A STANDARDIZED GI ENDOSCOPY PROCEDURE NOTE, IN EXTENSIBLE MARKUP LANGUAGE, FORMATTED USING HEALTH LEVEL SEVEN (VERSION 3), CLINICAL DOCUMENT ARCHITECTURE (RELEASE 2)

By

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CERTIFICATE OF APPROVAL

This is to certify that the Master's Capstone Project of

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Has been approved

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Abstract

As electronic medical record (EMR) adoption continues to increase, exchange of information between EMRs is increasingly important. Health Level Seven (HL7) standards were developed to facilitate that exchange by carrying information in a highly standardized format. Standardization allows for a minimum of customized interface between EMRs reducing cost and difficulty of implementing information exchange.

Clinical information is transmitted electronically as messages or documents. Documents can be constructed using Clinical Document Architecture, Release Two (CDA R2), one of the HL7 Version Three (HL7 V3) standards [1,2]. CDA R2 is implemented with extensible markup language (XML) using tags defined in the HL7 V3 Reference Information Model (RIM) [2,4].

CDA R2 is currently used to construct a variety of clinical documents after specifications are created for more specific purposes (implementation guides). An implementation guide for operative notes is available, but prior to this work there was no implementation guide for endoscopic, or any other non-operative, procedure note. This project describes the creation of a Procedure Note Implementation Guide, and as part of that, the construction of an endoscopy report example of a procedure note. The CDA R2 Procedure Note Implementation Guide was balloted by HL7 in January 2010, as a Draft Standard for Trial Use (DTSU), and included the XML example for endoscopy.

Introduction

Documents are the cornerstone of medical records and electronic records will require electronic documents. For systems to communicate, these documents will need to be able to be carried in electronic messages. Health Level Seven (HL7) is the most widely adopted set of standards for the transfer of electronic messages and, in Version Three (HL7 V3), there is a standard for the production of electronic documents. This standard is called Clinical Document Architecture, now in its second release (CDA R2). It may be carried by HL7 V3 or Version Two (HL7 V2) messages, but can also stand alone as a separate document outside of a message.

HL7 standards are developed by the HL7 organization. HL7 is an international group of industry representatives, healthcare providers, healthcare organizations, and consultants. It is divided into working groups by areas of expertise and interest. Interested individuals and organizations, through these working groups, propose standards. Several layers of committees then review them to ensure that a proposed standard is consistent with HL7 standards as a whole. Finally, they are taken to a balloting process for approval as a Draft Standard for Trial Use (DTSU) and, after a period of years, go through the process again to proceed to a normative ballot. Only by passing through the normative ballot process does a standard become an official HL7 standard.

A gap in the collection of CDA R2 documents was the absence of a procedure note, designed to cover non-operative procedures and complement an already existent Operative Note Implementation Guide (IG). From June 2009-March 2010, a group was assembled and developed the Procedure Note, CDA R2, DSTU IG. This standard was developed as a constraint on CDA R2. The actual process is described here as a series of meetings and decision points. Several of the most critical decision points will be covered in a separate section to follow the process description section.

An overview of HL7 V3, CDA R2, and the standards development process follows this introduction. Next, the Procedure Note IG development process will be explored in depth up through DTSU balloting, including the process of constructing the XML procedure note example. Finally, appendices containing the initial project scope statement, the DTSU IG submitted for balloting, and the full XML procedure note example are provided.

Overview

Health Level Seven Version Three (HL7 V3)

HL7 standards currently are in one of two versions. Version Two (V2) is the older and more widely implemented, with multiple varieties (V2.x) that are generally backwards-compatible [1]. It is the more widely used of the two versions but lacks consistency in data

modeling/application development, is not very accommodating to international use, and requires a significant amount (20%) of the interface to be customized.

HL7 V3 was designed as a clean break from version two and is not backwards compatible, though it does try to retain many of version two's data types to ease version two to version three mapping issues. It consists of the Reference Information Model (RIM), data types, vocabulary, and implementable technology standards (ITS). ITS define how to represent RIM objects and data types for transmission in messages.

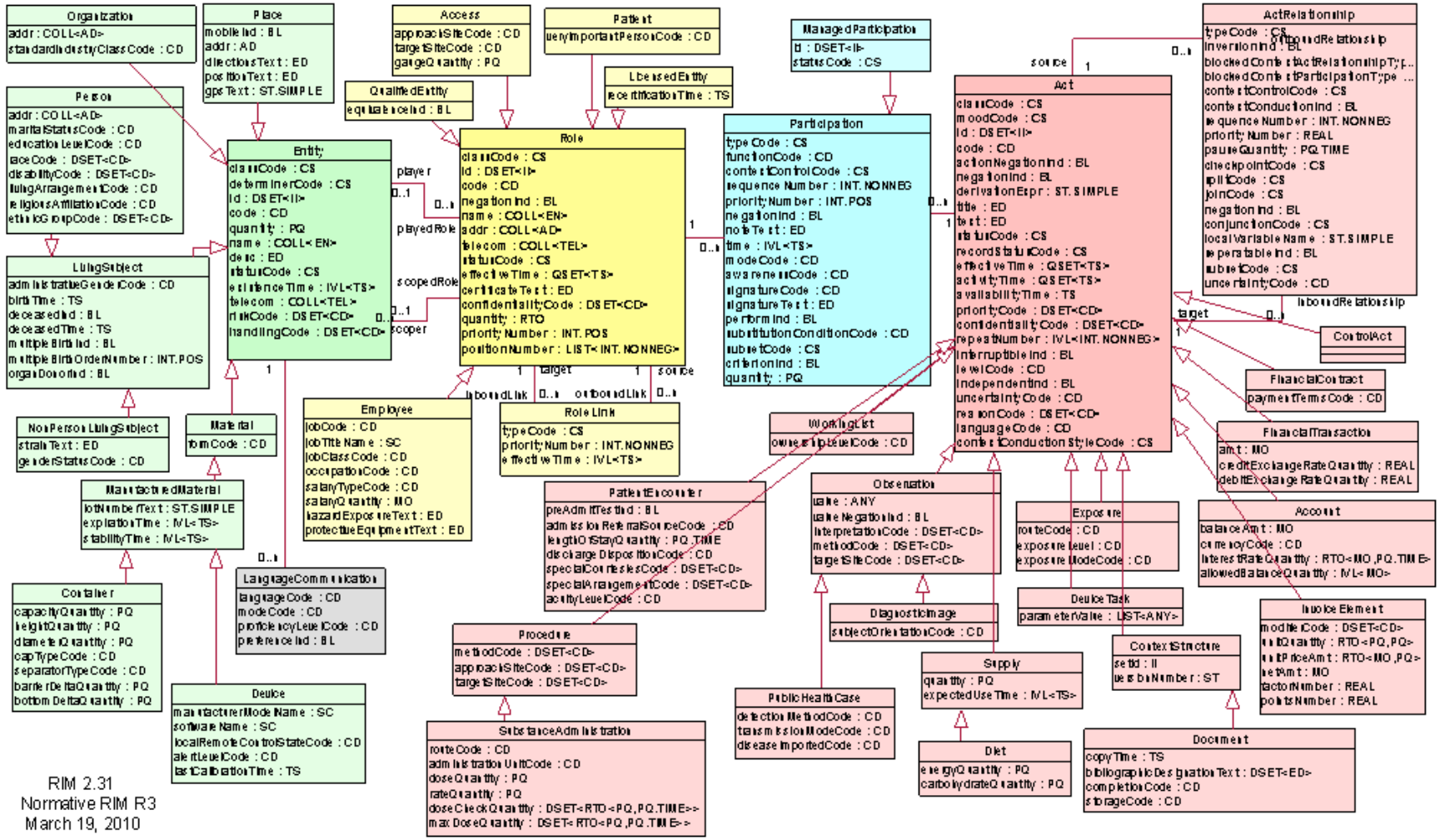
The core of HL7 V3 is the RIM represented as a UML diagram that defines classes, relationships, and attributes of healthcare information. It is very high-level and abstract. All information, including CDA R2 documents, is expressed as a constraint on this model. Use of the RIM produces a more consistent format allowing for much less custom interface development than required by version two [1,2,3,6]. It is purposely designed to accommodate the development of international standards [1].

HL7 V3 has standards for what vocabulary domains can be used. There are internal HL7 vocabulary domains and accepted external vocabulary domains. SNOMED and LOINC are examples of accepted external vocabulary domains[2]. If an attribute is to be expressed in a coded form for machine processing, it must be associated with a single vocabulary domain.

Data types are defined in the HL7 V3 standard and every attribute in the RIM has a single data type. Data types can be used zero to many times for attributes. As stated above, they are derived as much as possible from the version two data types. HL7 V3 incorporates several additional data types that augment usability and improve consistency.

The RIM is a collection of the information and relationships required for information exchange. The classes contain attributes and associations with other classes [1]. The associations describe the logical relationships between the classes. The attributes are data elements that describe the classes various aspects. Each attribute has an assigned data type from HL7 V3. Figure 1 is the graphic representation of the RIM.

Figure 1. HL7 Reference Information Model



Source: HL7 Version Three Normative Edition[2]

Clinical Document Architecture, Release Two (CDA R2)

In addition to being a messaging standard, HL7 V3 incorporates a document standard, Clinical Document Architecture, Release Two (CDA R2). Both the messaging and document standards are written in XML with the tags defined in the RIM. CDA R2 is a constraint of the higher-level RIM. CDA is independent of the messaging (transport) layer. The CDA specification provides wrappers for sending a document in a version three or version two message, but can exist as "a complete information object outside of a message [7] ".

The CDA R2 Implementation Guide (IG) states that an electronic clinical document possess six characteristics [4,7]:

- *Persistence*-continues to exist as long as necessary.
- *Stewardship*-maintained by an organization assigned.
- *Potential for authentication*-can be legally authenticated.
- *Context*-establishes the default context for its contents.
- *Wholeness*-authentication can only be of the whole, not the separate parts.
- *Human Readability*-can be read directly by the human eye.

If the above characteristics are required, then a CDA document should be considered in place of an HL7 version two or three message alone [1].

A CDA document consists of a header and a body. The header contains the information necessary to identify the document and enable its exchange/discovery/retrieval [7]. The

body carries the information of any content, but all forms of content are required to have a manual or electronic signature on file, though not necessarily in the CDA document, for authentication purposes[7].

The header can carry many different fields, but by the CDA R2 IG, is required to have the following [1]:

- Unique identifier of the document instance.
- Class of document, e.g. Procedure Note.
- Timestamp.
- Identity of participants.

The body can be XML (if so, however, it must conform to the CDA schema) or any of several other approved formats, e.g. PDF [1].

A CDA R2 body has 3 possible levels of semantic operability, which is the machine-readability of the document [4,7]. The first level is only a machine-readable header with a text body. The second level is the addition of machine-readable sections in the body. Finally, the third level is machine-readability of individual coded entries in the sections. All levels are required to have a narrative block and are human-readable [2,4]. At its simplest, it is a header and a reference to an external document. At its most complex, it can be a header and a body with sections down to the third level of semantic operability, machine–readable.

CDA R2 can be further constrained to create templates for specific documents, e.g. a History and Physical Examination document (H&P). Implementation guides define the document template [4]. The document template is further composed of templated sections that promote re-usability and standardization. They can be used in other future documents by referral to the earlier template identifier. An example would be using a templated section, like cardiac examination, of a full H&P in an abbreviated H&P as part of a future document.

HL7 Standard Development Process

HL7 has a process for the development of new standards. The process described below is summarized from the Governance and Operations Manual, the central reference on all HL7 operations [12].

Prospective standards are developed by interested individuals, cleared through groups/committees with oversight responsibilities, and presented for balloting. Ballots are either informative or normative. Informative ballots are designed by a working group to explain/support protocols or interpret implementation of an HL7 protocol specification. If appropriate, they can later be advanced to a normative ballot. Normative ballots are designed to establish a standard. DTSU Normative ballots are designed to evolve into future standards. The description below is of a normative ballot.

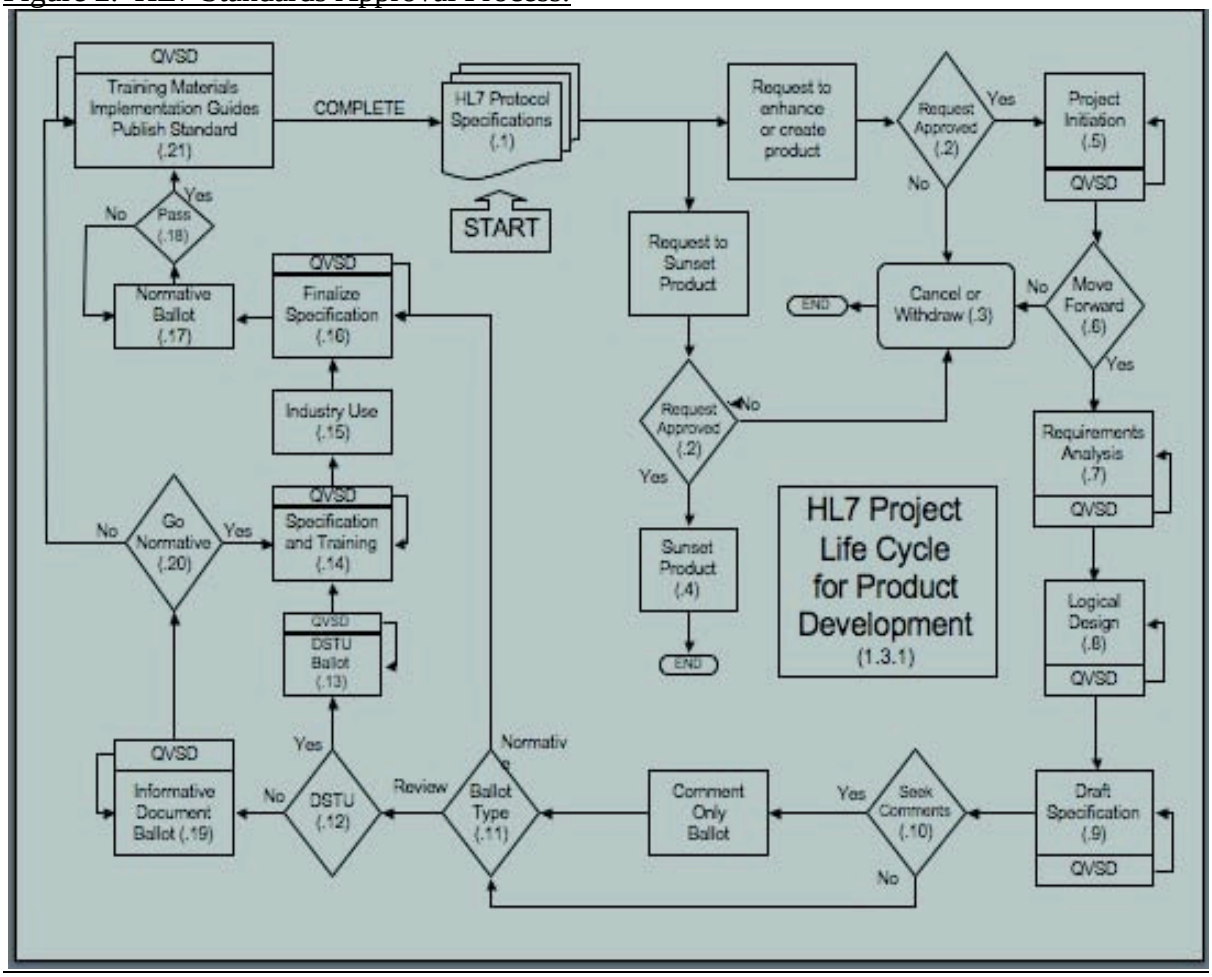
The idea for a standard is conceived and the development group is formed. That group puts together a project scope statement (PSS). The project scope statement is taken to the appropriate working group for review. Comment is also solicited from other working groups that might have an interest in the project. The working group then reviews and provides input on the PSS. The PSS may be altered during these discussions and, once the final form is decided, it is voted upon by the working group, e.g. Structured Document Working Group (SDWG). It is then passed to the supervising steering division responsible (SDWG goes to the Structure and Semantic Design) for approval. If approved by the steering division, it goes to the Technical Steering Committee (TSC). The TSC reviews the project to assure that it conforms to the mission and forms of HL7. If approved by the TSC, the project has formal approval to proceed.

The development group then proceeds to develop an implementation guide (IG) for a Draft Standard for Trial Use (DSTU). The designated primary working group and other interested working groups are kept informed of progress as the work proceeds. The working group input is used to mold the final DSTU IG. When the development group feels that they know what ballot cycle they will be placing the ballot into, they submit a Notice of Intent to Ballot (NIB). The NIB must be submitted before the ballot and is the official notification to HL7 that the ballot will be submitted. HL7 will provide public notice at least 30 days prior to the start of the balloting period. A ballot pool is recruited form the HL7 membership and reviewed for balance by the HL7 headquarters. HL7 attempts to recruit additional voters if there is a significant imbalance in the ballot voter pool.

Balloting cycles occur 3 times a year, starting one month before an HL7 Working Group meeting. One month is allowed for balloting. All negative votes are required to be explained by the voter. After the balloting the reconciliation process begins. During the reconciliation, by a vote of the sponsoring working group, negative votes are found as either not related, not persuasive, or persuasive. Not related and not persuasive negatives are recorded as “negative without comment” or “unresolved negative”. In persuasive negatives the recommended changes are incorporated into the standard and the negative vote withdrawn, or the negative is declared a “resolved negative”. A set quorum of voters and percent positive votes are required for a ballot to pass.

The requirements for a normative standard, the final step to becoming an HL7 standard, are more demanding than that required of a DSTU. A standard must start as a successful DSTU and go through an extensive period of trial implementation before proceeding to balloting as a normative standard. Figure 2 is the flow diagram from HL7 illustrating the process. (Note, I have resized the diagram to make it more readable.)

Figure 2. HL7 Standards Approval Process.



Source: Quinn, John. Introduction to Health Level Seven (HL7) Organization & Processes [8]

Procedure Note Development

Procedure Note Project Choice

The Health Story Project is an organization of vendors, providers, individuals, and associations [9]. It was formed to catalyze more rapid development of data standards for the exchange of clinical documents between electronic record systems. This is to be

achieved by the creation of essential HL7 CDA standards. Past projects have included Consultation, H&P, Diagnostic Imaging Report, Discharge Summary, and Operative Note Implementation Guides.

The Procedure Note IG is designed to describe documentation of non-operative procedures. The Operative Note IG covers documentation of surgeries, but there are a large number of diverse procedures that do not fit the surgery paradigm. A single note was needed to complete the coverage of procedures not covered by the Operative Note IG.

It was significantly difficult deciding whether the Procedure Note IG should be a parent or sibling of the Operative Note IG. Although a hierarchy for all IGs has been proposed, this has never been created. A long discussion about what constitutes a "procedure" carried on for several weeks with several possible definitions being offered. In the end, it was decided that the Procedure Note as defined in this IG would be a sibling, rather than a parent of the Operative Note. It would cover all procedures other than surgery. It was decided not to call it a "medical" procedure note since several of the procedures that might be documented using this IG are not performed by physicians, such as dental procedures.

Participants and Their Roles in the Process

The participants in the process were members of the Health Story Project Consortium, Oregon Health & Science University (OHSU), American Dental Association (ADA),

Industry, M*Modal, and the American Society of Gastrointestinal Endoscopy (ASGE). They can be divided functionally into the supervisory group, the work group, the consultant group, and the technical group. They are defined more fully in the IG in the appendix.

The supervisory group was the chairs and co-chairs of the DTSU implementation guide. They were senior structured documents experts and leaders in HL7, as well as the Structured Documents Working Group (SDWG) of HL7. They were responsible for the overall direction of the project and served as significant resource people for the work group.

The main work group was the implementation guide's primary editors from OHSU, and co-editors from Alschuler Associates, LLC. This group was responsible for assembling the DTSU implementation guide and XML example documents. This was done with the frequent assistance of the supervisory group.

The consultant group consisted of individuals/committees representing groups of stakeholders in the outcome of the final document. Industry representatives from Siemens, MTWerks, and GE were involved. Provider organizations such as Mayo Clinic and the Veterans Administration were also involved. Professional society input was obtained from representatives of the ADA and ASGE.

The technical group was responsible for several indispensable services. M*Modal, a member of the Health Story Project, provided invaluable analysis of procedure note headers from a large database of transcription records. This allowed the choice of the section headers in the body of the Procedure Note based on statistical analysis of the frequency of use of headers in actual dictated notes. Alschuler Associates LLC, also a Health Story Project member, provided technical review of the final document.

Finally, as this was an international realm document, input was obtained from representatives from the UK and Germany in the SDWG.

Steps in the Development of the Implementation Guide (IG)

In the section above, the process of DSTU IG development and approval were described. The timeline below and in following sections describe an actual instance of this process. The information below was gleaned from review of e-mails plus minutes of the SDWG and the procedure note work group. This is presented as a timeline with the first phase covering the effort from the initiation through approval by the HL7 Technical steering committee (TSC) at the HL7 Working Group and Plenary in Atlanta. The second phase covers the phase from TSC approval to the initial ballot submission. The participants and groups have been outlined above.

Initiation Process Through Approval by the Technical Steering Committee (7/15/2009-9/25/2009)

- Initial Work Group is formed.

- It was proposed that the project cover a CDA R2 general, non-surgical procedure note rather than just a specific CDA endoscopy note. This will complement the Operative Note currently available as a DSTU.
- It was suggested that it be sponsored by the SDWG with input from the Clinical Interoperability Council (CIC), another working group of HL7. The Clinical Interoperability Council is a working group that consists of clinicians that address the implications to the provider community of proposed HL7 standards.
- The initial plan for the individual roles in the group and time requirements were proposed. (8/31/2009) The ASGE Quality Committee agreed to be the primary source of endoscopy provider input to the project.
- (9/24/09) Final approval of role by ASGE executive board.
- CMS/JCAHO requirements are gathered and a draft Project Scope Statement (PSS) was prepared. The project scope statement is a standardized HL7 form required for all proposed projects. Appendix A contains the PSS for this project.
- (9/8/2009) The Initial Work Group met on teleconference approving the PSS and schedule.
- (9/10/2009) SDWG receives and starts discussion of the PSS. It is sent to the CIC for review and collaboration. Debate begins about the definition of a procedure.
- (9/11/2009) CIC suggests the expansion of the standard from US realm to Universal Realm and Initial Work Group agrees (9/14/2009).
- (9/20/2009) It is suggested adding the Imaging Integration Working Group and the DICOM working group as interested parties and all agree. They are to be kept

informed of progress and changes as the effort proceeds, but are not required to sign off on the project.

