.org/fhir) – is a next generation standards framework created by HL7. FHIR combines the best features of HL7's [v2](#), [HL7 v3](#) and [CDA](#) product lines while leveraging the latest web standards and applying a tight focus on implementability.

FHIR solutions are built from a set of modular components called "Resources". These resources can easily be assembled into working systems that solve real world clinical and administrative problems at a fraction of the price of existing alternatives. FHIR is suitable for use in a wide variety of contexts – mobile phone apps, cloud communications, EHR-based data sharing, server communication in large institutional healthcare providers, and much more.

FHIR offers many improvements over existing standards:

- A strong focus on implementation – fast and easy to implement (multiple developers have had simple interfaces working in a single day)
- Multiple implementation libraries, many examples available to kick-start development
- Specification is free for use with no restrictions
- Interoperability out-of-the-box– base resources can be used as is, but can also be adapted for local requirements
- Evolutionary development path from HL7 Version 2 and CDA – standards can co-exist and leverage each other
- Strong foundation in Web standards– XML, JSON, HTTP, OAuth, etc.
- Support for RESTful architectures and also seamless exchange of information using messages or documents
- Concise and easily understood specifications
- A Human-readable wire format for ease of use by developers
- Solid ontology-based analysis with a rigorous formal mapping for correctness

G.2 Introduction to FHIR Resources, Extensions

G.2.1 Resources

The basic building block in FHIR is a resource. All exchangeable content is defined as a resource. Resources all share the following set of characteristics:

- A common way to define and represent them, building them from data types that define common reusable patterns of elements
- A common set of metadata
- A human readable part

A resource is a FHIR entity that:

- has a known identity (a url) by which it can be addressed
- identifies itself as one of the types of resource defined in the FHIR specification
- contains a set of structured data items as described by the definition of the resource type
- has an identified version that changes if the contents of the resource change

The following optional elements and properties are defined for all resources:

- An identity
- Meta data
- A base language

G.2.2 Extensions

This exchange specification is based on generally agreed common requirements across healthcare - covering many jurisdictions, domains, and different functional approaches. It is common for specific implementations to have valid requirements that are not part of these agreed common requirements. Incorporating all of these requirements would make this specification very cumbersome and difficult to implement. Instead, this specification expects that these additional distinct requirements will be implemented as extensions.

As such, extensibility is a fundamental part of the design of this specification. Every element in a resource may have extension child elements to represent additional information that is not part of the basic definition of the resource. Applications should not reject resources merely because they contain extensions, though they may need to reject resources because of the specific contents of the extensions. In order to make the use of extensions safe and manageable, there is a strict governance applied to the definition and use of extensions. Though any implementer is allowed to define and use extensions, there is a set of requirements that must be met as part of their use and definition.

G.3 Using FHIR to request and exchange CDA documents

A DocumentReference resource is used to describe a document that is made available to a healthcare system. A document is some sequence of bytes that is identifiable, establishes its own context (e.g., what subject, author, etc. can be displayed to the user), and has defined update management. The DocumentReference resource can be used with any document format that has a recognized mime type and that conforms to this definition.

Typically, DocumentReference resources are used in document indexing systems and are used to refer to:

- [CDA](#) documents in FHIR systems
- [FHIR documents](#) stored elsewhere (i.e. registry/repository following the XDS model)
- [PDF documents](#), and even digital records of faxes where sufficient information is available
- Other kinds of documents, such as records of prescriptions

Using the DocumentReference resource, a payer can request and a provider can exchange a specific document.

APPENDIX H

EXAMPLES ON BASE64 ENCODING

H.1 Overview

This appendix addresses examples and guidance on embedding non-xml documents or graphics.

H.1.1 Example Using Embedding

nonXMLBody Example with Embedded Content

```
<component>
  <nonXMLBody>
    <text mediaType="text/rtf" representation="B64">e1xydGY...</text>
  </nonXMLBody>
</component>
```

nonXMLBody Example with Referenced Content

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

H.2 Unstructured Documents

Unstructured documents will likely be the most common type of document submitted for the attachments use case. Unstructured documents consist of a CDA header containing document metadata, followed by a non XML document such as a PDF file containing the human readable content.

Since unstructured documents always contain a single file as the body, embedding and extracting Base64 encoded content is fairly straightforward. See example in H.1.1 above.

H.3 Sample Source Code

External documents / images must be:

- 1) Base64 encoded and inserted appropriately in the CDA document prior to exchange
- 2) Extracted from the CDA document and Base64 decoded upon receipt.

A sample Java program showing how to embed or extract Base64 encoded content in a CDA can be found below. This is for reference only, and is not intended to be used in production without modification and testing. It is released under the Apache 2.0 license without warranty.

<https://github.com/lantanagroup/CDAEmbedExtract>.