- (9/20-25/2009) Working Group Meeting and Plenary in Atlanta with approval by SDWG. SDWG signs off on the change from US to Universal realm. PSS is taken to the Structure and Semantic Design Steering Division who approve it. It is then taken to the Technical Steering Committee where it receives final approval to proceed.

From TSC Approval to Ballot Submission (9/25/2009-12/11/2009)

- (9/24/2009) ASGE governing board officially approves Quality Committee involvement.
- Discussion of development of a domain analysis model is initiated. After much debate and several weeks, it is abandoned as a good idea, but not essential to the current process.
- (10/2/2009) ADA representative enters the process.
- Much discussion with the CIC about the place in the hierarchy of the procedure note. It is the ultimate consensus to drop "Medical" from the title, make it a level two note, and place a procedure note as a sibling of the Operative Note. Procedure Note is designated as the appropriate for all non-operative procedures.
- (10/8 &13/2009) ASGE updated.

- (10/8/2009) SDWG discusses Procedure Note proposal briefly at their weekly meeting and are updated.
- (10/9/2009) Procedure Note kick-off phone teleconference. Procedure Note definition and place in hierarchy confirmed. Schedule of deliverables reviewed.
- (10/22/2009) M*Modal statistical analysis of section titles delivered and first draft of participant scenario delivered. The M*Modal analysis was to be reviewed to find the most common section titles. The purpose of this exercise is to design a note that provides section titles with the highest prevalence in current use.
- (10/29/2009) Notice of Intention to Ballot (NIB) completed. This is a required official notification of the HL7 organization that the ballot will be submitted and in which ballot cycle. The SDWG emphasizes that implementation guide must not require US-only vocabularies.
- (10/30/2009) Initial Implementation guide is assembled and sent to the technical editors.
- (11/4/2009) Technical editor completes rough guide with the exception of the final section titles and cardinality. Certain issues in the Header remain unresolved at this point.
- (11/6/2009) Sections and cardinality decided and header issues resolved.
- (11/6/2009) Quality metrics section was rejected as a component of the Procedure Note. The eMeasure document currently under development was felt to be more consistent with the HL7 paradigm. The most significant determinant of this decision was that a quality metrics section wouldn't be part of authenticated content of a usual procedure note.

- (11/9/2009) Group discovers that the LOINC codes from the Operative Note can't be reused.
- (11/28/2009) Final section titles and LOINC codes are agreed upon.
- (12/2/2009) XML colonoscopy example procedure note completed and sent to the main procedure note work group for review and approval.
- (12/5/2009) Final review of the DSTU with sample XML procedure note, and hand off to the technical editors done.
- (12/11/2009) Ballot package of implementation guide and XML example file sent to HL7 office. The voting period will last one month.

Issues in IG Development

US vs. Universal (international) realm

Early in the process it was decided to put the Procedure Note forward as a Universal (i.e. International) Standard. The initial suggestion came from a UK member of the CIC as he felt that this would be a relevant standard worldwide. In the endoscopy community, equipment transcends national boundaries, as it is almost universally Japanese. This author's informal review of endoscopy reports from the UK, the Netherlands, Finland, Haiti, Peru, Japan, and Canada confirm that the information and form in which it is recorded are remarkably similar.

The major problem with internationalization is not usually the form or the information that is recorded, it is the formal vocabulary that is used. SNOMED and CPT codes are the intellectual property of the College of American Pathologists and American Medical Association respectively. The US and the UK are licensed and use SNOMED extensively, but few other countries do. LOINC, while free and open source, is a mostly US-specific vocabulary. NUCC codes are used in the US, but nowhere else, to define the type of healthcare provider involved. After extensive polling of the non-US members of the SDWG and the CIC, it was determined that a universal healthcare provider code did not exist.

Additionally, other countries have their own version of codes that are equivalent to codes the US uses. A truly "universal" procedure note would need to incorporate the ability to use those codes. An example would be provider codes, like the NUCC code used by the US. Germany uses OPS and the Netherlands uses CIBG Rolcodetabel (H. Koenig, personal communication, November 23, 2009) to designate the type of provider. The solution is often the use of SHOULD or MAY instead of SHALL as the action verb in conformance statements with a code set that is as international as possible.

In addition to codes, other US standards were used in the IG. The IG was originally designed to conform to requirements from the Center for Medicare and Medicaid Services (CMS) and Joint Commission on the Accreditation of Health Organizations (JCAHO) for what is to be included in a procedure note. When M*Modal did its analysis of the prevalence of section titles, it was done using a US only database. While this

author has viewed other procedure notes from several other nations, this would not really substitute for an actual analysis.

Code and Design issues

Other than the code issues above, the question about the reusability of LOINC codes became an issue. In the end, it was noted that the LOINC codes for the Operative Note section headers could not be re-used in the Procedure Note. This was decided because even though sections might have the same title in the two types of documents, a number of the LOINC codes were designated as being specifically for operations, and were therefore not appropriate to reuse in the Procedure Note IG.

The header elements for the Procedure Note were assembled out of elements from the Diagnostic Imaging Report and Operative Note. The H&P header was not usable as it contained LOINC coding and was not felt to be "international" enough. It was decided that the procedure title was best resident in the header, as in prior CDA documents, rather than as a section title in the body. Two body sections were proposed as new concepts for incorporation into the procedure note; a media section and a quality metrics section.

The media section was proposed to allow the document to carry specific pieces of media relevant to the procedure. An example, specific to the colonoscopy note, would be to allow incorporation of JPEGs of endoscopy images into the document. This would provide clinical information, in addition to contributing to quality metrics by providing documentation of reaching the cecum. It was elected not to include this section in the

document as it would best be provided in a separate document and, due to the varying size of the item, might be difficult to manage as a part of the document.

The quality metrics section was also proposed; as this is a part of many procedures today, and will certainly figure prominently in the future of documentation. A specific example for the colonoscopy note would be time to withdrawal from the cecum. Studies have shown that the miss rate for polyps increases if the withdrawal time from the cecum is less than six minutes, and improves if withdrawal takes longer than that [10]. It is therefore useful to record this number connected with the procedure for quality monitoring purposes. The SDWG was against this because it was not normally part of the "authenticated document" and a separate document to contain quality metrics, the eMeasure document, was under development to address this issue.

Construction of the XML Procedure Note Example

The XML note was assembled in three parts; the XML information, the CDA header, and the CDA body. The note below is the entire XML information and CDA header. It contains one section from the body as an example. The note below has been parsed out into sections with a brief description/explanation immediately below. The full, unabridged version of the note is in the appendix of this paper.

The XML Information

The XML information below is divided into three parts; the required XML information, the ClinicalDocument root element, and a comment section providing a narrative of the document not encoded in XML, but enclosed in comment <!-- --> brackets.

```
<?xml version="1.0" encoding="utf-8"?>
<?xml-stylesheet type="text/xsl" href="cda.xsl"?>
```
Required XML information, i.e. version, encoding, and stylesheet.

```
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:voc="urn:hl7-org:v3/voc"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3
CDA.xsd">
```
The root element ClinicalDocument containing one or more elements for namespace declaration.

```
<!--
Title: Procedure Note
Original Filename: Procedure_Note.xml
Version: 1.0
Revision History: 12/03/2009 TC created for 2009 winter ballot
Specification: CDAR2_PROCNOTE_R1D1_2010JAN

This sample document was created by Thomas Carr and Alschuler Associates, LLC, on behalf of a project
called Health Story founded by M*Modal, the American Health Information
Management Association (AHIMA), and the Association for Healthcare Documentation Integrity (AHDI).

For more information on Health Story please see www.healthstory.com
For more information on the "HL7 Implementation Guide for CDA Release 2: Procedure Note" see
www.hl7.org, Structured Documents Working Group
-->
```
Information about this XML note. The file name, version, revision history, HL7 specification, and author(s). It is a comment rather than XML, as indicated by the <! – and --> symbols at the start and end.

The CDA Header

The header includes the basic information required for a CDA document, i.e. the unique identifier of the document, the class (type, e.g. procedure note), the timestamp, and the identity of the participants. Required or optional, all of the items are a constraint on the CDA R2 specification

```
<!--
**********************************************************
CDA Header
**********************************************************
-->
```

<realmCode code="UV" />
Universal Realm, an international standard document designed to be adaptable to local standards/nomenclature.

<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040" />
This typeID is specific for CDA R2

<templateId root="2.16.840.1.113883.10.20.18.1" />
The templateId is the ID given to this template

<id extension="999021" root="2.16.840.1.113883.10.20.18" />
This id is the unique instance identifier for this particular document

<code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" code="34899-5"
displayName="Interventional Procedure Note Gastroenterology" />
<title>Endoscopy Procedure Note</title>
The code specifies the particular type of document. The nomenclature system used here is LOINC and it is an " procedure note" with the title, "endoscopy procedure note".

<effectiveTime value="20050303171504+0500" />
The timestamp in the year/month/day/hour/minute/second format. HL7 adopted the ISO8601 to encode this

<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25" />
Confidentiality code of "N" = normal, the lowest of the three levels. This is to note the degree of security required for the document and defined in the CDA R2 specifications.

<languageCode code="en-US" />
languageCode of "en-US" = US-type of the English language is used for the document.

<versionNumber value="1" />
This is the first version of this document.

<recordTarget>
Represents the subject of the report, usually a patient.

<patientRole>
The patient's particulars are provided. Here the patient's details, his guardian's details, and providing organization's details.

<id extension="12345" root="2.16.840.1.113883.3.933" />
Patient's ID in the organization, e.g. medical record number.

<addr>
<streetAddressLine>17 Daws Rd.</streetAddressLine>
<city>Blue Bell</city>
<state>MA</state>
<postalCode>02368</postalCode>
<country>USA</country>
</addr>
<telecom value="tel:(781)555-1212" use="HP" />
Patient's address and phone number.

<patient>
The patient's address location/contact information is provided as part of the patientRole.
the patient's personal information is provided below including date of birth, gender, name, and

guardian information (if a guardian is involved).

```
<name>
    <given>Adam</given>
    <family>Everyman</family>
</name>
<administrativeGenderCode code="10052007" displayName="Male"
codeSystem="2.16.840.1.113883.6.96" />
<birthTime value="19541125" />
```
Name, gender and date of birth of the patient

```
<guardian>
```
If the patient has a guardian, this information is provided here. It is included as part of the Patients's information.

```
    <id extension="23456" root="2.16.840.1.113883.10.20.18.2" />
    <addr>
        <streetAddressLine>17 Daws Rd.</streetAddressLine>
        <city>Blue Bell</city>
        <state>MA</state>
        <postalCode>02368</postalCode>
        <country>USA</country>
    </addr>
    <telecom value="tel:(555)555-2004" use="HP" />
    <guardianPerson>
        <name>
            <given>Ralph</given>
            <family>Relative</family>
        </name>
    </guardianPerson>
</guardian>
```
End of guardian information

```
</patient>
```
End of the patient information

```
<providerOrganization>
```
The identifying information of the organization that treated the patient is provided below.

```
    <id root="2.16.840.1.113883.10.20.18.3" />
    <name>Good Health Clinic</name>
    <telecom value="tel:(555)555-1212" use="WP" />
    <addr>
        <streetAddressLine>21 North Ave</streetAddressLine>
        <city>Burlington</city>
        <state>MA</state>
        <postalCode>01803</postalCode>
        <country>USA</country>
    </addr>
</providerOrganization>
```
End of the provider organizations information.

```
</patientRole>
```
Patient role ends here with the patient and provider's information complete.

</recordTarget>
Record target ends as there are no other participants. If there are other participants then more can be entered, but this is unusual.

<author>
The author is the person and/or machine that created the document. The time and assigned author (with identifier) are required, but the organization that the author is with is not.

<time value="20050329224411+0500" />
Time that the document was authored.

<assignedAuthor>
<id extension="IO00017" root="2.16.840.1.113883.10.20.18.4" />
<addr>
<streetAddressLine>21 North Ave</streetAddressLine>
<city>Burlington</city>
<state>MA</state>
<postalCode>01803</postalCode>
<country>USA</country>
</addr>
<telecom value="tel:(555)555-1002" use="WP" />
The authors ID, address, and telephone number

<assignedPerson>
<name>
<given>Henry</given>
<family>Seven</family>
</name>
</assignedPerson>
Name of the assigned person (optional)

</assignedAuthor>
The name of the assigned author can be provided. This is not required, only the unique identifier for the author
</author>
Author information is complete.

<custodian>
The custodian is the organization that is in charge of maintaining the document. As in the author, an ID is required, but the organization's name is optional. There can only be one custodian.

<assignedCustodian>
If a custodian element is present the child element of assigned custodian has to follow with all the information below, but the name provided is optional.

<representedCustodianOrganization>
Custodians are defined as organizations. Therefore, the child of the assigned custodian is the RepresentedCustodianOrganization, an organization.
<id root="2.16.840.1.113883.10.20.18.5" />
<name>Good Health Clinic</name>
<telecom value="tel:(555)555-1212" use="WP" />
<addr>
<streetAddressLine>21 North Ave</streetAddressLine>
<city>Burlington</city>

```
            <state>MA</state>
            <postalCode>01803</postalCode>
            <country>USA</country>
        </addr>
```
ID, name (optional), address, and telephone number of the custodial organization.

```
    </representedCustodianOrganization>
```
End of the represented custodian organization.

```
</assignedCustodian>
```
End of the assigned custodian.

```
</custodian>
```
End of the record custodian information.

```
<legalAuthenticator>
```
The legal authenticator is the person legally responsible for authenticating the document. This can be a different person than the author.

```
<time value="20050330224411+0500" />
```
Time that the document was authenticated.

```
<signatureCode code="S" />
```
Signature code "S" means that it has been signed.

```
<assignedEntity>
```
The person assigned to authenticate the document.

```
        <id extension="KP00017" root="2.16.840.1.113883.10.20.18.6" />
        <addr>
                <streetAddressLine>21 North Ave</streetAddressLine>
                <city>Burlington</city>
                <state>MA</state>
                <postalCode>01803</postalCode>
                <country>USA</country>
        </addr>
        <telecom value="tel:(555)555-1002" use="WP" />
```
Identifier, Address, and phone number of the person assigned to legally authenticate the document

```
        <assignedPerson>
                <name>
                    <given>Henry</given>
                    <family>Seven</family>
                </name>
        </assignedPerson>
```
Optional provision of the authenticating individual's name.

```
</assignedEntity>
```
End to the person assigned as the legal authenticator's information

```
</legalAuthenticator>
```
End of legal authenticator information.

```
<documentationOf>
```
The designated parent of the serviceEvent.

```
<serviceEvent classCode="PROC">
```
The serviceEvent being documented is a procedure

```
<code codeSystem="2.16.840.1.113883.6.12" codeSystemName="CPT-4" code="45385"
displayName="Colonoscopy with snare polypectomy" />
```
The name of the procedure provided as a narrative block and a coded entry in CPT-4 vocabulary.

```
<effectiveTime>
    <low value="200906251400" />
    <width value="15" unit="m" />
</effectiveTime>
```
The length of time of the procedure.

```
<performer typeCode="PRF">
```
The performer type is "performer".

```
<assignedEntity>
```
Information about the person performing the procedure.

```
<id extension="1" root="2.16.840.1.113883.10.20.18.7" />
```
ID of the person performing the procedure.

```
<code code="207RG0100X" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="NUCC " displayName="Gastroenterologist" />
```
The person performing the procedure is a gastroenterologist. The performer is encoded using NUCC, a machine-processable coding vocabulary for IDing providers.

```
<addr>
    <streetAddressLine>21 North Ave</streetAddressLine>
    <city>Burlington</city>
    <state>MA</state>
    <postalCode>01803</postalCode>
    <country>USA</country>
</addr>
<telecom value="tel:(999)555-1212" />
```
Address and phone number of the procedure performer.

```
<assignedPerson>
    <name>
        <prefix>Dr.</prefix>
        <given>Henry</given>
        <family>Seven</family>
    </name>
</assignedPerson>
```
The name of the procedure performer.

```
</assignedEntity>
</performer>
</serviceEvent>
</documentationOf>
```
End of the procedure name and performer information

```
<authorization typeCode="AUTH">
```
The procedure is noted to have been authorized by this consent.

```
<consent classCode="CONS" moodCode="EVN">
```
It is a consent and has a "mood" code of event.

```
<id extension="99370125" root="2.16.840.1.113883.10.20.18.8" />
<code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" code="CONSP-X"
displayName="Consent for Surgical Procedure" />
```
The surgical consent is expressed as a narrative block and a code from LOINC designating a Surgery consent.

```
<statusCode code="completed" />
```
The consent is noted to be completed.

```
</consent>
</authorization>
```
End of authorization process.

The CDA Body

The construction of the actual CDA body was made complex by the choice of included sections. The two considerations were the requirements of the certifying/paying organizations (CMS and JCAHO) and the frequency that sections appeared in actual notes. Section frequency was determined by a statistical analysis of thousands of diverse types of procedure notes to determine the most common. Figure 3 shows the requirements of the CMS and JCAHO.

Figure 3. CMS/JCAHO Procedure Note Requirements

Required

- Preoperative diagnosis
- Postoperative diagnosis
- Surgery description
- Findings
- Anesthesia
- Estimated blood loss
- Specimens

CDA op note required

Additional CMS/JCAHO required

- Surgical procedure
- Indications (not specifically asked for, but a focused H&P is a required part of our note. This is similar to example of indications in CDA Op note)
- Complications
- Implanted devices (broader category than drains; includes stents, feeding tubes, etc.)

Optional

- Planned procedure
- Disposition
- Plan
- Fluids
- Quality metrics & Media

Source: CMS & JCAHO standards [13,14] .

Figure 4 is the result of the statistical analysis by M*Modal.

Figure 4. Statistical Analysis of Section Titles.

1	Number of times this section occurred	Frequency (total documents 14,272)	Section Titles
2	9951	69.72%	IMPRESSION
3	9398	65.85%	FINDINGS
4	8862	62.09%	CLINICAL HISTORY
5	3756	26.32%	COMPARISON
6	2864	20.07%	TECHNIQUE
7	2696	18.89%	CONCLUSION
8	1623	11.37%	PROCEDURE
9	840	5.89%	PREOPERATIVE DIAGNOSIS
10	835	5.85%	INDICATIONS
11	750	5.26%	POSTOPERATIVE DIAGNOSIS
12	718	5.03%	ANESTHESIA
13	674	4.72%	REFERRING PHYSICIAN
14	563	3.94%	COMPLICATIONS
15	535	3.75%	DESCRIPTION OF PROCEDURE
16	499	3.50%	INTERPRETATION
17	462	3.24%	SURGEON
18	354	2.48%	CONCLUSIONS
19	337	2.36%	INDICATION
20	329	2.31%	POSTOPERATIVE DIAGNOSES
21	328	2.30%	RECOMMENDATIONS
22	318	2.23%	DIAGNOSIS
23	313	2.19%	PROCEDURE PERFORMED
24	304	2.13%	ESTIMATED BLOOD LOSS
25	293	2.05%	DATE OF STUDY
26	275	1.93%	RESULTS
27	272	1.91%	DATE
28	257	1.80%	PROCEDURES PERFORMED
29	240	1.68%	PLAN
30	237	1.66%	DESCRIPTION
31	226	1.58%	MEDICATIONS
32	213	1.49%	ASSISTANT
33	197	1.38%	RECOMMENDATION
34	186	1.30%	PHYSICAL EXAMINATION
35	174	1.22%	PREOPERATIVE DIAGNOSES
36	173	1.21%	CLINICAL PROBLEM
37	172	1.21%	HISTORY
38	170	1.19%	DRAINS
39	168	1.18%	TYPE OF STUDY
40	167	1.17%	PROCEDURE IN DETAIL
41	167	1.17%	ASSESSMENT
42	158	1.11%	ALLERGIES
43	149	1.04%	PAST MEDICAL HISTORY
44	146	1.02%	DIAGNOSES
45	144	1.01%	DATE OF PROCEDURE
46	135	0.95%	BLOOD LOSS
47	132	0.92%	SOCIAL HISTORY
48	129	0.90%	SUMMARY
49	128	0.90%	TECHNICAL SUMMARY
50	119	0.83%	HISTORY OF PRESENT ILLNESS

*Source: Willoughby, K. Statistical Analysis of Procedure Note Section Titles. M*Modal 2009.*

Using the above information, the following sections were agreed upon:

- Indications
- Procedure Description
- Post-procedure Description
- Complications
- Assessment & Plan
- Medical History
- Physical Examination
- Planned Procedure
- Anesthesia
- Medications Administered
- Medications History
- Estimated Blood Loss
- Specimens Removed
- Implants
- Findings
- Disposition

Using this information the XML body was assembled out of the sections. They were all similar in layout so included here, as an example, is the indication section

```
<!--
    ************************************************************
    CDA Body
    ************************************************************
    -->
Comment section indicating this is the start of the CDA body.
<component>
    <structuredBody>
    This indicates start of the structured CDA body. Its' parent is "component".
<!-- ********************************************
    Required Sections
    ********************************************-->
<!-- ************************************
    Indications
    ************************************ -->
      <component>
        <section>
        This indicates the start of a section. Its' parent is also "component".
          <templateId root="2.16.840.1.113883.10.20.18.2.1" />
          The ID number of the template of this section.
          <code code=" IND-X" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
          displayName="INDICATIONS" />
          <title>Indications</title>
          <text> The procedure is performed for screening in a low risk individual</text>
```

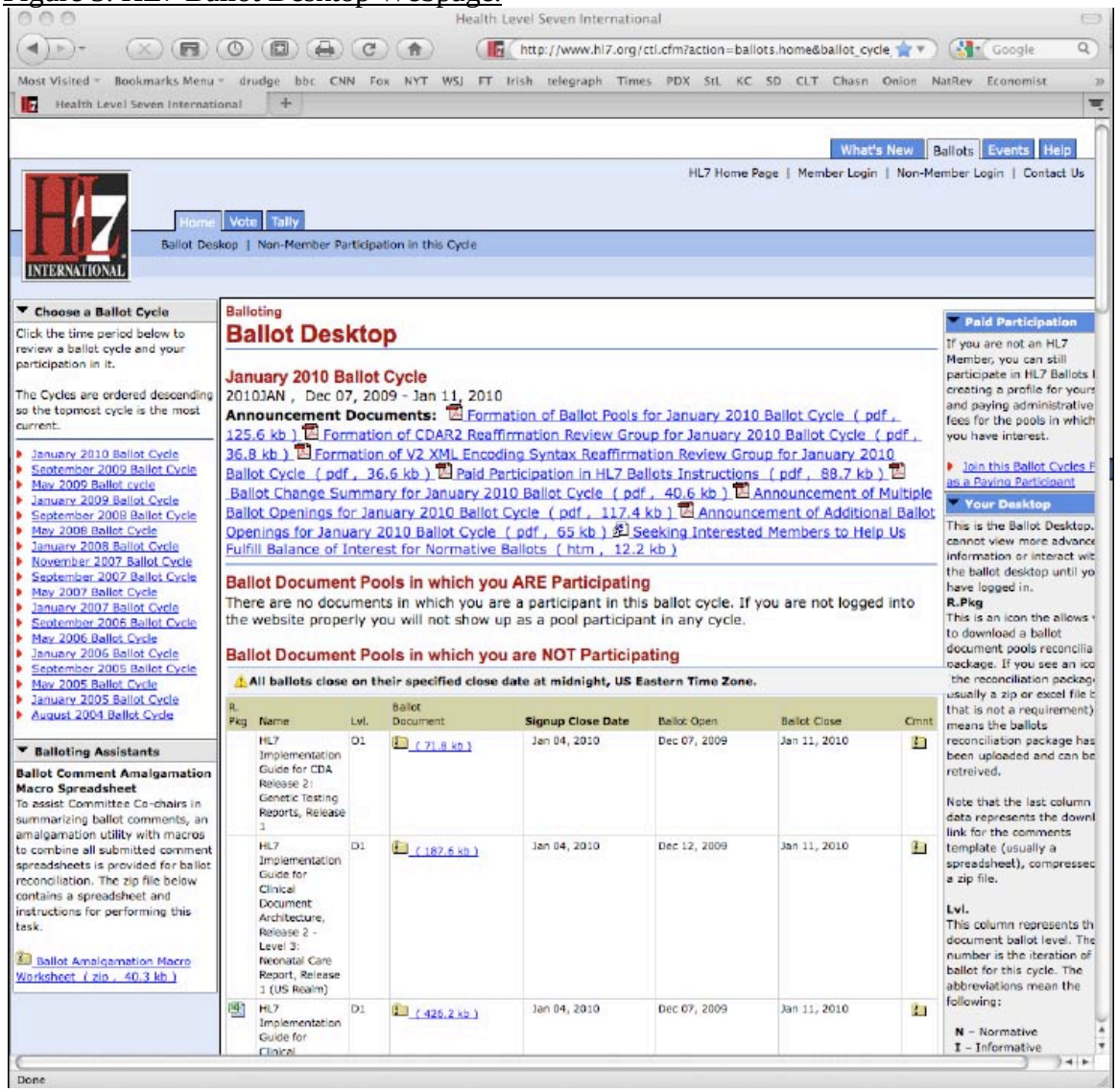
The section name in the LOINC code system, with narrative block, followed by the section title
</section>
</component>
End of the section whose parent is component.

Balloting Process

Initial Ballot Submission

On December 11, 2009 the ballot package was sent to HL7 International Headquarters in Ann Arbor, Michigan. The Ballot package included the Procedure Note Implementation Guide and the Procedure Note XML example, as included in the appendix. The XML example note chosen was a colonoscopy with polypectomy. The balloting period was for one month ending on January 11, 2010. Balloting was done electronically on the HL7 Ballot Desktop webpage. A running tabulation was kept on the HL7 Ballot Desktop webpage (Figure 5.). It is tabulated on the January 2010 cycle page.

Figure 5. HL7 Ballot Desktop Webpage.



Source http://www.hl7.org/ctl.cfm?action=ballots.home&ballot_cycle_id=519&ballot_voter_id=0

Results of Initial Balloting

Figure 6 provides a table of final results from the January 2010 Ballot cycle for the Procedure Note IG. There were a total of 106 eligible voters of who 34 voted for, 36 against, 21 abstained, and 15 did not vote. This allowed the ballot to attain a quorum. However, a 60% affirmative vote was not obtained as is required for the ballot to pass.

The next step, then, was the reconciliation process to address all the comments from balloting.

Ballot Reconciliation

After balloting, the package enters the reconciliation process [8,12]. All comments must be addressed by the working group and negative votes are resolved by one of the following measures:

- Accept the voter's comment and recommendations (or accept with modification)
- Get the voter to withdraw their negative vote
- Declare the vote non-persuasive

Voters can appeal to the TSC and Board if they disagree with the working group decision. They can also re-vote no on next ballot. If substantive changes are made to a ballot, another round of balloting may occur.

All comments on the Procedure Note IG were discussed over a period of 4 months, and enough negative votes were withdrawn to allow the IG to pass without re-balloting.

This was a DTSU ballot. The Procedure Note IG DTSU will be evaluated for a period of about 2 years before being considered for balloting as a normative standard. Normative standards require a higher level of affirmative response to pass [12]. If successful in a normative standard ballot, it becomes an official part of the HL7 version three standard [8].

Figure 6. Initial January 2010 Results of Ballot on Procedure Note

AFFIRMATIVE	34
NEGATIVE	36
ABSTAIN	21
NO VOTE RECORDED	15
TOTAL PARTICIPANTS	106
QUORUM ACHIEVED (NO QUORUM REQUIRED FOR DSTU)	85.85%
AFFIRMATIVES REQUIRED FOR APPROVAL	42

Source: http://www.hl7.org/ctl.cfm?action=ballots.tally&ballot_cycle_id=519&ballot_voter_id=0

Epilogue

Clinical Document Architecture represents a significant advance in communications between electronic records systems. Documents are central to medical records so a document standard such as CDA must exist to have a viable exchange between electronic record systems. A part of HL7 V3, a CDA document can still be transported by V2 messages and produce stand-alone documents. Therefore, it can produce a document that can be used within a record system and one that can be transported by the two HL7 messaging systems. It is close to the ideal electronic document standard.

The adoption process outlined from HL7 documents and illustrated by an actual example (up through the DSTU balloting process), is complex. It highly values consensus to produce a standard that will be used and adherence to process to ensure that it will produce a usable standard. Consensus is necessary for a standard to be used. No one is mandating a particular standard currently, so people must be persuaded to use it. The

multiple steps in the adoption process represent a necessary vetting to avoid premature adoption of a poor design and ensure a usable standard.

As outlined above, CDA is essential to an electronic healthcare network. It is versatile enough to work within EMRs and be transported by all current HL7 messages. It is produced by the HL7 development process; designed to produce usable and used standards. The only significant deficiency is that there are gaps in the library of available types of CDA documents. A great deal of work has yet to be done to produce a complete library of document types. More efforts, like this development of a Procedure Note standard, are going to have to be done in order to produce all the documents necessary for a truly comprehensive health IT infrastructure.

References

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Appendix I.

Project Scope Statement

Project Scope Statement

Template Usage Information:

- Replace **RED** text with appropriate content; do not change the name/format/font of the template sections
- To check a box, double click on the box then select the 'Checked' Radio Button under the 'Default Value' heading.
- For assistance in completing each section, refer to Appendix A.
- The Project Approval Process is documented in Appendix B.
- For FAQs (Frequently Asked Questions), refer to Appendix C
- Submit template change requests to PMO@HL7.org

1. Project Name, ID and Products

The name should be concise, based on the objective and unique among all other projects the group takes on. ***Project Insight:*** *Enter into "Project Name" and "Product Type".*
Click here to go to Appendix A for more information regarding this section.

An ID will be assigned by Project Insight

Implementation Guide for CDA Release 2: Procedure Note	Project ID:

☐ -Non Product Project- (Educ. Marketing, Elec. Services, etc.)	☐ V3 Documents - Knowledge
☐ Arden Syntax	☐ V3 Foundation – RIM
☐ Clinical Context Object Workgroup (CCOW)	☐ V3 Foundation – Vocab Domains & Value Sets
☐ Domain Analysis Model (DAM)	☐ V3 Messages - Administrative
☐ Electronic Health Record (EHR)	☐ V3 Messages - Clinical
☐ V2 Messages – Administrative	☐ V3 Messages - Departmental
☐ V2 Messages - Clinical	☐ V3 Messages - Infrastructure
☐ V2 Messages - Departmental	☐ V3 Rules - GELLO
☐ V2 Messages – Infrastructure	☐ V3 Services – Java Services (ITS Work Group)
☐ V3 Documents – Administrative (e.g. SPL)	☐ V3 Services – Web Services
☒ V3 Documents – Clinical (e.g. CDA)	☐ - New Product Definition-

1.a. Implementation Guide

Indicate if you're creating/modifying an implementation guide (in addition to a standard or just on it's own). ***Project Insight:*** This information will appear in the "Implementation Guide?" radio button.

☒ Implementation Guide? Check this box if you're creating an implementation guide

2. Project Intent

Project Insight: *Enter into "Project Intent"; add notes if needed, especially for "Project Intent – Other' (below).*

☐ Create new standard	
☐ Revise current standard	☐ Supplement to a current standard ☐ Withdraw current standard

2.a. Project Intent - Other

If not categorized above, indicate other and specify***. Project Insight:*** This information will appear in the "Project Intent Notes".

☒ Other (Please Specify): DSTU

☐ Public Document(s) to be created? Check this box if one of the project deliverables will be a publically available document (for example a governmen mandated or funded specification, or otherwise subsidized publication), To track this information in Project Insight, add a comment in Project Insight's Project Intent Notes text box indicating a public document will be created.
NOTE: When a deliverable is specified as a Public Document, the TSC must make a determination as prescribed in the GOM Section 09.01, part (d).

3. Sponsoring Group(s)

Click here to go to Appendix A for more information regarding this section.

Primary Sponsor/Work Group (**1 Mandatory**)	Structured Documents Work Group
Co-sponsor Work Group(s)	Patient Care (invited); Clinical Interoperabily Council (invited)
Project Team	**Name and E-mail Address**
Project facilitator (**1 Mandatory**)	Liora Alschuler, liora@alschulerassociates.com Tom Carr, carrt@ohsu.edu
Other interested parties	Judy Logan (OHSU), loganju@ohsu.edu

	Bob Dolin, SYLLC, bobdolin@gmail.com Bret Petersen, ASGE Quality Committee, petersen.bret@mayo.edu
Multi-disciplinary project team (recommended)	
Modeling facilitator	Bob Dolin, SYLLC, bobdolin@gmail.com
Publishing facilitator	Peter Gilbert, peter.gilbert@altarum.org
Vocabulary facilitator	Gay Giannone MSN, RN, gay@alschulerassociates.com
Domain expert rep	Tom Carr, carrt@ohsu.edu Bret Petersen, ASGE Quality Committee, petersen.bret@mayo.edu Judy Logan (OHSU), loganju@ohsu.edu
Data Analyst facilitator	Kristen Willoughby (M*Modal), Kristen.Willoughby@mmodal.com
Business requirement analyst	Brett Marquard, brett@alschulerassociates.com
Requirements process facilitator	Tom Carr, carrt@ohsu.edu Brett Marquard, brett@alschulerassociates.com

Implementers **(2 Mandatory** for DSTU projects):
1) OHSU, Clinical Outcomes Research Initiative
2) M*Modal

4. Project Scope

Click here to go to Appendix A for more information regarding this section. ***Project Insight:*** *Enter into "Description".*

This project is to design a basic procedure note in XML as a constraint on HL7 v3 CDA r2. The note will be basic enough to be used for all procedures and will develop a sample note for endoscopy. To promote standardization and acceptance, it will be closely modeled on the current HL7 CDA Operative Note. CMS and JCAHO requirements, with specialty group input, will be used to choose the contents. CMS and JCAHO, the primary regulators, requirements will dictate the minimum content standards. Implementer institutions will be given opportunity for input as to compatibility with current/planned systems.

5. Project Objectives and Deliverables

Click here to go to Appendix A for more information regarding this section. ***Project Insight:*** *Enter into "Project Objectives and Deliverables".*

• Sample endoscopy note in XML as a constraint on HL7 v3 CDA r2. • Implementation guide for procedure note for HL7 v3 CDA r2.	

6. Project Dependencies

Click here to go to Appendix A for more information regarding this section. ***Project Insight:*** *Enter into "Dependencies & IDs".*

None.	ID

7. Project Approval Dates

Sponsoring Group approval Date ***Project Insight:*** *Enter into "Start Date".*	Sept 09 WG meeting in Atlanta.
Steering Division Approval Date	
Technical Steering Committee Approval Date	
PMO Approval Date	

8. Project Plan

Click here to go to Appendix A for more information regarding this section

8.a. Project Schedule

- Review developing design with HL7 Structured Documents Work Group (SDWG) and ASGE, September 2009 – December 2009
- Review complete draft Implementation Guide with SDWG and Patient Care WG, December 2009
- Draft Standard for Trial Use (DSTU) ballot submittal, December 2009
- Ballot reconciliation, January – February 2010

8.b. Project Resources

Health Story Project, Tom Carr (OHSU), Judy Logan (OHSU), and ASGE participants are volunteers, in coordination with Structured Documents, Patient Care and CIC

8.c. Project Budget

Additional funding not required

8.d. Ballot Plan - general

☐ Comment Only ☐ Informative ☒ DSTU	☐ Normative ☐ Joint Ballot (with other SDOs or HL7 Work Groups)
• Create a Procedure Note DSTU • Eventually merge with the collection of "common document type" DSTUs into a single, normative standard	

8.e. Ballot Plan for cross-cutting Projects

Not Applicable.

8.f. Industry Outreach

ASGE to provide list of possible implementer institutions that will review for suitability. We will work with CIC on this as well and will reach out to the Clinical Information Interchange Collaborative (CIIC).

8.g. Success Criteria

Production of the deliverables with successful completion of the balloting process.

9. External Project Collaboration and Interested Parties

Click here to go to Appendix A for more information regarding this section. ***Project Insight:*** *Enter into "Collaboration Efforts".*

Collaborating with	Agreement Status	Comments
Health Story Project	Associate Charter Agreement	
American Society of Gastrointestinal Endoscopy (ASGE)	none	1. Solicit participation in the HL7 Clinical Interoperability Council

10. Realm

Click here to go to Appendix A for more information regarding this section. ***Project Insight:*** *Enter into "Realm"*

☐ Universal	☒ Realm Specific (if checked, select from list below)
	☒ US
	☐ Other [Enter name of HL7 affiliate]

11. Roadmap Reference

Click here to go to Appendix A for more information regarding this section. For more detail regarding the Roadmap Strategies, go to: http://www.hl7.org/documentcomments/index.cfm. ***Project Insight:*** *Enter into "Roadmap Reference".*

Check which Roadmap Strategy best relates to your project.

- ☐ 1. Expand, reinvigorate, and streamline HL7's production, processes, technologies and products
- ☐ 2. Evaluate HL7's competitive environment and define HL7's roles, positions and actions
- ☐ 3. Enhance communication and outreach: make HL7 more useable, useful and understandable and share the ideas worldwide
- ☐ 4. Embrace EHR/Electronic Health Record System (ERH-S)/Personal Health Record (PHR) and Public Health Management capabilities as the foca point of technical development of health informatics standards
- ☒ 5. Connect to the clinicians, an essential HL7 community.

Appendix II.

Implementation Guide

Implementation Guide for CDA Release 2.0 Procedure Note

(Universal Realm)

Release 1

Levels 1, 2 and 3

May 2010

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Introduction

Purpose

This document describes constraints on the Clinical Document Architecture (CDA) Header and Body elements for Procedure Note documents. Procedure Note is a broad term that encompasses many specific types of non-operative procedures including interventional cardiology, interventional radiology, gastrointestinal endoscopy, osteopathic manipulation, and many other specialty fields. Procedures Notes are differentiated from Operative Notes in that the procedures documented do not involve incision or excision as the primary act.

The Procedure Note or Report is created immediately following a non-operative procedure and records the indications for the procedure and, when applicable, post-procedure diagnosis, pertinent events of the procedure, and the patient tolerance of the procedure. The report should be sufficiently detailed to justify the procedure, document the course of the procedure, and provide continuity of care.

Audience

The audience for this document includes software developers, consultants, and clinicians responsible for implementation of Electronic Health Record (EHR) systems, Personal Health Record (PHR) systems, dictation/transcription systems, and document management applications, and local, regional, and national health information exchange networks who wish to create and/or process CDA documents developed according to this specification.

Clinical and other non-technical reviewers will also be interested in some sections of this guide, in particular the text descriptions for Required Sections and Optional Sections.

Approach

To develop this specification, we reviewed existing draft and final specifications or implementation guides for similar artifacts in the U.S., specifically:

- Clinical LOINC® document and section codes
- HL7 ASIG CDA R2 Attachment for Clinical Notes
- HL7 "Clinical Document Architecture, Release 2" Normative Web Edition, 2005
- *HL7 Implementation Guide for CDA Release 2: History and Physical (H&P) Notes*
- *HL7 Implementation Guide for CDA Release 2: Operative Note*
- *HL7 Implementation Guide for CDA Release 2: Imaging Integration; Basic Imaging Reports in CDA and DICOM, Release 1*. Available to non-HL7 members at https://www.hl7.or/store/index.cfm.
- CDA Release 2 – *CCD: Continuity of Care Document* (CCD)
- Joint Commission Operative Note Requirements

- Centers for Medicare & Medicaid Services (CMS) Operative Note Requirements: *State Operations Manual, Appendix A: Survey Protocol, Regulations and Interpretive Guidelines for Hospitals*: A-0396 §482.51(b)(6).
- Non-CDA sample documents supplied by participating providers and vendors

In addition, M*Modal provided statistical analysis of approximately 14,000 sample procedure reports. The American Society for Gastrointestinal Endoscopy (ASGE), American Health Information Management Association (AHIMA), the Association for Healthcare Documentation Integrity (AHDI), and participating providers contributed extensive subject matter expertise. The design was matched against operational templates from transcription vendors and reviewed with the HL7 Structured Documents Working Group. While current divergent industry practices cannot be perfectly reflected in any consensus model, this design is designed to increase the degree of consistency with minimal disruption to current practice and workflow.

Organization of This Guide

The requirements in the body of this Draft Standard for Trial Use (DSTU) are on track to become normative after a trial period of use and will be subject to change under the policies for DSTU per the *HL7 Governance and Operations Manual*[1]. The document is organized into the following major sections:

- Header Constraints
- Required Sections
- Optional Sections

Each major section or subsection of the document provides:

- A narrative overview and scope for that section
- CDA R2 constraints

Use of Templates

When valued in an instance, the template identifier (`templateId`) signals the imposition of a set of template-defined constraints. The value of this attribute provides a unique identifier for the templates in question.

Originator Responsibilities: General Case

An originator can apply a `templateId` if there is a desire to assert conformance with a particular template.

In the most general forms of CDA exchange, an originator need not apply a `templateId` for every template that an object in an instance document conforms to. The implementation guide (IG) shall assert whenever `templateIds` are required for conformance.

[1] HL7 Governance and Operations Manual: http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf

Recipient Responsibilities: General Case

A recipient may reject an instance that does not contain a particular `templateId` (e.g., a recipient looking to receive only Procedure Note documents can reject an instance without the appropriate `templateId`).

A recipient may process objects in an instance document that do not contain a `templateId` (e.g., a recipient can process entries that contain `Observation` acts within a Problems section, even if the entries do not have `templateIds`).

Conventions Used in This Guide

Conformance Requirements

The conformance statements within this implementation guide are labeled as CONF-PN-nn, where PN represents Procedure Note. They are numbered sequentially (nn) and appear in the format:

> **CONF-PN-nn:** This is an example conformance requirement original to this Procedure Note DSTU.

Vocabulary Conformance

Formalisms for value set constraints are based on the latest recommendations from the HL7 Vocabulary Working Group. Value set constraints can be "**STATIC**," meaning that they are bound to a specified version of a value set, or "**DYNAMIC**," meaning that they are bound to the most current version of a value set. A simplified constraint is used when binding is to a single code.

Syntax for vocabulary binding to **DYNAMIC** or **STATIC** value sets is as follows:

The value for (`pathName of coded element`) (**SHALL | SHOULD | MAY**) be selected from Value Set `valueSetOID localValueSetName` **DYNAMIC | STATIC** (`valueSetEffectiveDate`).

> **CONF-ex1:** The value for `ClinicalDocument/code` **SHALL** be selected from Value Set `2.16.840.1.113883.1.11.10870 DocumentType` **DYNAMIC**.

> **CONF-ex2:** The value for `ClinicalDocument/code` **SHALL** be selected from Value Set `2.16.840.1.113883.1.11.10870 DocumentType` **STATIC** 20061017.

Syntax for vocabulary binding to a single code is as follows:

The value for (`pathName of coded element`) (**SHALL** | **SHOULD** | **MAY**) be (`code` [`displayName`] `codeSystemOID` [`codeSystemName`] **STATIC**.

> **CONF-ex3:** The value for `ClinicalDocument/code` **SHALL** be `34133-9 Summarization of episode note 2.16.840.1.113883.6.1 LOINC` **STATIC**.

XPath Notation

Instead of the traditional dotted notation used by HL7 to represent Reference Information Model (RIM) classes, this document uses XPath notation in conformance statements and elsewhere to identify the Extended Markup Language (XML) elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the

document. This notation provides a mechanism that will be familiar to developers for identifying parts of an XML document.

Keywords

The keywords **SHALL**, **SHALL NOT**, **SHOULD**, **SHOULD NOT**, **MAY**, and **NEED NOT** in this document are to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide.

- **SHALL**: an absolute requirement
- **SHALL NOT**: an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT**: valid reasons to include or ignore a particular item, but must be understood and carefully weighed
- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications

XML Examples

XML examples appear in various figures in this document in `this monospace font`. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (…) as shown in the example below.

Figure 1: ClinicalDocument example

```
<ClinicalDocument xmins="urn:h17-org:v3">
  ...
</ClinicalDocument>
```

Within the narrative, XML element and attribute names also appear in `this monospace font`.

Sample XML

A sample document is provided that conforms to the Level 1 and Level 2 constraints of this DSTU (see the Levels of Constraint section). The document is an actual sample of a patient's Procedure Note with identifying information changed for privacy. A project participant provided the sample to test the DSTU design. Because it is drawn from actual practice rather than composed to illustrate the DSTU, the sample document covers all requirements and some, but not all, of the options described here.

Scope

This specification defines constraints on CDA Header and Body elements used in a Procedure Note document in the universal realm.

This implementation guide is a conformance profile, as described in the Refinement and Localization section of the HL7 Version 3 standards. The base standard for this implementation guide is the "HL7 Clinical Document Architecture, Release 2.0". As defined in that document, this implementation guide is both an annotation profile and a localization profile. CDA R2 is not fully described in this guide, so implementers must be familiar with the requirements of the base specification.

As an annotation profile, portions of this implementation guide summarize or explain the base standard; therefore, not all requirements stated here are original to the DSTU. Some originate in the base specification. Those requirements that do not add further constraints to the base standard and that can be validated through CDA.xsd do not have corresponding conformance statements.

Where no constraints are stated in this guide, Procedure Note instances are subject to and are to be created in accordance with the base CDA R2 specification. Where, for instance, the CDA R2 specification declares an attribute to be optional and the Procedure Note specification contains no additional constraints, that attribute remains optional for use in a Procedure Note instance.

This DSTU implementation guide is one of a series of DSTUs being developed through the efforts of Health Story (formerly CDA4CDT), where the CDA architecture is defined down to CDA Level 2 granularity with reuse of previously created Level 3 entry-level templates where appropriate. Level 3 entry-level templates referenced in the guide are not required; these templates are available for use by institutions that are ready to implement a Level 3 CDA.

Levels of Constraint

Within this DSTU, the required and optional clinical content within the body is identified.

This DSTU specifies three levels of conformance requirements:

- Level 1 requirements specify constraints upon the CDA Header and the content of the document.
- Level 2 requirements specify constraints at the section level of the `structuredBody` of the `ClinicalDocument` element of the CDA document.
- Level 3 requirements specify constraints at the entry level within a section. The only Level 3 entries defined in this implementation guide are those that have been previously created in Continuity of Care (CCD) or other HL7 CDA implementation guides if deemed appropriate for a procedure report.

Note that these levels are rough indications of what a recipient can expect in terms of machine-processable coding and content reuse. They do not reflect the level or type of clinical content, and many additional distinctions in reusability could be defined.

Conformance to the DSTU carries with it an implicit adherence to Level 1. Level 1 asserts header element constraints. Therefore, conformance to the DSTU with no level specified or with Level 1 specified asserts header element constraints and allows for the use of a non-XML body or an XML body that may or may not conform to additional templates defined herein. Likewise, conformance to the DSTU at Level 2 does not require conformance to entry-level templates, but does assert conformance to header- and section-level templates. In all cases, required clinical content must be present. For example, a CDA Procedure Note carrying the `templateId` that asserts conformance with Level 1 may use a PDF or HTML format for the body of the document that contains the required clinical content.

Future Work

Future work includes the definition of increasingly refined (granular) machine-verifiable processing structures. This work will be performed in conjunction with other HL7 working groups and in cooperation with professional societies and other standards development organizations (SDOs). There are many parallel efforts to create CDA implementation guides and standards based on CDA. Future work will address libraries of templates, including those defined and reused here, and refinement of the document type hierarchy.

Future related work may create specific Procedure Note examples or implementation guides with Level 3 constraints according to type of procedure, specialty, or clinical setting.

We intend to compile the series of Health Story DSTUs into a single implementation guide for normative balloting after the DSTU trial periods have completed.

This implementation guide is a universal realm document. The guide includes binding to terminologies that may not be universally available or accepted and reuse of templates from non-universal IGs; the guide does not require either except as constrained in the base CDA. Future work will include specialization of this document for U.S. and other realms.

Content of the DSTU

The following files comprise the DSTU:

Table 1: Content of the Published Package

Filename	**Description**
CDAR2_PROCNOTE_R1_D1_2010MAY.doc	Implementation Guide
Procedure_Note.xml	Procedure Note Sample File
cda.xsl	CDA stylesheet
Procedure_Note_LOINC_Request_Spreadsheet.xls	LOINC code request

CDA Header Constraints

This section describes constraints that apply to the CDA Procedure Note header. These are additional constraints on the CDA R2 base standard to meet the needs of a Procedure Note. Not every available CDA component is reiterated in this guide nor is it precluded.

This implementation guide does not include the CDA - General Header Constraints described in the *Implementation Guide for History and Physical Notes* because they are for U.S.-realm documents. This guide does not add additional constraints on the following header attributes:

- ClinicalDocument/realmCode
- ClinicalDocument/typeID
- ClinicalDocument/ID
- ClinicalDocument/confidentialityCode
- ClinicalDocument/setId
- ClinicalDocument/versionNumber

In addition, this guide does not add additional constraints on the following header participants:

- Authenticator
- Custodian
- Informant
- Information recipient
- Legal authenticator

Header Attributes

This section describes the CDA attributes in a Procedure Note header.

CDA requires that a `ClinicalDocument/typeId` be present to identify the constraints imposed by CDA Release 2.0, essentially acting as a CDA version identifier. The value of `typeId/@root` is `2.16.840.1.113883.1.3` and the value of `typeId/@extension` is `POCD_HD000040`. [CDA R2]

ClinicalDocument/templateId

This `ClinicalDocument/templateId` element identifies the template that defines constraints on the content of a CDA Procedure Note document.

CONF-PN-1: A `ClinicalDocument/templateId/`**SHALL** be present representing conformance to the constraints of the CDA Procedure Note (`templateId 2.16.840.1.113883.10.20.18.1`).

Figure 2: ClinicalDocument/templateId category I example

```
<templateId root= "2.16.840.1.113883.10.20.18.1"/>
<!-- conforms to the DSTU -->
```

Name, Address, and Telephone Numbers

Names for the receiver of the document, the patient, or any other person or organization mentioned must be included to support communication among these individuals or entities.

CONF-PN-2: All `patient`, `guardianPerson`, `assignedPerson`, `maintainingPerson`, `relatedPerson`, `intendedRecipient/informationRecipient`, `associatedPerson`, and `relatedSubject/subject` elements **SHALL** have a `name` element.

CONF-PN-3: All `patientRole, assignedAuthor, assignedEntity` [not(parent::`dataEnterer`)], and `associatedEntity` elements **SHOULD** have an `addr` and `telecom` element.

ClinicalDocument/code

CDA R2 states that LOINC is the preferred vocabulary for document type specification. The CDA Procedure Note is a universal realm document, therefore it does not mandate use of LOINC; however, LOINC is still the preferred document code vocabulary.

The LOINC Codes for Procedure Note Documents table lists the preferred code and pre-coordinated LOINC codes that have the scale DOC (document) and a 'component' referring to a non-operative procedure, whether or not the text string "Procedure" is present. Although these pre-coordinated LOINC codes are available for use, we recommend the preferred code (`28570-0 Procedure Note`) with specialization further defined in `ClinicalDocument/documentationOf/serviceEvent/code.` When these pre-coordinated codes are used, any coded values describing the author or performer of the service act or the practice setting must be consistent with the LOINC document type.

CDA requires a `code` element that specifies the type of the clinical document.

CONF-PN-4: The value for `ClinicalDocument/code` **SHOULD** be `28570-0 Procedure Note 2.16.840.1.113883.6.1 LOINC` **STATIC** and **MAY** be selected from Value Set `2.16.840.1.113883.11.20.6.1` LOINC Codes for Procedure Note Documents **DYNAMIC**

Table 2: LOINC Codes for Procedure Note Documents

Value Set: ProcedureNoteDocumentTypeCodes: 2.16.840.1.113883.11.20.6.1 Code System: LOINC 2.16.840.1.113883.6.1			
LOINC Code	**Type of Service 'Component'**	**Setting 'System'**	**Specialty/Training/Professional Level 'Method_Type'**
Preferred code			
28570-0	Procedure note	{Setting}	{Provider}
Additional codes			
11505-5	Procedure note	{Setting}	Physician
18744-3	Study report	Respiratory system	Bronchoscopy
18745-0	Study report	Heart	Cardiac catheterization
18746-8	Study report	Lower GI tract	Colonoscopy
18751-8	Study report	Upper GI tract	Endoscopy
18753-4	Study report	Lower GI tract	Flexible sigmoidoscopy
18836-7	Procedure	Cardiac stress study	*
28577-5	Procedure note	{Setting}	Dentistry
28625-2	Procedure note	{Setting}	Podiatry
29757-2	Study report	Cvx/Vag	Colposcopy
33721-2	Bone marrow biopsy report	Bone mar	
34121-4	Interventional procedure note	{Setting}	
34896-1	Interventional procedure note	{Setting}	Cardiology
34899-5	Interventional procedure note	{Setting}	Gastroenterology
47048-4	Diagnostic interventional study report	{Setting}	Interventional radiology
48807-2	Bone marrow aspiration report	Bone mar	

Figure 3: ClinicalDocument/code example

```
<code codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC" code="28570-0" displayName="PROCEDURE NOTE"/>
```

ClinicalDocument/title

CONF-PN-5: A CDA Procedure Note **SHALL** contain exactly one `ClinicalDocument/title` element valued with a text string that specifies the local name used for the document.

CONF-PN-6: The `clinicalDocument/title` **SHALL** not conflict with the `clinicalDocument/code`.

Figure 4: ClinicalDocument/title example

```
<title>Endoscopy Procedure Note</title>
```

ClinicalDocument/effectiveTime

CDA requires a `ClinicalDocument/effectiveTime` element to signify the document creation time when the document first came into being.

CONF-PN-7: The `ClinicalDocument/effectiveTime` element **SHOULD** record an `effectiveTime` that is precise to the minute.

ClinicalDocument/languageCode

The `ClinicalDocument/languageCode` specifies the language of the Procedure Note. Procedure Notes must be readable by medical practitioners, caregivers, and patients.

CONF-PN-8: `ClinicalDocument/languageCode` **SHALL** be present.

CONF-PN-9: `ClinicalDocument/languageCode` **SHALL** be in the form `nn`, or `nn-CC`.

CONF-PN-10: The `nn` portion of `ClinicalDocument/languageCode` **SHALL** be a legal ISO-639-1 language code in lowercase.

CONF-PN-11: The `CC` portion `ClinicalDocument/languageCode`, if present, **SHALL** be an ISO-3166 country code in uppercase.

Figure 5: ClinicalDocument/languageCode example with language only

```
<languageCode code="en"/>
```

Figure 6: ClinicalDocument/languageCode example with language and country

```
<languageCode code="en-US"/>
```

Header Participants

This section describes the participants in a Procedure Note header.

RecordTarget

CDA requires a `recordTarget` element that must contain a `patientRole` element. The record target records the patient whose health information is described by the clinical document.

CONF-PN-12: A `patient/birthTime` element **SHALL** be present. The `patient/birthTime` element **SHALL** be precise at least to the year,

and **SHOULD** be precise at least to the day. If unknown, it **SHALL** be represented with a `nullFlavor`.

CONF-PN-13: A `patient/administrativeGenderCode` element **SHALL** be present. If unknown, it **SHALL** be represented with a `nullFlavor`. The value for `administrativeGenderCode` **SHOULD** be selected from the Value Set `2.16.840.1.113883.1.11.1 Administrative Gender (HL7 V3)` **STATIC** and **MAY** be selected from a realm-specific vocabulary

Table 3: HL7 V3 Administrative Gender Value Set

Value Set: HL7 V3 Administrative Gender 2.16.840.1.113883.1.11.1 Code System: HL7 2.16.840.1.113883.5.1	
Code	**Meaning**
F	Female
M	Male
UN	Undifferentiated

CONF-PN-14: The `guardian` element **SHOULD** be present when the patient is a minor child.

Figure 7: RecordTarget example

```
<recordTarget>
  <patientRole>
    <id extension="12345" root="2.16.840.1.113883.19.5" />
    <addr>
      <streetAddressLine>555 Residential Lane</streetAddressLine>
      <city>Ann Arbor</city>
      <state>MI</state>
      <postalCode>99999</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:(555)555-1212" use="HP" />
    <patient>
      <name>
        <given>Adam</given>
        <family>Everyman</family>
      </name>
      <administrativeGenderCode code="M"
codeSystem="2.16.840.1.113883.5.1"
          displayName="Male" />
      <birthTime value="19541125" />
      <!-- Guardian if patient is a minor -->
      <guardian>
        <id extension="23456" root="2.16.840.1.113883.19.5" />
        <addr>
          <streetAddressLine>4444 Home Street</streetAddressLine>
          <city>Ann Arbor</city>
          <state>MI</state>
          <postalCode>99999</postalCode>
          <country>USA</country>
        </addr>
        <telecom value="tel:(555)555-2004" use="HP" />
        <guardianPerson>
          <name>
             <given>Ralph</given>
             <family>Relative</family>
          </name>
        </guardianPerson>
      </guardian>
    </patient>
    <!--Providing Organization -->
    <providerOrganization>
      <id root="2.16.840.1.113883.19.5" />
      <name>Good Health Hospitals and Community Health System</name>
      <telecom value="tel:(555)555-5000" use="WP" />
      <addr>
        <streetAddressLine>1000 Enterprise Blvd</streetAddressLine>
        <city>Ann Arbor</city>
        <state>MI</state>
        <postalCode>99999</postalCode>
        <country>USA</country>
      </addr>
    </providerOrganization>
  </patientRole>
</recordTarget>
```

Author

The `author` element represents the creator of the clinical document. The author may be a device, a person, or an organization.

CONF-PN-15: A Procedure Note **SHALL** contain one or more `ClinicalDocument/author/assignedAuthor/assignedPerson` and/or `ClinicalDocument/author/assignedAuthor/assignedAuthoringDevice` elements.

CONF-PN-16: The `assignedAuthor/id` element **SHALL** be present.

Figure 8: AssignedAuthor example

```
<author>
  <time value="20100329224411+0500" />
  <assignedAuthor>
    <id extension="IO00017" root="2.16.840.1.113883.19.5" />
    <addr>
      <streetAddressLine>1001 Hospital Lane</streetAddressLine>
      <city>Ann Arbor</city>
      <state>MI</state>
      <postalCode>99999</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:(555)555-3101" use="WP" />
    <assignedPerson>
      <name>
        <prefix>Dr.</prefix>
        <given>Tony</given>
        <family>Tum</family>
      </name>
    </assignedPerson>
  </assignedAuthor>
</author>
```

DataEnterer

The `dataEnterer` element represents the person who transferred the content of the note, written or dictated by someone else, into the clinical document. The guiding rule of thumb is that an `author` provides the content found within the header or body of the document, subject to their own interpretation, and the `dataEnterer` adds that information to the electronic system. In other words, a `dataEnterer` transfers information from one source to another (e.g., transcription from paper form to electronic system).

CONF-PN-17: When `dataEnterer` is present, an `assignedEntity/assignedPerson` element **SHALL** be present.

Figure 9: DataEnterer example

```
<dataEnterer>
  <time value="20050329222451+0500"/>
  <assignedEntity>
    <id extension="2" root="2.16.840.1.113883.19"/>
    <assignedPerson>
      <name>
        <prefix>Mrs.</prefix>
        <given>Enter</given>
        <family>Ellen</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</dataEnterer>
```

Facility Location of Performed Procedure

The physical location where the procedure was performed is recorded in `EncompassingEncounter/location/healthCareFacility/id` in combination with the type of location, such as "Gastroenterology Clinic" recorded in `healthcareFacity/code`.

CONF-PN-18: A Procedure Note **SHOULD** contain information about where the procedure was performed.

CONF-PN-19: If present, the physical location of the procedure **SHALL** be represented with `componentOf/encompassingEncounter/location/healthCareFacility/id` element.

CONF-PN-20: If present, the `location/healthCareFacility` element **SHALL** contain a `code` element representing the type of location.

Figure 10: EncompassingEncounter/location example

```
<ClinicalDocument
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns:mif="urn:hl7-org:v3/mif" xmlns="urn:hl7-org:v3">
  ...
<componentOf>
  <encompassingEncounter>
    ...
    <location>
      <healthCareFacility classCode="SDLOC">
        <id root="2.16.840.1.113883.19.5" extension="1234" />
        <code codeSystem="2.16.840.1.113883.6.259"
              codeSystemName="HL7 HealthcareServiceLocation"
              code="1118-9"
              displayName=" Gastroenterology clinic" />
      </healthCareFacility>
    </location>
  </encompassingEncounter>
</componentOf>
```

EncompassingEncounter/encounterParticipant – Referring Provider

The referring provider in CDA is represented as a `componentOf/EncompassingEncounter/encounterParticipant`.

CONF-PN-21: A Procedure Note **MAY** contain information about the referring provider.

CONF-PN-22: If present, the referring provider **SHALL** be represented with a `componentOf/encompassingEncounter/encounterParticipant` element.

CONF-PN-23: When an `encompassingEncounter/encounterParticipant` representing the referring provider is present, the `encounterParticipant/@typeCode` **SHALL** be `REF` (referrer) and an `assignedEntity` **SHALL** be present.

CONF-PN-24: If elements required in `componentOf/encompassingEncounter/encounterParticipant` are unknown, these elements **SHALL** be represented with the appropriate HL7 null value.

Figure 11: EncompassingEncounter/encounterParticpant example with null values for a referring provider

```
<componentOf>
  <encompassingEncounter>
    <effectiveTime>
      <low nullFlavor="NA" />
      <high nullFlavor="NA" />
    </effectiveTime>
    <encounterParticipant typeCode="REF">
      <assignedEntity>
        <id nullFlavor="NA" />
        <assignedPerson>
          <name>
            <given>Harold</given>
            <family>Hippocrates</family>
            <suffix>MD</suffix> </name>
        </assignedPerson>
        <representedOrganization>
          <id nullFlavor="NA" />
        </representedOrganization>
      </assignedEntity>
    </encounterParticipant>
  </encompassingEncounter>
</componentOf>
```

Generic Participant – Primary Care Provider

The primary care provider (PCP), also known as the general practitioner (GP), for a patient undergoing a procedure may be different from the referring provider and may not be a `participant` in an `encompassingEncounter`.

CONF-PN-25: A Procedure Note **MAY** contain a `participant` who is the primary care provider.

CONF-PN-26: When a `participant` representing the primary care provider is present, the `participant/@typeCode` **SHALL** be `IND`.

CONF-PN-27: When a `participant` representing the primary care provider is present, the value for `functionCode/@code` **SHALL** be `PCP 2.16.840.1.113883.5.88 HL7 ParticipationFunction` **STATIC**.

CONF-PN-28: The `participant` **SHALL** have an `associatedEntity` and the `associatedEntity/@classCode` **SHALL** be `PROV`.

CONF-PN-29: The `associatedEntity` **SHALL** have an `associatedPerson`.

Figure 12: Participant example for a primary care provider

```
<participant typeCode="IND">
   <functionCode code="PCP" codeSystem="2.16.840.1.113883.5.88"/>
   <associatedEntity classCode="PROV">
     <associatedPerson>
       <name>
         <given>Mary</given>
         <family>Smith</family>
         <suffix>MD</suffix>
       </name>
     </associatedPerson>
   </associatedEntity>
 </participant>
```

Participant Scenarios

The Participant Scenarios table shows a number of scenarios and the values for various participants. Note that not all participants in the scenario table below are stated above in Header Participants if there are no additional constraints on the base standard regarding those participants. An Appendix provides XML examples of participant scenarios.

Table 4: Participant Scenarios

Scenario	Author	Custo-dian	Data Enterer	Encom-passing Encounter/ Encounter Participant	Legal Authen-ticator	Parti-cipant	Service Event/ Performer
Colonoscopy Participant Scenario: A surgeon refers a patient to an endoscopist. A colonoscopy is performed at an outpatient surgery center. The endoscopist inputs information into an EHR. The outpatient surgery center EHR generates a Procedure Note to send to the Hospital EHR.							
Endo-scopic CDA Procedure Note	Endo-scopist	Out-patient surgery center	None	Surgeon [REF (referrer)]	Endo-scopist	None	Endoscopist

Scenario	Author	Custo-dian	Data Enterer	Encom-passing Encounter/ Encounter Participant	Legal Authen-ticator	Parti-cipant	Service Event/ Performer
Office Removal of Wart Participation Scenario: A wart is removed during an office visit. The PCP dictates the procedure into the local transcription system. The transcription system generates a CDA Procedure Note to the EHR.							
CDA Procedure Note	PCP	PCP office	Transcrip-tionist	None	PCP	None	PCP
Dental Procedure Participation Scenario: Dentist extracts a tooth after the patient has a cleaning by the hygenist. He enters the information into his Dental EHR.							
Procedure input to EHR	Dentist	Dentist office	Varies	None	Dentist	None	Dentist Hygenist
Transjugular Intrahepatic Portosystemic Shunt (TIPS) Procedure (Interventional Radiology) Participant Scenario: At a university hospital, a TIPS procedure is performed by the interventional radiology fellow, with the help of an interventional radiology nurse, under the supervision of an attending interventional radiologist. The radiology technician enters the data into the EMR. The patient was referred to the university hospital by his oncologist. The patient is insured by Cigna.							
Procedure Note is input in EHR	Interven-tional radiology fellow	Good Health Hospital	Interven-tional radiology technician	REF (referrer) Oncologist	Attending interven-tional radiolo-gist	Cigna	Interven-tional radiology fellow Nurse Attending interven-tional radiologist
Lumbar Puncture (spinal tap) Procedure Participant Scenario: At a university hospital, a lumbar puncture is performed by a medical student, with the help of an intern, under the supervisory authority of an attending neurologist. The student performs the procedure and dictates the note. The note is signed by the intern and attending. The patient has a family doctor that is not participating in the procedure, did not refer the patient, and does not have privledges at the providing organization but is recorded in the note.							
Procedure Note is dictated by the medical student	Medical student	Good Health Hospital	Transcrip-tionist	None	Neurology attending (Intern is authen-ticator)	Family doctor	Medical student Intern

Consent

The CDA Header provides a construct for handling consents associated with a procedure; the CDA Body may also record information about the patient's consent.

The type of consent (e.g., a consent to perform the related `serviceEvent` or a consent for the information contained in the document to be released to a third party) is conveyed in `consent/code`. Consents referenced in the CDA Header have been finalized

(consent/statusCode must equal Completed) and should be on file. The following conformance statement does not represent an additional constraint over base CDA; it calls out CDA's construct for handling consent as consents are usually required prior to a procedure.

CONF-PN-30: A consent, if present, **SHALL** be represented as ClinicalDocument/authorization/consent.

Figure 13: Consent example

```
 <authorization typeCode="AUTH">
    <consent classCode="CONS" moodCode="EVN">
       <id root="629deb70-5306-11df-9879-0800200c9a66" />      <id
extension="99370125" root="2.16.840.1.113883.19"/>
       <code codeSystem=" 2.16.840.1.113883.6.1" codeSystemName="LOINC"
             code="CONSP-X" displayName="Consent for Procedure"/>
       <statusCode code="completed"/>
    </consent>
 </authorization
```

ServiceEvent

This class represents the main act, such as a colonoscopy or a cardiac stress study, being documented. A serviceEvent is required in the Procedure Note. It must be equivalent to or further specialize the value inherent in the ClinicalDocument/@code (such as where the ClinicalDocument/@code is simply "Procedure Note" and the procedure is "colonoscopy"), and it shall not conflict with the value inherent in the ClinicalDocument/@code, as such a conflict would create ambiguity. A serviceEvent/effectiveTime element indicates the time the actual event (as opposed to the encounter surrounding the event) took place.

CONF-PN-31: A Procedure Note **SHALL** contain one or more documentationOf/serviceEvent elements.

CONF-PN-32: The value for serviceEvent/code **SHOULD** be selected from code system 2.16.840.1.113883.6.96 SNOMED CT and **MAY** be selected from a localized procedure coding system for a given country such as 2.16.840.1.113883.6.104 ICD9 CM Procedures or 2.16.840.1.113883.6.12 CPT-4 in the U.S.

ServiceEvent/effectiveTime may be represented two different ways in the Procedure Note. For accuracy to the second, the best method is effectiveTime/low together with effectiveTime/high. If a more general time, such as minutes or hours, is acceptable OR if the duration is unknown, an effectiveTime/low with a width element may be used. If the duration is unknown, the appropriate HL7 null value such as "NI" or "NA" must be used for the width element.

CONF-PN-33: The serviceEvent/effectiveTime **SHALL** be present with effectiveTime/low and **SHALL** include effectiveTime/high if effectiveTime/width is not present. The serviceEvent/effectiveTime **SHALL** be accurate to the day, and **MAY** be accurate to the second.

CONF-PN-34: If the date and only the general length of the procedure are known, the serviceEvent/effectiveTime/low **SHALL** be present with an effectiveTime/width element. The

serviceEvent/effectiveTime/low **SHALL** be accurate to the day, and **MAY** be accurate to the second.

CONF-PN-35: If only the date is known and the duration of the procedure is unknown, the serviceEvent/effectiveTime/width element **SHALL** contain the appropriate HL7 null value.

Figure 14: ServiceEvent example

```
<serviceEvent classCode="PROC">
   <code code="118155006" codeSystem="2.16.840.1.113883.6.96"
         codeSystemName="SNOMED CT"
         displayName="Gastrointestinal tract endoscopy"/>
   <effectiveTime>
     <low value=" 20100329224020090625140O" />
     <width value="15" unit="m"/>
   </effectiveTime>
   ...
</serviceEvent>
```

Figure 15: ServiceEvent example with null value in width element

```
<serviceEvent classCode="PROC">
   <code code="118155006" codeSystem="2.16.840.1.113883.6.96"
         codeSystemName="SNOMED CT"
         displayName="Gastrointestinal tract endoscopy"/>
   <effectiveTime>
     <low value=" 20100329224020090625140O" />
     <width nullFlavor="NI"/>
   </effectiveTime>
   ...
</serviceEvent>
```

Figure 16: ServiceEvent international example with effectiveTime to the seconds

```
<serviceEvent classCode="PROC">
   <code code="8-836.0cR" codeSystem="1.2.276.0.76.5.357"
         codeSystemName="OPS 2009"
         displayName="PTA (Ballon): Gefäße Unterschenkel, Rechts"/>
   <effectiveTime>
     <low value="20090723091546" />
     <high value="20090723100053" />
   </effectiveTime>
   ...
</serviceEvent>
```

Performer

The performer participant represents clinicians who actually and principally carry out the serviceEvent. Typically, these are clinicians who have the appropriate privileges in their institutions such as gastroenterologists, interventional radiologists, and family practice physicians. Performers may also be non-physician providers (NPPs) who have other significant roles in the procedure such as a radiology technician, dental assistant, or nurse.

CONF-PN-36: The primary performers (PPRF) **SHALL** be identified.

CONF-PN-37: For all performers, `serviceEvent/performer/assignedEntity/code` **SHALL** be present.

CONF-PN-38: The value for `serviceEvent/performer/assignedEntity/code` **SHOULD** be selected from a localized `assignedEntity` coding system for a given country and **MAY** be selected from code system `2.16.840.1.113883.11.19465 Healthcare Provider Taxonomy Code (NUCC)`.

CONF-PN-39: Any assistants **SHALL** be identified and **SHALL** be identified as secondary performers (SPRF).

Figure 17: Performer example

```
<performer typeCode="PPRF">
    <assignedEntity>
      <id extension="IO00017" root="2.16.840.1.113883.19.5" />
      <code code="207RG0100X"
            codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="NUCC"
            displayName="Gastroenterologist" />
      <addr>
        <streetAddressLine>1001 Hospital Lane</streetAddressLine>
        <city>Ann Arbor</city>
        <state>MI</state>
        <postalCode>99999</postalCode>
        <country>USA</country>
      </addr>
      <telecom value="tel:(999)555-1212" />
      <assignedPerson>
        <name>
          <prefix>Dr.</prefix>
          <given>Tony</given>
          <family>Tum</family>
        </name>
     </assignedEntity>
</performer>
```

Rendering Header Information for Human Presentation

Metadata carried in the header may already be available for rendering from EHRs or other sources external to the document; therefore, there is no strict requirement to render directly from the document. An example of this would be a doctor using an EHR that already contains the patient's name, date of birth, and current address and phone number. When a CDA document is rendered within that EHR, those pieces of information may not need to be displayed since they are already known and displayed within the EHR's user interface.

In a Procedure Note, the following information is typically displayed in the EHR and/or rendered directly in the document:

- The performers of the procedure, including any assistants
- The procedure performed (`serviceEvent`)
- The date of the procedure

Best practice recommends that the following also be present whenever a document is viewed:

- Document title and document date
- Service and encounter types, and dates and date ranges as appropriate
- All persons named along with their roles, participations, participation date ranges, identifiers, and address and telecommunications information
- Selected organizations named along with their roles, participations, participation date ranges, identifiers, and address and telecommunications information
- Date of birth for `recordTarget`(s)

Body

A Procedure Note shall have either a `structuredBody` or `nonXMLBody` element. The contents of these elements include the human-readable text of the document. This information shall be organized into sections and may have subsections. A `nonXMLBody` element may contain the actual CDA content or may reference it by URL.

This guide describes section headers that are appropriate for universal use; it does not define clinical statements. Some templates for clinical statements can be obtained from other implementation guides, such as the History and Physical (H&P) Note, CCD, and Public Health Case Reports (PHCR) standards. All of these are, however, U.S. realm standards. No comparable templates are available at this time for an international realm. Use of these templates for clinical statements is always optional and may not be appropriate for some implementations.

The current scope of this guide includes narrative sections, with suggestions for reuse of clinical statements where indicated. Implementers may constrain the specification for different procedures through selective use of these clinical statements to represent procedure specific data elements together with the appropriate selection of sections and header attribute and participant definition.

Section Descriptions

This implementation guide defines required and optional sections.

All `section` elements in the body of the document shall have a `code` and some nonblank text or one or more subsections, even if the purpose of the text is only to indicate that information is unknown.

CONF-PN-40: LOINC codes **SHOULD** be used with the sections in a Procedure Note. Procedure Note sections are shown in the LOINC Codes for Procedure Note Sections table. Other sections not listed in the table **MAY** be present as well. The exact text of the section names are not mandated.

CONF-PN-41: All sections **MAY** occur in any order and **MAY** be nested under other sections according to local policy.

CONF-PN-42: Sections and subsections **SHALL** have a `title` and the `title` **SHALL NOT** be empty.

CONF-PN-43: The `sections` described in this document **SHALL** contain at least one `text` element or one or more `component` elements. A section **MAY** contain both `text` and `component` elements.

Table 5: LOINC Codes for Procedure Note Sections

Section Name	Required/ Optional	Code	Component Name
Indications	R	IND-X	INDICATIONS
Procedure Description	R	29554-3	PROCEDURE
Postprocedure Diagnosis	R	POSTPR-X	POSTPROCEDURE DIAGNOSIS
Complications/Adverse Events	R	55109-3	COMPLICATIONS
Assessment and Plan	R	51847-2	ASSESSMENT AND PLAN
		51848-0	ASSESSMENT
		18776-5	PLAN
Medical History	O	11329-0	MEDICAL HISTORY
Additional Medical History Sections			
Social History	O	29762-2	SOCIAL HISTORY
Family History	O	10157-6	FAMILY HISTORY
Review of Systems	O	10187-3	REVIEW OF SYSTEMS
Chief Complaint	O	10154-3	CHIEF COMPLAINT
History of Present Illness	O	10164-2	HISTORY OF PRESENT ILLNESS
Past Medical History	O	11348-0	PAST MEDICAL HISTORY
Past Surgical History	O	10167-5	PAST SURGICAL HISTORY
Procedure History	O	47519-4	PROCEDURE HISTORY
Medication History	O	10160-0	HISTORY OF MEDICATION USE
Allergies	O	48765-2	ALLERGIES
Physical Examination	O	29545-1	PHYSICAL FINDINGS
		Optional Subsections	
		10210-3	GENERAL STATUS, PHYSICAL FINDINGS (optional, must be subsection)
		8716-3	VITAL SIGNS
		See Additional Physical Examination Subsections	Additional optional subsections.
Planned Procedure	O	PLNPROC-X	PLANNED PROCEDURE
Anesthesia	O	ANES-X	ANESTHESIA
Medications Administered	O	29549-3	MEDICATIONS ADMINISTERED
Estimated Blood Loss	O	EBL-X	ESTIMATED BLOOD LOSS
Specimens Removed	O	SPECRE-X	SPECIMENS
Implants	O	IMPL-X	IMPLANTS
Surgical drains	O	11537-8	SURGICAL DRAINS
Findings	O	FIND-X	FINDINGS
Disposition	O	DISPO-X	DISPOSTION

Required Sections

Required sections in a Procedure Note are determined by data that is mandated by regulatory agencies, where such regulations are available. Each section must contain text that addresses the section title. If no content is available, this must be specified in the appropriate section. Local practices must ensure that their legal authenticator is aware that the "no content" notation must be included in the legally authenticated document.

CONF-PN-44: A Procedure Note **SHALL** include the sections listed as Required (R) in the LOINC Codes for Procedure Note Sections table.

Assessment and Plan 51847-2/51848-0/18776-5

All constraints from this section are derived from the H&P Note Assessment and Plan section and the CCD Plan of Care section; all conformance requirements are included below. "Assessment" and for "Assessment and Plan" have new unique `templateIds`, and the "Plan" section uses the CCD Plan of Care `templateId`.

A Procedure Note contains either discrete sections for Assessment and for Plan or a single section combining the two (Assessment and Plan). The sections may be combined or separated to meet local policy requirements.

The Assessment section (also called impression or diagnoses) represents the clinician's conclusions and working assumptions that will guide treatment of the patient. The assessment formulates a specific plan or set of recommendations. The assessment may be a list of specific disease entities or a narrative block.

The Plan section contains data that defines pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current care of the patient should be listed unless constrained due to privacy issues. The plan may also contain information about ongoing care of the patient and information regarding goals and clinical reminders. Clinical reminders are placed here to provide prompts for disease prevention and management, patient safety, and health-care quality improvements, including widely accepted performance measures. The plan may also indicate that patient education was given or will be provided.

CONF-PN-45: When the Assessment and Plan are recorded separately, there **SHALL** be a section where the value for `Section/code` **SHALL** be `51848-0 ASSESSMENT 2.16.840.1.113883.6.1 LOINC` **STATIC** and the `templateId` **SHALL** be `2.16.840.1.113883.10.20.18.2.13`; **AND** there **SHALL** be a section where the value for `Section/code` **SHALL** be `18776-5 PLAN 2.16.840.1.113883.6.1 LOINC` **STATIC** and the `templateId` **SHALL** be `2.16.840.1.113883.10.20.1.10;` **AND** there **SHALL NOT** be a section where the value for `Section/code` is `51847-2 ASSESSMENT AND PLAN 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-46: When the Assessment and Plan and are recorded together, the value for `Section/code` **SHALL** be `51847-2 ASSESSMENT AND PLAN 2.16.840.1.113883.6.1 LOINC` **STATIC** and the `templateId` **SHALL** be `2.16.840.1.113883.10.20.18.2.14`; **AND** there **SHALL NOT** be a section where the value for `Section/code` is `51848-0 ASSESSMENT`; **AND** there **SHALL NOT** be a section where the value for `Section/code` is `18776-5 PLAN`.

CONF-PN-47: The Assessment, Plan, and Assessment and Plan section(s) **MAY** contain clinical statements. If present, the clinical statements **MAY** conform to the CCD Plan of care activities template (`2.16.840.1.113883.10.20.1.25`).

Figure 18: Assessment and plan example

```
<component>
  <section>
    <templateId root="2.16.840.1.113883.10.20.18.2.14"/>
    <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
          code="51847-2" displayName="ASSESSMENT AND PLAN"/>
    <title>Assessment and Plan</title>
    <text>
      <list listType="ordered">
        <item> Sigmoid diverticulosis, moderate. High fiber diet</item>
        <item> Internal hemorrhoids. Treat conservatively with Canasa
               suppositories </item>
        <item> Colon polyp, 6mm, ascending colon, removed by snare.
Patient to
               call for results </item>
      </list>
    </text>
</section>
</component>
```

Complications/Adverse Events 55109-3

The Complications section records problems that occurred during the procedure. The complications may have been known risks or unanticipated problems. The Complications section may be a subsection of another section such as the Procedure Description section. This section should include all adverse events that occurred during the procedure, but inclusion does not imply that the adverse event was a result or complication of the procedure.

CONF-PN-48: The Procedure Note **SHALL** contain exactly one and **SHALL NOT** contain more than one Complications section.

CONF-PN-49: A `Section/code` element **SHALL** be present where the value for `@code` is `55109-3 COMPLICATIONS 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-50: The Complications section **SHALL** include a `templateId` element where `@root` is `2.16.840.1.113883.10.20.18.2.4`.

CONF-PN-51: There **SHALL** be a statement providing details of the complication(s) or it **SHALL** explicitly state there were no complications.

CONF-PN-52: The Complications section **MAY** contain clinical statements. If present, the clinical statements **MAY** conform to the CCD Problem observation template (2.16.840.1.113883.10.20.1.28).

CONF-PN-53: The Complications section **MAY** contain clinical statements referring to imaging observations. If present, these clinical statements **MAY** conform to the PHCR Imaging observation template (2.16.840.1.113883.10.20.15.3.5), DIR Text Observation template (2.16.840.1.113883.10.20.6.2.12), DIR Code Observation template (2.16.840.1.113883.10.20.6.2.13), DIR Quantity Measurement Observation template (2.16.840.1.113883.10.20.6.2.14) or DIR SopInstance Observation template (2.16.840.1.113883.10.20.6.2.8).

Figure 19: Complications section example

```
<component>
   <section>
      <templateId root="2.16.840.1.113883.10.20.18.2.4."/>
      <code code="55109-3" codeSystem="2.16.840.1.113883.6.1"
       codeSystemName="LOINC" displayName="COMPLICATIONS"/>
      <title>Complications</title>
      <text>None</text>
   </section>
</component>
```

Indications IND-X

The Indications section records details about the reason for the procedure. This section may include the pre-procedure diagnosis or diagnoses as well as one or more symptoms that contribute to the reason the procedure is being performed.

CONF-PN-54: The Procedure Note **SHALL** contain exactly one and **SHALL NOT** contain more than one Indications section.

CONF-PN-55: A `Section/code` element **SHALL** be present where the value for `@code` is `IND-X INDICATIONS 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-56: The Indications section **SHALL** include a `templateId` element where `@root` is `2.16.840.1.113883.10.20.18.2.1.`

CONF-PN-57: The Indications section **MAY** contain clinical statements referring to the reason for the procedure. If present, these clinical statements **MAY** conform to the CCD Problem observation template (2.16.840.1.113883.10.20.1.28).

CONF-PN-58: If clinical statements conforming to the CCD Problem observation template and referring to the reason for the procedure are present, there **SHALL** be an `entryRelationship` with `typeCode RSON`. This `entryRelationship` **SHALL** adhere to CCD CONF 439.

CONF-PN-59: The Indications section **MAY** contain clinical statements referring to imaging observations. If present, these clinical statements **MAY** conform to the PHCR Imaging observation template (2.16.840.1.113883.10.20.15.3.5), DIR Text Observation template (2.16.840.1.113883.10.20.6.2.12), DIR Code Observation template (2.16.840.1.113883.10.20.6.2.13), DIR Quantity Measurement Observation template (2.16.840.1.113883.10.20.6.2.14) or DIR SopInstance Observation template (2.16.840.1.113883.10.20.6.2.8).

Figure 20: Indications section example

```
<component>
   <section>
      <templateId root="2.16.840.1.113883.10.20.18.2.1"/>
      <code code="IND-X" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="INDICATIONS"/>
      <title>INDICATIONS</title>
         <text> The procedure is performed for screening in a low risk
                individual. </text>
   </section>
</component>
```

Postprocedure Diagnosis POSTPR-X

The Postprocedure Diagnosis section records the diagnosis or diagnoses discovered or confirmed during the procedure. Often it is the same as the pre-procedure diagnosis or indication.

CONF-PN-60: The Procedure Note **SHALL** contain exactly one and **SHALL NOT** contain more than one Postprocedure Diagnosis section.

CONF-PN-61: A `Section/code` element **SHALL** be present where the value for `@code` is `POSTPR-X POSTPROCEDURE DIAGNOSIS 2.16.840.1.113883.6.1 LOINC` **STATIC.**

CONF-PN-62: The Postprocedure Diagnosis section **SHALL** include a `templateId` element where `@root` is `2.16.840.1.113883.10.20.18.2.3`.

CONF-PN-63: The Postprocedure Diagnosis section **MAY** contain clinical statements. If present, the clinical statements **MAY** conform to the CCD Problem observation template (2.16.840.1.113883.10.20.1.28).

CONF-PN-64: The Postprocedure section **MAY** contain clinical statements referring to imaging observations. If present, these clinical statements MAY conform to the PHCR Imaging observation template (2.16.840.1.113883.10.20.15.3.5), DIR Text Observation template (2.16.840.1.113883.10.20.6.2.12), DIR Code Observation template (2.16.840.1.113883.10.20.6.2.13), DIR Quantity Measurement Observation template (2.16.840.1.113883.10.20.6.2.14) or DIR SopInstance Observation template (2.16.840.1.113883.10.20.6.2.8).

Figure 21: Postprocedure diagnosis section example

```
 <component>
    <section>
      <templateId root="2.16.840.1.113883.10.20.18.2.3"/>
         <code code="POSTPR-X" codeSystem="2.16.840.1.113883.6.1"
               codeSystemName="LOINC" displayName="POSTPROCEDURE
DIAGNOSIS"/>
         <title>Postprocedure Diagnosis</title>
         <text>Polyps, biopsied</text>
    </section>
 </component>
```

Procedure Description 29554-3

The Procedure Description section records the particulars of the procedure with a narrative and may include procedure site preparation, pertinent details related to measurements and markings, procedure times, instrumentation, and vital signs and other monitoring data. Complications and Anesthesia may be recorded as subsections of this section. Local practice often identifies the level and type of detail required based on the procedure or specialty.

CONF-PN-65: The Procedure Note **SHALL** contain exactly one and **SHALL NOT** contain more than one Procedure Description section.

CONF-PN-66: A `Section/code` element **SHALL** be present where the value for `@code` is `29554-3 PROCEDURE DESCRIPTION 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-67: The Procedure Description section **SHALL** include a `templateId` element where `@root` is `2.16.840.1.113883.10.20.18.2.2`.

CONF-PN-68: If the Medications Administered section is NOT present, there **MAY** be a statement in the Procedure Description section providing details of medications or fluids administered during the procedure or explicitly stating that there were no medications or fluids administered.

CONF-PN-69: If the Estimated Blood Loss section is NOT present, there **MAY** be a statement in the Procedure Description section providing details of the estimated blood lost during the procedure or explicitly stating there was no blood loss.

CONF-PN-70: If the Specimens Removed section is NOT present, there **MAY** be a statement in the Procedure Description section providing details of the specimens removed during the procedure or explicitly stating that there were no specimens removed.

CONF-PN-71: If the Implants section is NOT present, there **MAY** be a statement in the Procedure Description section providing details of implants such as stents, clips or drains left during the procedure or explicitly stating that there were no implants left.

CONF-PN-72: The Procedure Description section **MAY** contain clinical statements about the procedure activity. If present, these clinical statements **MAY** conform to the CCD Procedure activity template

(2.16.840.1.113883.10.20.1.29), the CCD Product template (2.16.840.1.113883.10.20.1.53), and the CCD Product instance template (2.16.840.1.113883.10.20.1.52).

CONF-PN-73: The Procedure Description section **MAY** also contain clinical statements referring to the procedure related problems. If present, these clinical statements **MAY** conform to the CCD Problem observation template (2.16.840.1.113883.10.20.1.28).

CONF-PN-74: The Procedure Description section **MAY** contain clinical statements referring to imaging observations. If present, these clinical statements MAY conform to the PHCR Imaging observation template (2.16.840.1.113883.10.20.15.3.5), DIR Text Observation template (2.16.840.1.113883.10.20.6.2.12), DIR Code Observation template (2.16.840.1.113883.10.20.6.2.13), DIR Quantity Measurement Observation template (2.16.840.1.113883.10.20.6.2.14) or DIR SopInstance Observation template (2.16.840.1.113883.10.20.6.2.8).

Figure 22: Procedure description section example

```
<component>
   <section>
      <templateId root="2.16.840.1.113883.10.20.18.2.2"/>
      <code code="29554-3" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="PROCEDURE DESCRIPTION"/>
      <title>Procedure Description</title>
      <text>The patient was taken to the endoscopy suite where
...</text>
    </section>
</component>
```

Optional Sections

A Procedure Note may contain additional sections that provide more information.

Anesthesia ANES-X

The Anesthesia section records the type of anesthesia (e.g., general, conscious, or local) and may state the actual agent(s) used. This may or may not be a subsection of the Procedure Description section. The full details of anesthesia are sometimes found in a separate Anesthesia Note.

This section may include clinical statements describing the details of anesthetic substance administration, including timing of medications and start and end time of procedures.

CONF-PN-75: The Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Anesthesia section.

CONF-PN-76: A Section/code element **SHALL** be present where the value for @code is ANES-X ANESTHESIA 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-PN-77: The Anesthesia section **SHALL** include a templateId element where @root is 2.16.840.1.113883.10.20.18.2.7.

CONF-PN-78: The Anesthesia section **MAY** contain clinical statements. If present, the clinical statements **MAY** conform to the CCD Procedure activity template (2.16.840.1.113883.10.20.1.29) or the CCD Medication activity template (2.16.840.1.113883.10.20.1.24).

Figure 23: Anesthesia section example

```
<component>
   <section>
      <templateId root="2.16.840.1.113883.10.20.18.2.7"/>
      <code code="ANES-X" codeSystem="2.16.840.1.113883.6.1"
       codeSystemName="LOINC" displayName="ANESTHESIA"/>
      <title>Anesthesia</title>
      <text> Conscious sedation with propofol 200 mg IV </text>
   </section>
</component>
```

Disposition DISPO-X

The Disposition section records the status and condition of the patient at the completion of the procedure. It often also states where the patent was transferred for the next level of care. The Disposition section may be a subsection of another section such as Procedure Description.

Following are some examples of typical disposition narratives:

- The patient was taken to the post anesthesia care unit (PACU) in stable condition and then discharged home.
- The patient was returned to the intensive care unit (ICU) in stable condition.
- The patient was discharged home on completion of the procedure.

CONF-PN-79: The Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Disposition section.

CONF-PN-80: A `Section/code` element **SHALL** be present where the value for `@code` is `DISPO-X DISPOSITION 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-81: The Disposition section **SHALL** include a `templateId` element where the value for `@root` is `2.16.840.1.113883.10.20.18.2.12`.

Figure 24: Disposition section example

```
<component>
   <section>
      <templateId root="2.16.840.1.113883.10.20.18.2.12"/>
      <code code="DISPO-X" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="DISPOSITION"/>
      <title>Disposition</title>
      <text>The patient was taken to the Endoscopy Recovery Unit in
stable
            condition.</text>
   </section>
</component>
```

Estimated Blood Loss EBL-X

Estimated blood loss should be recorded in a Procedure Note. The Estimated Blood Loss section may be a subsection of another section such as the Procedure Description section. The Estimated Blood Loss section records the approximate amount of blood that the patient lost during the procedure. It may be an accurate quantitative amount, e.g., 250 milliliters, or it may be descriptive, e.g., “minimal” or “none”.

CONF-PN-82: The Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Estimated Blood Loss section.

CONF-PN-83: A `Section/code` element **SHALL** be present where the value for `@code` is `EBL-X ESTIMATED BLOOD LOSS 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-84: The Estimated Blood Loss section **SHALL** include a `templateId` element where the value for `@root` is `2.16.840.1.113883.10.20.18.2.9`.

Figure 25: Estimated blood loss section example

```
<component>
   <section>
      <templateId root="2.16.840.1.113883.10.20.18.2.9"/>
      <code code="EBL-X" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="ESTIMATED BLOOD LOSS"/>
      <title>Estimated Blood Loss</title>
      <text>Minimal</text>
   </section>
</component>
```

Estimated Blood Loss Observation

The Estimated Blood Loss section may contain an entry representing the quantity of blood lost. This entry is derived from *Healthcare Associated Infection DSTU Release 4* Estimated Maternal Blood Loss clinical statement (`templateId 2.16.840.1.113883.10.20.5.2.2.7.12`); the difference here is that a general SNOMED CT code is recommended to record estimated blood loss.

CONF-PN-85: An Estimated Blood Loss Observation **MAY** be present.

CONF-PN-86: An Estimated Blood Loss Observation **SHALL** be represented with an `observation` element where the value for `@classCode` is `OBS` and the value for `@moodCode` is `EVN`.

CONF-PN-87: A `templateId` element **SHALL** be present where the value for `@root` is `2.16.840.1.113883.10.20.18.3.1`.

CONF-PN-88: A `code` element **SHOULD** be present where the value for `@code` **MAY** be `409084000 Estimated blood loss 2.16.840.1.113883.6.96 SNOMED CT` **STATIC**.

CONF-PN-89: A `value` element **SHALL** be present where the value for `value/@xsi:type` is "`PQ`" (Physical Quantity). The value for `value/@value` **SHALL** be a non-negative real number representing the estimated blood loss in terms of the units specified in `@unit`.

Figure 26: Estimated blood loss observation example

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.18.3.1"/>
  <code code="409084000"
        codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED CT"
        displayName="Estimated blood loss"/>
  <value xsi:type="PQ" value="250" unit="mL"/>
</observation>
```

Findings FIND-X

The Findings section records clinically significant observations confirmed or discovered during the procedure. Often this section is a subsection of the Procedure Description section. This section is not for diagnostic findings that may be found in a History and Physical Note, as the results of observations generated by laboratories, imaging procedures, and other procedures would not yet be available.

CONF-PN-90: The Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Findings Section.

CONF-PN-91: A `Section/code` element **SHALL** be present where the value for `@code` is `FIND-X FINDINGS 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-92: The Findings section **SHALL** include a `templateId` element where the value for `@root` is `2.16.840.1.113883.10.20.18.2.15.`

CONF-PN-93: The Findings section **MAY** contain clinical statements. If present, the clinical statements **MAY** conform to the CCD Problem observation template (`templateId 2.16.840.1.113883.10.20.1.28`).

Figure 27: Findings section example

```
 <component>
    <section>
       <templateId root="2.16.840.1.113883.10.20.18.2.15"/>
       <code code="FIND-X" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC" displayName="FINDINGS"/>
       <title>Procedure Note Findings</title>
       <text>A 9 mm sessile polyp was found in the ascending colon and
removed
             by snare, no cautery.  Bleeding was controlled.
       </text>
    </section>
 </component>
```

Implants IMPL-X

The Implants section records any materials placed during the procedure including stents, tubes, and drains. This section may include clinical statements containing implant details.

CONF-PN-94: The Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Implants section.

CONF-PN-95: A `Section/code` element **SHALL** be present where the value for `@code` is `IMPL-X IMPLANTS 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-96: The Implants section **SHALL** include a `templateId` element where the value for `@root` is `2.16.840.1.113883.10.20.18.2.11`.

CONF-PN-97: The Implants section **MAY** contain clinical statements. If present, the clinical statements **MAY** include one or more CCD Supply activities (`templateId 2.16.840.1.113883.10.20.1.34`), **MAY** include CCD Product instance (`templateId 2.16.840.1.113883.10.20.1.52`), and **MAY** include one or more CCD Medication activities (`templateId 2.16.840.1.113883.10.20.1.24`).

Figure 28: Implants section example

```
<component>
    <section>
       <templateId root="2.16.840.1.113883.10.20.18.2.11"/>
       <code code="IMPL-X" codeSystem="2.16.840.1.113883.6.1"
             codeSystemName="LOINC" displayName="IMPLANTS"/>
       <title>Implants</title>
          <text>No implants were placed.</text>
    </section>
 </component>
```

Medical History 11329-0

The Medical History section describes all aspects of the medical history of the patient even if not pertinent to the current procedure, and may include chief complaint, past medical history, social history, family history, surgical or procedure history, medication history, and other history

information. The history may be limited to information pertinent to the current procedure or may be more comprehensive. The history may be reported as a collection of random clinical statements or it may be reported categorically. Categorical report formats may be divided into multiple subsections including Past Medical History, Social History, and any of the other sections in Medical History: Additional Sections.

CONF-PN-98: A Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Medical History section (`templateId 2.16.840.1.113883.10.20.18.2.5`).

CONF-PN-99: A `Section/code` element **SHALL** be present where the value for `@code` is `11329-0 MEDICAL HISTORY 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-100: If the Medication History section is NOT present, there **MAY** be a statement in the Medical History section providing details of historical medications taken by the patient before the procedure including medications in preparation for the procedure such as pre-procedure antibiotics, body system preps, and modifications to anticoagulant use for the procedure.

CONF-PN-101: The Medical History section **MAY** contain clinical statements. If present, the clinical statements **MAY** conform to the CCD Problem observation template (`2.16.840.1.113883.10.20.1.28`) and the CCD Problem status observation template (`2.16.840.1.113883.10.20.1.50`) and the CCD Problem healthstatus observation template (`2.16.840.1.113883.10.20.1.51`).

CONF-PN-102: The Medical History section **MAY** contain clinical statements referring to imaging observations. If present, these clinical statements **MAY** conform to the PHCR Imaging observation template (`2.16.840.1.113883.10.20.15.3.5`), DIR Text Observation template (`2.16.840.1.113883.10.20.6.2.12`), DIR Code Observation template (`2.16.840.1.113883.10.20.6.2.13`), DIR Quantity Measurement Observation template (`2.16.840.1.113883.10.20.6.2.14`) or DIR SopInstance Observation template (`2.16.840.1.113883.10.20.6.2.8`).

Figure 29: Medical history section example

```
 <component>
    <section>
       <templateId root="2.16.840.1.113883.10.20.18.2.5"/>
       <code code="11329-0" codeSystem="2.16.840.1.113883.6.1"
             codeSystemName="LOINC" displayName="MEDICAL HISTORY"/>
       <title>Medical History</title>
       <text>The patient is a 55 year old Caucasian male with a history
of
             non-insulin dependent diabetes.</text>
    </section>
 </component>
```

Figure 30: Medical history section example with a subsection

```
<component>
   <section>
      <templateId root="2.16.840.1.113883.10.20.18.2.5"/>
      <code code="11329-0" codeSystem="2.16.840.1.113883.6.1"
       codeSystemName="LOINC" displayName="MEDICAL HISTORY"/>
      <title>Medical History</title>
      <component>
        <section>
           <code code ="10164-2" codeSystem="2.16.840.1.113883.6.1"
                 codeSystemName = "LOINC"
                 displayName = "History of Present Illness"/>
          <title> History of Present Illness</title>
          <text>The patient is a 55 year old Caucasian male with no
history of
                major medical or surgical problems. </text>
        </section>
      </component>
   </section>
</component>
```

Medical History: Additional Sections

These additional medical history sections may be subsections of the Medical History section or may stand alone in their own sections.

Allergies 48765-2

The Allergies section lists and describes any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items, and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives) used to assure the safety of health care delivery. In general, environmental allergies, even if severe, should not be included in the Allergies section of an procedure note since they constitute a medical problem and should be listed in the problem list and past medical history, even if directly related to the presenting problem.

Constraints from this section are derived from the CCD Alerts section.

The Allergies section may be a subsection of the Medical History section.

CONF-PN-103: A Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Allergies section (`templateId 2.16.840.1.113883.10.20.1.2`).

CONF-PN-104: A `Section/code` element **SHALL** be present where the value for `@code` is `48765-2 ALLERGIES 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-105: If the Allergies section is NOT present, there **MAY** be a statement in the Medical History section providing details of the patient's allergies.

CONF-PN-106: The Allergy section **MAY** contain clinical statements. If present, the clinical statements **MAY** conform to the CCD Problem Act template (`2.16.840.1.113883.10.20.1.27`) and the CCD Alert Observation template (`2.16.840.1.113883.10.20.1.18]`.

Chief Complaint 10154-3

The Chief Complaint section records the patient's chief complaint (the patient's own description).

The Chief Complaint section may be a subsection of the Medical History section.

CONF-PN-107: A Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Chief Complaint section (`templateId 2.16.840.1.113883.10.20.18.2.16`).

CONF-PN-108: A `Section/code` element **SHALL** be present where the value for `@code` is `10154-3 CHIEF COMPLAINT 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-109: If the Chief Complaint section is NOT present, there **MAY** be a statement in the Medical History section providing the patient's chief compliant.

Family History 10157-6

The Family History section contains data defining the patient's genetic relatives in terms of relevant health-risk factors that have a potential impact on the patient's health care profile.

The Family History section may be a subsection of the Medical History section.

CONF-PN-110: A Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Family History section (`templateId 2.16.840.1.113883.10.20.18.2.17`).

CONF-PN-111: A `Section/code` element **SHALL** be present where the value for `@code` is `10157-6 FAMILY HISTORY 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-112: If the Family History section is NOT present, there **MAY** be a statement in the Medical History section providing details of relevant health-risk factors in the patient's genetic relatives that have a potential impact on the patient's health care profile.

History of Present Illness 10164-2

The History of Present Illness section describes the history related to the reason for the procedure. It contains the historical details leading up to and pertaining to the patient's current complaint or reason for seeking medical care. Because history of present illness can include past surgical history and other procedures, the Procedure History section may be included under the History of Present Illness section or it may stand alone as its own section.

Constraints from this section are derived from the H&P History of Present Illness section.

The History of Present Illness section may be a subsection of the Medical History section.

CONF-PN-113: A Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one H&P History of Present Illness section (`templateId 1.3.6.1.4.1.19376.1.5.3.1.3.4`).

CONF-PN-114: A `Section/code` element **SHALL** be present where the value for `@code` is `10164-2 HISTORY OF PRESENT ILLNESS 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-115: If the History of Present Illness section is NOT present, there **MAY** be a statement in the Medical History section providing details of the patient's history leading up to and pertaining to the current chief complaint or reason for seeking medical care.

Medication History 10160-0

The Medication History Section defines a patient's current (pre-procedural) medications and pertinent medication history. At a minimum, the currently active pre-procedural medications should be listed with an entire medication history as an option. The Medication History section should also include any medications administered prior to but in preparation for the current procedure such as pre-procedure antibiotics, modifications to anticoagulant regimens, and body system preps.

All constraints from this section are from CCD; see the CCD Medications section for conformance requirements.

CONF-PN-116: The Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Medications History section.

CONF-PN-117: The Medication History section **SHOULD** include the `templateId` for the CCD Medications section (`2.16.840.1.113883.10.20.1.8`).

Figure 31: Medications example with Level 3 coding

```
<!--Note: this simple coding of medications reflects what we might expect
to see
in a dictated note. For a complete sample of medications encoding, see
CCD  -->

<component>
  <section>
    <templateId root="2.16.840.1.113883.10.20.1.8"/>
    <code codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC"
          code="10160-0"
          displayName="HISTORY OF MEDICATION USE"/>
    <title>Current Medication History</title>
    <text>
      <list listType="ordered">
        <item><content ID="m1">Lisinopril 5 mg</content> 1 tablet once a
day
        </item>
        <item><content ID="m2">Atenolol 25 mg</content> 1 tablet once a
day
        </item>
      </list>
    </text>
    <entry>
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <consumable>
          <manufacturedProduct>
            <manufacturedLabeledDrug>
              <code codeSystem="2.16.840.1.113883.6.88"
                    codeSystemName="RxNorm"
                    code="203644"
                    displayName="LISINOPRIL (PRINIVIL)--PO 5MG TAB">
                <originalText>
                  <reference value="#m1"/>
                </originalText>
              </code>
            </manufacturedLabeledDrug>
          </manufacturedProduct>
        </consumable>
      </substanceAdministration>
    </entry>
```

```
    <entry>
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <consumable>
          <manufacturedProduct>
            <manufacturedLabeledDrug>
              <code codeSystem="2.16.840.1.113883.6.88"
                    codeSystemName="RxNorm"
                    code="197380" displayName="ATENOLOL--PO 25MG TAB">
                <originalText>
                  <reference value="#m2"/>
                </originalText>
              </code>
            </manufacturedLabeledDrug>
          </manufacturedProduct>
        </consumable>
      </substanceAdministration>
    </entry>
  </section>
</component>
```

Past Medical History 11348-0

The Past Medical History section describes the past medical history for the patient. It may contain information about past illnesses or other operative or non-operative procedures that might have a bearing on the current procedure. Because past medical history can include past surgical history and other procedures, the Procedure History section may be included under the Past Medical History section or it may stand alone as its own section.

Constraints from this section are derived from the H&P Past Medical History Section.

The Past Medial History section may be a subsection of the Medical History section.

CONF-PN-118: A Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one H&P Past Medical History section (`templateId 2.16.840.1.113883.10.20.2.9`).

CONF-PN-119: A `Section/code` element **SHALL** be present where the value for `@code` is `11348-0 PAST MEDICAL HISTORY 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-120: If the Past Medical History section is NOT present, there **MAY** be a statement in the Medical History section providing details of the patient's past illnesses or other operative or non-operative procedures that might have a bearing on the current procedure.

Procedure History 47519-4

The Procedure History section describes prior operative or non-operative procedures. This information may instead appear in the Past Medical History section or the History of Present Illness section when a procedure list is inserted into either of these sections.

The Procedure History section may be a subsection of the Medical History section.

CONF-PN-121: A Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Procedure History section (templateId 2.16.840.1.113883.10.20.18.2.18).

CONF-PN-122: A Section/code element **SHALL** be present where the value for @code is 47519-4 PROCEDURE HISTORY 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-PN-123: If the Procedure History section is NOT present, there **MAY** be a statement in the Medical History section providing details ofprior operative or non-operative procedures.

Review of Systems 10187-3

The Review of Systems section contains a relevant collection of symptoms and functions systematically gathered by a clinician. It includes symptoms the patient is currently experiencing, some of which were not elicited during the history of present illness, as well as a potentially large number of pertinent negatives, e.g., symptoms that the patient denied experiencing.

Constraints from this section are derived from the H&P Review of Systems section.

The Review of Systems section may be a subsection of the Medical History section.

CONF-PN-124: A Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one H&P Review of Systems section (templateId 1.3.6.1.4.1.19376.1.5.3.1.3.18).

CONF-PN-125: A Section/code element **SHALL** be present where the value for @code is 10187-3 REVIEW OF SYSTEMS 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-PN-126: If the Review of Systems section is NOT present, there **MAY** be a statement in the Medical History section providing details of relevant symptoms and functions gathered by a clinician.

Social History 29762-2

The Social History section contains data defining the patient's occupational, personal (i.e., lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity, and religious affiliation.

Constraints from this section are derived from the CCD Social History section.

The Social History section may be a subsection of the Medical History section.

CONF-PN-127: A Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Social History section (templateId 2.16.840.1.113883.10.20.1.15).

CONF-PN-128: A Section/code element **SHALL** be present where the value for @code is 29762-2 SOCIAL HISTORY 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-PN-129: If the Social History section is NOT present, there **MAY** be a statement in the Medical History section data defining the patient's occupational, personal (i.e., lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity, and religious affiliation.

CONF-PN-130: The Social History Section **MAY** contain clinical statements. If present, the clinical statements **MAY** conform to the CCD Social History Observation template [2.16.840.1.113883.10.20.1.33].

Medications Administered 29549-3

The Medications Administered section defines medications and fluids administered during the procedure excluding anesthetic medications. Medications administered for anesthesia should be documented as described in the section on Anesthesia.

CONF-PN-131: The Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Medications Administered section.

CONF-PN-132: A `Section/code` element **SHALL** be present where the value for `@code` is `29549-3 MEDICATIONS ADMINISTERED 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-133: The Medications Administered section **SHALL** include a `templateId` element where the value for `@root` is `2.16.840.1.113883.10.20.18.2.8`.

CONF-PN-134: The Medications Administered section **MAY** contain clinical statements. If present, the clinical statements **MAY** conform to CCD Medication activity template (2.16.840.1.113883.10.20.1.24).

Figure 32: Medications administered section example

```
 <component>
    <section>
       <templateId root="2.16.840.1.113883.10.20.18.2.8"/>
       <code code="29549-3" codeSystem="2.16.840.1.113883.6.1"
             codeSystemName="LOINC" displayName="MEDICATIONS
ADMINISTERED"/>
       <title>Medications Administered</title>
       <text>Secretin 100 IU administered IV</text>
    </section>
 </component>
```

Figure 33: Medications administered section example with coded entry

```
<component>
  <section>
    <templateId root="2.16.840.1.113883.10.20.18.2.8"/>
    <code code="29549-3" codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC" displayName="MEDICATION ADMINISTERED"/>
    <title>Medication administered</title>
    <text>2 mg glucagon IV</text>
    <entry>
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <consumable>
          <manufacturedProduct>
            <manufactured LabeledDrug>
              <code codeSystem="2.16.840.1.113883.6.88"
                    codeSystemName=”RxNorm” code="253170"
                    displayName="GLUCAGON HCL FOR INJECTION">
              </code>
            </manufactured LabeledDrug>
          </manufacturedProduct>
        <consumable>
      </substanceAdministration>
    </entry>
  </section>
</component>
```

Physical Examination 29545-1

All constraints from this section are from H&P Note; for convenience, conformance requirements are copied here.

The Physical Examination section describes the pre-procedural examination only. Observations during the procedure should be included in the Procedure Description section.

The Physical Examination section includes direct observations made by the clinician. The examination may include the use of simple instruments and may also describe simple maneuvers performed directly on the patient’s body. This section includes only observations made by the examining clinician using inspection, palpation, auscultation, and percussion; it does not include laboratory or imaging findings. The exam may be limited to pertinent body systems based on the patient’s chief complaint or it may include a comprehensive examination. The examination may be reported as a collection of random clinical statements or it may be reported categorically. Categorical report formats may be divided into multiple subsections, including Vital Signs, General Status, and any of the subsections in Additional Physical Examination Subsections. Note that Vital Signs can be a top-level section or a subsection of Physical Exam.

CONF-PN-135: A Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Physical Examination section (`templateId 2.16.840.1.113883.10.20.2.10`).

CONF-PN-136: A `Section/code` element **SHALL** be present where the value for `@code` is `29545-1 PHYSICAL FINDINGS 2.16.840.1.113883.6.1 LOINC` **STATIC**.

Figure 34: Physical examination section example

```
<component>
  <section>
    <templateId root="2.16.840.1.113883.10.20.2.10"/>
    <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
          code="29545-1" displayName="PHYSICAL FINDINGS"/>
    <title>Physical Examination</title>

    <component>
      <section>
        <templateId root="2.16.840.1.113883.10.20.2.4"/>
        <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
              code="8716-3" displayName="VITAL SIGNS"/>
        <title>Physical Findings - Vital Signs</title>
        <text>
          <paragraph>Heart Rate: 78, Respiratory Rate: 12,
               Temp (degF): 96.7, Oxygen Sat (%): 100.</paragraph>
          <paragraph>Non-invasive Blood Pressure: Systolic: 107,
               Diastolic: 51, Mean: 64.</paragraph>
        </text>
      </section>
    </component>

    <component>
      <section>
        <templateId root="2.16.840.1.113883.10.20.2.5"/>
        <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
              code="10210-3" displayName="GENERAL STATUS "/>
        <title>GENERAL STATUS</title>
        <text>
          <paragraph>Alert and in good spirits, no acute distress.
</paragraph>
        </text>
      </section>
    </component>

     <component>
       <section>
         <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
               code="51850-6" displayName="HEENT"/>
         <title>Physical Findings - HEENT</title>
         <text> <content>All normal to examination.</content>
         </text>
       </section>
     </component>
```

```
    <component>
      <section>
        <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
              code="10200-4" displayName="HEART"/>
        <title>Physical Findings - HEART</title>
        <text>
          <content> RRR, no murmur.</content>
        </text>
      </section>
    </component>
          ...
  </section>
</component>
```

Planned Procedure PLNPROC-X

The Planned Procedure section records the procedure(s) that the clinician thought would be needed based on the pre-procedure assessment. The section will contain the procedure or procedures the patient specifically consented to. It may be important to record the procedure(s) that were originally planned for, consented to, and perhaps pre-approved by the payer, particularly if different from the actual procedure(s) and procedure details, to provide evidence to various stakeholders that the providers are aware of the discrepancy and the justification can be found in the procedure details.

CONF-PN-137: The Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Planned Procedure section.

CONF-PN-138: A `Section/code` element **SHALL** be present where the value for `@code` is `PLNPROC-X PLANNED PROCEDURE 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-139: The Planned Procedure section **SHALL** include a `templateId` element where the value for `@root` is `2.16.840.1.113883.10.20.18.2.6`.

CONF-PN-140: The Planned procedure section **MAY** contain clinical statements. If present, the clinical statements **MAY** conform to the CCD Procedure activity template (`2.16.840.1.113883.10.20.1.29`), the CCD Product template (`2.16.840.1.113883.10.20.1.53`), and the CCD Product instance template (`2.16.840.1.113883.10.20.1.52`).

CONF-PN-141: The Indications section **MAY** contain clinical statements referring to imaging observations. If present, these clinical statements **MAY** conform to the PHCR Imaging observation template (`2.16.840.1.113883.10.20.15.3.5`), DIR Text Observation template (`2.16.840.1.113883.10.20.6.2.12`), DIR Code Observation template (`2.16.840.1.113883.10.20.6.2.13`), DIR Quantity Measurement Observation template (`2.16.840.1.113883.10.20.6.2.14`) or DIR SopInstance Observation template (`2.16.840.1.113883.10.20.6.2.8`).

Figure 35: Planned procedure section example

```
<component>
   <section>
      <templateId root="2.16.840.1.113883.10.20.18.2.6”
      <code code="PLNPROC-X" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="PLANNED PROCEDURE"/>
      <title>Planned Procedure</title>
      <text>Colonoscopy</text>
   </section>
</component>
```

Specimens Removed SPECRE-X

The Specimens Removed section records the tissues, objects, or samples taken from the patient during the procedure including biopsies, aspiration fluid, or other samples sent for pathological analysis. The narrative may include a description of the specimens.

CONF-PN-142: The Procedure Note **MAY** contain exactly one and **SHALL NOT** contain more than one Specimens Removed section.

CONF-PN-143: A `Section/code` element **SHALL** be present where the value for `@code` is `SPECRE-X SPECIMENS REMOVED 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-PN-144: The Specimens Removed section **SHALL** include a `templateId` element where the value for `@root` is `2.16.840.1.113883.10.20.18.2.10`.

CONF-PN-145: Specimens Removed section **SHALL** list all specimens removed or **SHALL** explicitly state that no specimens were removed.

CONF-PN-146: The Specimens Removed section **MAY** contain clinical statements. If present, the clinical statements **MAY** conform to the CCD Procedure activity template (`2.16.840.1.113883.10.20.1.29`).

CONF-PN-147: Specimens Removed section clinical statements **MAY** contain one or more `specimen` participant entries to reflect specimens that were obtained as part of the procedure.

CONF-PN-148: Each specimen **SHOULD** contain one `specimen/specimenRole/id`.

Figure 36: Specimens removed section with entry example

```
<component>
   <section>
      <templateId root="2.16.840.1.113883.10.20.18.2.10"/>
      <code code="SPECRE-X" codeSystem="2.16.840.1.113883.6.1"
       codeSystemName="LOINC" displayName="SPECIMENS REMOVED"/>
      <title>Specimens Removed</title>
      <text>
         <list>
           <item>Ascending colon polyp</item>
         </list>
      </text>
      <entry>
         <procedure classCode="PROC" moodCode="EVN">
           <id root="d68b7e32-7810-4f5b-9cc2-acd54b0fd86d"/>
           <code code="274025005" codeSystem="2.16.840.1.113883.6.96"
                 displayName="Colonic polypectomy"/>
           <specimen typeCode="SPC">
             <specimenRole classCode="SPEC">
               <id root="c2ee9ee9-ae31-4628-a919-fec1cbb58683"/>
               <specimenPlayingEntity>
                  <code code="309226005"
codeSystem="2.16.840.1.113883.6.96"
                        displayName="Colonic polyp sample"/>
               </specimenPlayingEntity>
             </specimenRole>
           </specimen>
         </procedure>
       </entry>
   </section>
</component>
```

References

- ASTM's Standard Specifications for Healthcare Document Formats (E2184.02) (Headings and subheadings used in the health care industry and associated with specific report types)
- LOINC®: Logical Observation Identifiers Names and Codes, Regenstrief Institute
- CDAR2AIS0000R021: *HL7 Additional Information Specification Implementation Guide* [HL7 Attachments Special Interest Group (ASIG)]
- CDAR2AIS0004R030: *Additional Information Specification 0004, Clinical Reports Attachment*
- *HL7 ASIG CDA R2 Attachment for Clinical Notes*
- CDA: Clinical Document Architecture Release 2: May 2005
- IHE XDS-MS: *IHE Patient Care Coordination, Technical Framework*, Volumes 1, 2, 3 and 10, Revision 3.0, 2007-2008
- *HL7 Implementation Guide for CDA Release 2: History and Physical (H&P) Notes, DSTU Release 1* CDAR2_HPRPT_R1_D2_2007SEP approved as DSTU - Published July 2008. DSTU period: begin Aug 20, 2008, end Aug 20, 2010.
- *HL7 Implementation Guide for CDA Release 2: Consultation Notes*
- *HL7 Implementation Guide for CDA Release 2: Imaging Integration; Basic Imaging Reports in CDA and DICOM, Release 1*. Available to non-HL7 members at https://www.hl7.or/store/index.cfm.
- *CCD: Continuity of Care Document* (CCD) ASTM/HL7
- Joint Commission Operative Note Requirements: Standard IM.6.30, Elements of Performance for IM.6.30

APPENDIX A — ACRONYMS AND ABBREVIATIONS

AHDI	Association for Healthcare Documentation Integrity
AHIMA	American Health Information Management Association
ASGE	American Society for Gastrointestinal Endoscopy
CCD	Continuity of Care Document
CDA	Clinical Document Architecture
CRS	Care Record Summary
DICOM	Digital Imaging and Communications in Medicine
DIR	Diagnostic Imaging Report
EHR	electronic health record
DSTU	Draft Standard for Trial Use
GP	general practitioner
H&P	History and Physical
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
HTML	Hyper-text Markup Language
ICU	intensive care unit
IG	implementation guide
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standard Development Organisation
LOINC	Logical Observation Identifiers Names and Codes
MTIA	Medical Transcription Industry Association
NPP	non physician providers
NUCC	Healthcare Provider Taxonomy Code
PACU	post anesthesia care unit
PCP	primary care provider
PDF	portable document format
PHCR	Public Health case reports
PHR	personal health record
PPRF	primary performers
RIM	Reference Information Model
SDO	Standards Development Organization
SNOMED CT	Systemized Nomenclature for Medicine – Clinical Terms
SOP	Service Object Pair
SPRF	secondary performers
SR	supplemental report

TIPS	transjugular intrahepatic portosystemic shunt
WADO	Web Access to Persistent DICOM Objects

APPENDIX B — TEMPLATE IDS IN THIS GUIDE

Table 6: Template IDs in This Guide

Template IDs defined in this guide	Description
2.16.840.1.113883.10.20.18.1	Procedure Note Clinical Document
2.16.840.1.113883.10.20.18.2.1	Indications Section
2.16.840.1.113883.10.20.18.2.2	Procedure Description Section
2.16.840.1.113883.10.20.18.2.3	Postprocedure Diagnosis Section
2.16.840.1.113883.10.20.18.2.4	Complications Section
2.16.840.1.113883.10.20.18.2.5	Medical History Section
2.16.840.1.113883.10.20.18.2.6	Planned Procedure Section
2.16.840.1.113883.10.20.18.2.7	Anesthesia Section
2.16.840.1.113883.10.20.18.2.8	Medications Administered Section
2.16.840.1.113883.10.20.18.2.9	Estimated Blood Loss Section
2.16.840.1.113883.10.20.18.2.10	Specimens Removed Section
2.16.840.1.113883.10.20.18.2.11	Implants Section
2.16.840.1.113883.10.20.18.2.12	Disposition Section
2.16.840.1.113883.10.20.18.2.13	Assessment Section
2.16.840.1.113883.10.20.18.2.14	Assessment and Plan Section
2.16.840.1.113883.10.20.18.2.15	Findings Section
2.16.840.1.113883.10.20.18.2.16	Chief Complaint Section
2.16.840.1.113883.10.20.18.2.17	Family History Section
2.16.840.1.113883.10.20.18.2.18	Procedure History Section
2.16.840.1.113883.10.20.18.3.1	Estimated Blood Loss Entry
CCD Template IDs	**Description**
2.16.840.1.113883.10.20.1.2	Allergies (Alerts) Section
2.16.840.1.113883.10.20.1.8	Medication History Section
2.16.840.1.113883.10.20.1.15	Social History Section
2.16.840.1.113883.10.20.1.10	Plan Section
2.16.840.1.113883.10.20.1.18	Alert Observation
2.16.840.1.113883.10.20.1.33	Social History Observation
2.16.840.1.113883.10.20.1.25	Plan of Care Activities
2.16.840.1.113883.10.20.1.27	Problem Act
2.16.840.1.113883.10.20.1.28	Problem Observation
2.16.840.1.113883.10.20.1.29	Procedure Activity
2.16.840.1.113883.10.20.1.24	Medication Activity
2.16.840.1.113883.10.20.1.34	Supply Activity
2.16.840.1.113883.10.20.1.50	Problem Status Observation
2.16.840.1.113883.10.20.1.51	Problem Healthstatus Observation
2.16.840.1.113883.10.20.1.52	Product Instance
2.16.840.1.113883.10.20.1.53	Product

H&P Template IDs	Description
2.16.840.1.113883.10.20.2.4	Vital Signs
2.16.840.1.113883.10.20.2.5	General Status
1.3.6.1.4.1.19376.1.5.3.1.3.4	History of Present Illness Section
2.16.840.1.113883.10.20.2.9	Past Medical History Section
1.3.6.1.4.1.19376.1.5.3.1.3.18	Review of Systems
2.16.840.1.113883.10.20.2.10	Physical Examination Section
PHCR Template ID	**Description**
2.16.840.1.113883.10.20.15.3.5	Imaging Observation
DIR Template IDs	**Description**
2.16.840.1.113883.10.20.6.2.13	Code Observation
2.16.840.1.113883.10.20.6.2.14	Quantity Measurement Observation
2.16.840.1.113883.10.20.6.2.8	SopInstance Observation
2.16.840.1.113883.10.20.6.2.12	Text Observation

APPENDIX C — ADDITIONAL PHYSICAL EXAMINATION SUBSECTIONS

Below is the list of additional optional subsections that may be used under the Physical Examination section. Most of the codes for these subsections are included in the HL7 document *CDAR2AIS0004R030, Additional Information Specification 0004: Clinical Reports Attachment*, which also lists General Status (10210-3) and Vital Signs (8716-3), defined in this guide in the appendix on External References.

Table 7: Additional Physical Examination Subsections

LOINC Code	Component Name
10190-7	MENTAL STATUS
11451-2	PSYCHIATRIC FINDINGS
10199-8	HEAD, PHYSICAL FINDINGS
10197-2	EYE, PHYSICAL FINDINGS
10195-6	EAR, PHYSICAL FINDINGS
10203-8	NOSE, PHYSICAL FINDINGS
11393-6	EARS & NOSE & MOUTH & THROAT, PHYSICAL FINDINGS
10201-2	MOUTH & THROAT & TEETH, PHYSICAL FINDINGS
51850-6	HEAD & EARS & EYES & NOSE & THROAT, PHYSICAL FINDINGS
11411-6	NECK, PHYSICAL FINDINGS
10207-9	THORAX & LUNGS, PHYSICAL FINDINGS
11391-0	CHEST, PHYSICAL FINDINGS
11392-8	CHEST WALL, PHYSICAL FINDINGS
10200-4	HEART, PHYSICAL FINDINGS
10193-1	BREASTS, PHYSICAL FINDINGS
10192-3	BACK, PHYSICAL FINDINGS
10191-5	ABDOMEN, PHYSICAL FINDINGS
10204-6	PELVIS, PHYSICAL FINDINGS
11403-3	GROIN, PHYSICAL FINDINGS
10198-0	GENITOURINARY TRACT, PHYSICAL FINDINGS
11400-9	GENITALIA, PHYSICAL FINDINGS
11401-7	GENITALIA FEMALE, PHYSICAL FINDINGS
11402-5	GENITALIA MALE, PHYSICAL FINDINGS
11388-6	BUTTOCKS, PHYSICAL FINDINGS
10205-3	RECTUM, PHYSICAL FINDINGS
10196-4	EXTREMITIES, PHYSICAL FINDINGS
11413-2	SHOULDER, PHYSICAL FINDINGS
11387-8	AXILLA, PHYSICAL FINDINGS
11386-0	UPPER ARM, PHYSICAL FINDINGS
11394-4	ELBOW, PHYSICAL FINDINGS
11398-5	FOREARM, PHYSICAL FINDINGS
11415-7	WRIST, PHYSICAL FINDINGS

LOINC Code	Component Name
11404-1	HAND, PHYSICAL FINDINGS
11406-6	HIP, PHYSICAL FINDINGS
11414-0	THIGH, PHYSICAL FINDINGS
11407-4	KNEE, PHYSICAL FINDINGS
11389-4	CALF, PHYSICAL FINDINGS
11385-2	ANKLE, PHYSICAL FINDINGS
11397-7	FOOT, PHYSICAL FINDINGS
10209-5	BALANCE+COORDINATION, PHYSICAL FINDINGS
10212-9	STRENGTH PHYSICAL FINDINGS
10211-1	SENSATION, PHYSICAL FINDINGS
10206-1	SKIN, PHYSICAL FINDINGS
10194-9	DEEP TENDON REFLEXES, PHYSICAL FINDINGS
10208-7	VESSELS, PHYSICAL FINDINGS
11384-5	PHYSICAL EXAMINATION BY ORGAN SYSTEMS
11447-0	HEMATOLOGIC+LYMPHATIC+IMMUNOLOGIC PHYSICAL FINDINGS
11390-2	CARDIOVASCULAR SYSTEM, PHYSICAL FINDINGS
11399-3	GASTROINTESTINAL SYSTEM, PHYSICAL FINDINGS
10202-0	NEUROLOGIC SYSTEM, PHYSICAL FINDINGS
11410-8	MUSCULOSKELETAL SYSTEM, PHYSICAL FINDINGS

APPENDIX D — EXTERNALLY DEFINED CONSTRAINTS

This appendix lists all of the external conformance statements referenced from the body of this document. For a complete description of these constraints, please refer to the original specification they were derived from.

As noted earlier, use of these templates for clinical statements in a Procedure Note is always optional and may not be appropriate for some implementations. The templates in this appendix are included for implementers who wish to implement a Level 3 CDA.

CCD Constraints

The Continuity of Care Document (CCD) was developed as a collaborative effort between ASTM and HL7. It is intended as an alternate implementation to the one specified in ASTM ADJE2369 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture.

The following constraints are from the final publication of (CCD) dated April 1, 2007. Any discrepancy between this and the original is inadvertent and in all cases, the CCD source takes precedence.

Alert Observation (Template ID: 2.16.840.1.113883.10.20.1.18)

CCD-CONF-262: An alert observation (templateId 2.16.840.1.113883.10.20.1.18) **SHALL** be represented with **Observation**.

CCD-CONF-263: The value for "**Observation / @moodCode**" in an alert observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CCD-CONF-264: An alert observation **SHALL** include exactly one **Observation / statusCode**.

CCD-CONF-265: The value for "**Observation / statusCode**" in an alert observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CCD-CONF-266: An alert observation **MAY** contain exactly one **Observation / effectiveTime**, to indicate the biological timing of condition (e.g. the time the condition started, the onset of the illness or symptom, the duration of a condition).

CCD-CONF-267: The value for "**Observation / value"** in an alert observation **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.4 AlertTypeCode **STATIC** 20061017.

CCD-CONF-268: The absence of known allergies **SHOULD** be represented in an alert observation by valuing **Observation / value** with 160244002 "No known allergies" 2.16.840.1.113883.6.96 SNOMED CT **STATIC**.

CCD-CONF-269: An alert observation **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

Medication Activity (Template ID: 2.16.840.1.113883.10.20.1.24)

CCD-CONF-304: A medication activity (templateId 2.16.840.1.113883.10.20.1.24) **SHALL** be represented with **SubstanceAdministration**.

CCD-CONF-305: The value for "**SubstanceAdministration / @moodCode**" in a medication activity **SHALL** be "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CCD-CONF-306: A medication activity **SHALL** contain at least one **SubstanceAdministration / id**.

CCD-CONF-307: A medication activity **SHOULD** contain exactly one **SubstanceAdministration / statusCode**.

CCD-CONF-308: A medication activity **SHOULD** contain one or more **SubstanceAdministration / effectiveTime** elements, used to indicate the actual or intended start and stop date of a medication, and the frequency of administration. (See section ***5.4.1 Dates and Times*** for additional details about time representation).

CCD-CONF-309: A medication activity **SHOULD** contain exactly one **SubstanceAdministration / routeCode**.

CCD-CONF-310: The value for "**SubstanceAdministration / routeCode**" in a medication activity **SHOULD** be selected from the HL7 RouteOfAdministration (2.16.840.1.113883.5.112) code system.

CCD-CONF-311: A medication activity **SHOULD** contain exactly one **SubstanceAdministration / doseQuantity** or **SubstanceAdministration / rateQuantity**.

CCD-CONF-312: A medication activity **MAY** contain exactly one **SubstanceAdministration / maxDoseQuantity**, which represents a maximum dose limit.

CCD-CONF-313: A medication activity **MAY** contain one or more **SubstanceAdministration / performer**, to indicate the person administering a substance.

CCD-CONF-314: A medication activity **MAY** have one or more associated consents, represented in the CCD Header as **ClinicalDocument / authorization / consent**.

CCD-CONF-315: A medication activity **SHALL** contain one or more sources of information, as defined in section **5.2 Source**.

Medications Section (Template ID: 2.16.840.1.113883.10.20.1.8)

The Medications section defines a patient's current medications and pertinent medication history. At a minimum, the currently active medications should be listed, with an entire medication history as an option, particularly when the summary document is used for comprehensive data export. The section may also include a patient's prescription history, and enables the determination of the source of a medication list (e.g. from a pharmacy system vs. from the patient).

CCD-CONF-298: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Medications section (templateId

2.16.840.1.113883.10.20.1.8). The Medications section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more medication activities (templateId 2.16.840.1.113883.10.20.1.24) and/or supply activities (templateId 2.16.840.1.113883.10.20.1.34).

CCD-CONF-299: The absence of known medications **SHALL** be explicitly asserted.

Plan of Care Activities (Template ID: 2.16.840.1.113883.10.20.1.25)

CCD-CONF-485: A plan of care activity (templateId 2.16.840.1.113883.10.20.1.25) **SHALL** be represented with **Act, Encounter, Observation, Procedure, SubstanceAdministration,** or **Supply**.

CCD-CONF-486: A plan of care activity **SHALL** contain at least one **[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply] / id**.

CCD-CONF-487: A plan of care activity **SHALL** contain exactly one **[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply] / @moodCode**.

CCD-CONF-488: The value for "**[Act | Encounter | Procedure] / @moodCode**" in a plan of care activity **SHALL** be ["INT" (intent) | "ARQ" (appointment request) | "PRMS" (promise) | "PRP" (proposal) | "RQO" (request)] 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CCD-CONF-489: The value for "**[SubstanceAdministration | Supply] / @moodCode**" in a plan of care activity **SHALL** be ["INT" (intent) | "PRMS" (promise) | "PRP" (proposal) | "RQO" (request)] 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CCD-CONF-490: The value for "**Observation / @moodCode**" in a plan of care activity **SHALL** be ["INT" (intent) | "PRMS" (promise) | "PRP" (proposal) | "RQO" (request) | "GOL" (goal)] 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CCD-CONF-491: A plan of care activity **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

Table 8: Summary of Allowable moodCode Values in CCD Plan of Care Section (CCD Table 2)

	Act	Encounter	Procedure	Substance Admin	Supply	Observation
INT (intent)	Allowed	Allowed	Allowed	Allowed	Allowed	Allowed
ARQ (appt request)	Allowed	Allowed	Allowed	Not Allowed	Not Allowed	Not Allowed
PRMS (promise)	Allowed	Allowed	Allowed	Allowed	Allowed	Allowed
PRP (proposal)	Allowed	Allowed	Allowed	Allowed	Allowed	Allowed
RQO (request)	Allowed	Allowed	Allowed	Allowed	Allowed	Allowed
GOL (goal)	Not Allowed	Not Allowed	Not Allowed	Not Allowed	Not Allowed	Allowed

Problem Act (Template ID: 2.16.840.1.113883.10.20.1.27)

CCD-CONF-145: A problem act (templateId 2.16.840.1.113883.10.20.1.27) **SHALL** be represented with **Act**.

CCD-CONF-146: The value for "**Act / @classCode**" in a problem act **SHALL** be "ACT" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CCD-CONF-147: The value for "**Act / @moodCode**" in a problem act **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CCD-CONF-148: A problem act **SHALL** contain at least one **Act / id**.

CCD-CONF-149: The value for "**Act / code / @NullFlavor**" in a problem act **SHALL** be "NA" "Not applicable" 2.16.840.1.113883.5.1008 NullFlavor **STATIC**.

CCD-CONF-150: A problem act **MAY** contain exactly one **Act / effectiveTime**, to indicate the timing of the concern (e.g. the interval of time for which the problem is a concern).

CCD-CONF-151: A problem act **SHALL** contain one or more **Act / entryRelationship**.

CCD-CONF-152: A problem act **MAY** reference a problem observation, alert observation (see section ***3.8 Alerts***) or other clinical statement that is the subject of concern, by setting the value for "**Act / entryRelationship / @typeCode**" to be "SUBJ" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC.

CCD-CONF-153: The target of a problem act with **Act / entryRelationship / @typeCode="**SUBJ**" SHOULD** be a problem observation (in the Problem section) or alert observation (in the Alert section, see section ***3.8 Alerts***), but **MAY** be some other clinical statement.

Problem Healthstatus Observation (Template ID: 2.16.840.1.113883.10.20.1.51)

CCD-CONF-166: A problem healthstatus observation (templateId 2.16.840.1.113883.10.20.1.51) **SHALL** be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57) (as defined in section *5.1 "Type" and "Status" Values*), except that the value for "**Observation / code**" in a problem healthstatus observation **SHALL** be "11323-3" "Health status" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CCD-CONF-167: The value for "**Observation / value**" in a problem healthstatus observation **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.12 ProblemHealthStatusCode **STATIC** 20061017.

Problem Observation (Template ID: 2.16.840.1.113883.10.20.1.28)

CCD-CONF-154: A problem observation (templateId 2.16.840.1.113883.10.20.1.28) **SHALL** be represented with **Observation**.

CCD-CONF-155: The value for "**Observation / @moodCode**" in a problem observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CCD-CONF-156: A problem observation **SHALL** include exactly one **Observation / statusCode**.

CCD-CONF-157: The value for "**Observation / statusCode**" in a problem observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CCD-CONF-158: A problem observation **SHOULD** contain exactly one **Observation / effectiveTime**, to indicate the biological timing of condition (e.g. the time the condition started, the onset of the illness or symptom, the duration of a condition).

CCD-CONF-159: The value for "**Observation / code"** in a problem observation **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.14 ProblemTypeCode **STATIC** 20061017.

CCD-CONF-160: The value for "**Observation / entryRelationship / @typeCode**" in a problem observation **MAY** be "SUBJ" "Subject" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC** to reference an age observation (templateId 2.16.840.1.113883.10.20.1.38).[2]

CCD-CONF-161: A problem observation **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

Problem Status Observation(Template ID: 2.16.840.1.113883.10.20.1.50)

ASTM CCR, in addition to the Status observations defined in many sections, defines a restricted set of optional **HealthStatus** values ("Alive And Well", "In Remission", "Symptom Free", "Chronically Ill", "Severely Ill", "Disabled", "Severely Disabled", "Deceased") that describe the status of the patient

[2] Note that entryRelationship / inversionInd can be used to distinguish relationship source vs. target.

overall as a result of a particular problem, represented in CCD as an associated problem healthstatus observation.

CCD-CONF-162: A problem observation **MAY** contain exactly one problem status observation.

CCD-CONF-163: A problem status observation (templateId 2.16.840.1.113883.10.20.1.50) **SHALL** be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57) (as defined in section *5.1 "Type" and "Status" Values*).

CCD-CONF-164: The value for "**Observation / value**" in a problem status observation **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.13 ProblemStatusCode **STATIC** 20061017.

CCD-CONF-165: A problem observation **MAY** contain exactly one problem healthstatus observation.

Procedure Activity (Template ID: 2.16.840.1.113883.10.20.1.29)

CCD-CONF-427: A procedure activity (templateId 2.16.840.1.113883.10.20.1.29) **SHALL** be represented with **Act**, **Observation**, or **Procedure**.

CCD-CONF-428: The value for "**[Act | Observation | Procedure] / @moodCode**" in a procedure activity **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CCD-CONF-429: A procedure activity **SHALL** contain at least one **[Act | Observation | Procedure] / id**.

CCD-CONF-430: A procedure activity **SHALL** contain exactly one **[Act | Observation | Procedure] / statusCode**.

CCD-CONF-431: The value for "**[Act | Observation | Procedure] / statusCode**" in a procedure activity **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.15 ProcedureStatusCode **STATIC** 20061017.

CCD-CONF-432: A procedure activity **SHOULD** contain exactly one **[Act | Observation | Procedure] / effectiveTime**.

CCD-CONF-433: A procedure activity **SHALL** contain exactly one **[Act | Observation | Procedure] / code**.

CCD-CONF-434: The value for "**[Act | Observation | Procedure] / code**" in a procedure activity **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and **MAY** be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12), ICD9 Procedures (codeSystem 2.16.840.1.113883.6.104), ICD10 Procedure Coding System (codeSystem 2.16.840.1.113883.6.4).

CCD-CONF-435: A procedure activity **MAY** contain one or more **[Observation | Procedure] / methodCode** if the method isn't inherent in **[Observation | Procedure] / code** or if there is a need to

further specialize the method in **[Observation | Procedure] / code**. **[Observation | Procedure] / methodCode SHALL NOT** conflict with the method inherent in **[Observation | Procedure] / code**.

CCD-CONF-436: A procedure activity **MAY** contain one or more **[Observation | Procedure] / targetSiteCode** to indicate the anatomical site or system that is the focus of the procedure, if the site isn't inherent in **[Observation | Procedure] / code** or if there is a need to further specialize the site in **[Observation | Procedure] / code**. **[Observation | Procedure] / targetSiteCode SHALL NOT** conflict with the site inherent in **[Observation | Procedure] / code**.

CCD-CONF-437: A procedure activity **MAY** contain one or more location participations (templateId 2.16.840.1.113883.10.20.1.45) (see section ***3.15.22 Encounter location***), to represent where the procedure was performed.

CCD-CONF-438: A procedure activity **MAY** contain one or more **[Act | Observation | Procedure] / performer**, to represent those practioners who performed the procedure.

CCD-CONF-439: A procedure activity **MAY** contain one or more **entryRelationship / @typeCode="RSON"**, the target of which represents the indication or reason for the procedure.

CCD-CONF-440: **[Act | Observation | Procedure] / entryRelationship / @typeCode="RSON"** in a procedure activity **SHALL** have a target of problem act (templateId 2.16.840.1.113883.10.20.1.27), problem observation (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement.

CCD-CONF-441: A procedure activity **MAY** contain one or more patient instructions (templateId 2.16.840.1.113883.10.20.1.49) (see section ***3.9.2.2.2 Patient instructions***), to represent any additional information provided to a patient related to the procedure.

CCD-CONF-442: A procedure activity **MAY** have one or more associated consents, represented in the CCD Header as **ClinicalDocument / authorization / consent**.

CCD-CONF-443: A **Procedure** in a procedure activity **MAY** have one or more **Procedure / specimen**, reflecting specimens that were obtained as part of the procedure.

CCD-CONF-444: **Procedure / specimen / specimenRole / id SHOULD** be set to equal an **Organizer / specimen / specimenRole / id** (see section ***3.13 Results***) to indicate that the Procedure and the Results are referring to the same specimen.

CCD-CONF-445: The value for "**[Act | Observation | Procedure] / entryRelationship / @typeCode**" in a procedure activity **MAY** be "SUBJ" "Subject" 2.16.840.1.113883.5.1002 ActRelationshipType

STATIC to reference an age observation (templateId 2.16.840.1.113883.10.20.1.38).[3]

CCD-CONF-446: A procedure activity **MAY** have one or more **[Act | Observation | Procedure] / entryRelationship [@typeCode="COMP"]**, the target of which is a medication activity (templateId 2.16.840.1.113883.10.20.1.24) (see section ***3.9.2.1.1 Medication activity***, to describe substances administered during the procedure.

CCD-CONF-447: A procedure activity **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

Product (Template ID: 2.16.840.1.113883.10.20.1.53)

[Note: In the CCD IG, this section is called "Representation of a product".]

The template identifier for a product is 2.16.840.1.113883.10.20.1.53.

The template identifier for a product instance is 2.16.840.1.113883.10.20.1.52.

CCD-CONF-354: A medication activity **SHALL** contain exactly one **SubstanceAdministration / consumable**, the target of which is a product template.

CCD-CONF-355: A supply activity **MAY** contain exactly one **Supply / product**, the target of which is a product template.

CCD-CONF-356: A product (templateId 2.16.840.1.113883.10.20.1.53) **SHALL** be represented with the **ManufacturedProduct** class.

CCD-CONF-357: A **ManufacturedProduct** in a product template **SHALL** contain exactly one **manufacturedProduct / manufacturedMaterial**.

CCD-CONF-358: A **manufacturedMaterial** in a product template **SHALL** contain exactly one **manufacturedMaterial / code**.

CCD-CONF-359: The value for "**manufacturedMaterial / code**" in a product template **SHOULD** be selected from the RxNorm (2.16.840.1.113883.6.88) code system for medications, and from the CDC Vaccine Code (2.16.840.1.113883.6.59) code system for immunizations[4], or **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.8 MedicationTypeCode **STATIC** 20061017.

CCD-CONF-360: The value for "**manufacturedMaterial / code**" in a product template **MAY** contain a precoordinated product strength, product form, or product concentration (e.g. "metoprolol 25mg tablet", "amoxicillin 400mg/5mL suspension").

CCD-CONF-361: If **manufacturedMaterial / code** contains a precoordinated unit dose (e.g. "metoprolol 25mg tablet"), then

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[3] Note that entryRelationship / inversionInd can be used to distinguish relationship source vs. target.

[4] A table of CDC Vaccine Codes can be found at http://www.cdc.gov/vaccines/programs/iis/stds/cvx.htm.

SubstanceAdministration / doseQuantity SHALL be a unitless number that indicates the number of products given per administration.

CCD-CONF-362: If **manufacturedMaterial / code** does not contain a precoordinated unit dose (e.g. “metoprolol product”), then **SubstanceAdministration / doseQuantity SHALL** be a physical quantity that indicates the amount of product given per administration.

CCD-CONF-363: A **manufacturedMaterial** in a product template **SHALL** contain exactly one **Material / code / originalText**, which represents the generic name of the product.

CCD-CONF-364: A **manufacturedMaterial** in a product template **MAY** contain exactly one **Material / name**, which represents the brand name of the product.

ASTM CCR defines an optional product size element which can be used to describe the physical characteristics of a product. CDA R2 has no corresponding field, but can uniquely identify a given manufacturer’s product, thereby enabling a complete lookup of any detail related to the product.

CCD-CONF-365: A **ManufacturedProduct** in a product template **MAY** contain exactly one **manufacturedProduct / manufacturerOrganization**, which represents the manufacturer of the **Material**.

CCD-CONF-366: A **ManufacturedProduct** in a product template **MAY** contain one or more **manufacturedProduct / id**, which uniquely represent a particular kind of product.

CCD-CONF-367: If **ManufacturedProduct** in a product template contains **manufacturedProduct / id**, then **ManufacturedProduct SHOULD** also contain **manufacturedProduct / manufacturerOrganization**.

CCD-CONF-368: A medication activity **MAY** contain one or more product instance templates (templateId 2.16.840.1.113883.10.20.1.52) (see section ***3.14.2.2 Procedure related products***), to identify a particular product instance.

CCD-CONF-369: A supply activity **MAY** contain one or more product instance templates (templateId 2.16.840.1.113883.10.20.1.52) (see section ***3.14.2.2 Procedure related products***), to identify a particular product instance.

CCD-CONF-370: **Supply / participant / participantRole / id SHOULD** be set to equal a **[Act | Observation | Procedure] / participant / participantRole / id** (see section ***3.14.2.2 Procedure related products***) to indicate that the Supply and the Procedure are referring to the same product instance.

Product Instance (Template ID: 2.16.840.1.113883.10.20.1.52)

[Note: In the CCD IG, this section is called “Procedure related products”.]

The template identifier for a product is 2.16.840.1.113883.10.20.1.53.

The template identifier for a product instance is 2.16.840.1.113883.10.20.1.52.

CCD-CONF-448: A procedure activity **MAY** have one or more **[Act | Observation | Procedure] / participant [@typeCode="DEV"]**, the target of which is a product instance template.

CCD-CONF-449: A product instance (templateId 2.16.840.1.113883.10.20.1.52) **SHALL** be represented with the **ParticipantRole** class.

CCD-CONF-450: The value for "**participantRole / @classCode**" in a product instance **SHALL** be "MANU" "Manufactured product" 2.16.840.1.113883.5.110 RoleClass **STATIC**.

CCD-CONF-451: If **participantRole** in a product instance contains **participantRole / id**, then **participantRole SHOULD** also contain **participantRole / scopingEntity**.

CCD-CONF-452: **[Act | Observation | Procedure] / participant / participantRole / id SHOULD** be set to equal a **Supply / participant / participantRole / id** (see section ***3.9.2.4 Representation of a product***) to indicate that the Procedure and the Supply are referring to the same product instance.

Social History Observation (Template ID: 2.16.840.1.113883.10.20.1.33)

CCD-CONF-237:A social history observation (templateId 2.16.840.1.113883.10.20.1.33) **SHALL** be represented with **Observation.**

CCD-CONF-238: The value for "**Observation / @classCode**" in a social history observation **SHALL** be "OBS" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CCD-CONF-239: The value for "**Observation / @moodCode**" in a social history observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CCD-CONF-240: A social history observation **SHALL** contain at least one **Observation / id**.

CCD-CONF-241: A social history observation **SHALL** include exactly one **Observation / statusCode**.

CCD-CONF-242: The value for "**Observation / statusCode**" in a social history observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CCD-CONF-243: The value for "**Observation / code**" in a social history observation **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), or **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.18 SocialHistoryTypeCode **STATIC** 20061017.

CCD-CONF-244: **Observation / value** can be any datatype. Where **Observation / value** is a physical quantity, the unit of measure

SHALL be expressed using a valid Unified Code for Units of Measure (UCUM) expression.

CCD-CONF-245: A social history observation **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

Social History Section (Template ID: 2.16.840.1.113883.10.20.1.15)

This section contains data defining the patient's occupational, personal (e.g. lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity and religious affiliation. Social history can have significant influence on a patient's physical, psychological and emotional health and wellbeing so should be considered in the development of a complete record.

CCD-CONF-232: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Social history section (templateId 2.16.840.1.113883.10.20.1.15). The Social history section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more social history observations (templateId 2.16.840.1.113883.10.20.1.33).

CCD-CONF-233: The social history section **SHALL** contain **Section / code**.

CCD-CONF-234: The value for "**Section / code**" **SHALL** be "29762-2" "Social history" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CCD-CONF-235: The social history section **SHALL** contain **Section / title.**

CCD-CONF-236: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "social history".

Supply Activity (TemplateID: 2.16.840.1.113883.10.20.1.34)

ASTM CCR defines a <FulfillmentHistory> element, used to indicate details about a dispensing activity. This corresponds to a supply event (a supply activity in "EVN" mood) in CCD, used to report what was actually filled.

CCD-CONF-316: A supply activity (templateId 2.16.840.1.113883.10.20.1.34) **SHALL** be represented with **Supply**.

CCD-CONF-317: The value for "**Supply / @moodCode**" in a supply activity **SHALL** be "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CCD-CONF-318: A supply activity **SHALL** contain at least one **Supply / id**.

CCD-CONF-319: A supply activity **SHOULD** contain exactly one **Supply / statusCode**.

CCD-CONF-320: A supply activity **SHOULD** contain exactly one **Supply / effectiveTime**, to indicate the actual or intended time of dispensing.

CCD-CONF-321: A supply activity **MAY** contain exactly one **Supply / repeatNumber**, to indicate the number of fills. (Note that Supply / repeatNumber corresponds to the number of "fills", as opposed to the number of "refills").

CCD-CONF-322: A supply activity **MAY** contain exactly one **Supply / quantity**, to indicate the actual or intended supply quantity.

CCD-CONF-323: A supply activity **MAY** contain one or more **Supply / author**, to indicate the prescriber.

CCD-CONF-324: A supply activity **MAY** contain one or more **Supply / performer**, to indicate the person dispensing the product.

CCD-CONF-325: A supply activity **MAY** contain exactly one **Supply / participant / @typeCode = "LOC"**, to indicate the supply location.

CCD-CONF-326: A supply activity **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

DIR Constraints

The following constraints are from the final publication of the *Basic Imaging Reports in CDA and DICOM Diagnostic Imaging Reports (DIR)*, Release 1, dated February 2009. Any discrepancy between this and the original is inadvertent and in all cases, the DIR source takes precedence.

Code Observation (Template ID: 2.16.840.1.113883.10.20.6.2.13)

DICOM Template 2000 specifies that Imaging Report Elements of Value Type Code are contained in sections. The Imaging Report Elements are inferred from Basic Diagnostic Imaging Report Observations that consist of image references and measurements (linear, area, volume, and numeric). Coded Digital Imaging and Communications in Medicine (DICOM) Imaging Report Elements in this context are mapped to CDA-coded observations that are section components and are related to the `SopInstance` Observations (`templateId 2.16.840.1.113883.10.20.6.2.8`) or Quantity Measurement Observations (`templateId 2.16.840.1.113883.10.20.6.2.14`) by the `SPRT` (Support) act relationship.

CONF-DIR-157: The `templateId` for a Code Observation **SHALL** be `2.16.840.1.113883.10.20.6.2.13`.

CONF-DIR-158: Code Observations **SHALL** be represented as `observation` elements where `@classCode` is `OBS` and `@moodCode` is `EVN`.

CONF-DIR-159: A `code` element **SHALL** be present.

CONF-DIR-160: A `value` element **SHALL** be present.

CONF-DIR-161: An `effectiveTime` element **SHOULD** be present.

CONF-DIR-162: Code Observations **SHALL** be rendered into `section/text` in separate paragraphs.

CONF-DIR-163: Zero or more `entryRelationship` elements where `@typeCode` is `SPRT` **MAY** be present, each containing a `SopInstance` Observation (`templateId 2.16.840.1.113883.10.20.6.2.8`), or a Quantity Measurement Observation (`templateId 2.16.840.1.113883.10.20.6.2.14`).

Quantity Measurement Observation (Template ID: 2.16.840.1.113883.10.20.6.2.14)

A Quantity Measurement Observation is used to record quantity measurements based on image data such as linear, area, volume, and numeric measurements. The SNOMED CT codes in the SNOMED CT Quantity Measurement Type Codes table are from the qualifier hierarchy and are not valid for `observation/code` according to the Term Info guidelines. These codes can be used for backwards compatibility, but going forward, codes from the observable entity hierarchy will be requested and used.

CONF-DIR-164: The `templateId` for Quantity Measurement observations **SHALL** be `2.16.840.1.113883.10.20.6.2.14`.

CONF-DIR-165: A Quantity Measurement Observation **SHALL** be represented with an `observation` element.

CONF-DIR-166: A `code` element **SHALL** be present.

CONF-DIR-167: The value for `code/@code` and `code/@codeSystem` **SHOULD** be selected from the codes listed in the SNOMED CT Quantity Measurement Type Codes table or in the DICOM Quantity Measurement Type Codes table **DYNAMIC.**

Note that CDA and DICOM Supplemental Report (SR) have different conventions for the use of SNOMED identifiers. DICOM uses the old style SNOMED ID, while CDA uses the new concept ID format. This distinction is especially important when transforming from one standard to another.

CONF-DIR-168: In a CDA Diagnostic Imaging Report, SNOMED CT® concept IDs **SHOULD** be used.

CONF-DIR-169: A `value` element **SHALL** be present where `@xsi:type` **SHALL** be `PQ` (physical quantity), `@value` **SHALL** contain a numeric measurement, and `@unit` **SHALL** contain a valid UCUM expression.

CONF-DIR-170: An `effectiveTime` element **SHOULD** be present.

CONF-DIR-171: Zero or more `entryRelationship` elements where `@typeCode` is `SPRT` **MAY** be present, each containing a `SopInstance` Observation.

The value set of the `observation/code` includes numeric measurement types for linear dimensions, areas, volumes, and other numeric measurements. This value set is extensible and comprises the union of SNOMED codes for observable entities as reproduced in the SNOMED CT Quantity Measurement Type Codes table and DICOM codes contained in the Context Groups 7470 and 7472,as listed in the DICOM Quantity Measurement Type Codes table.

Table 9: SNOMED CT Quantity Measurement Type Codes (DIR Table 7)

SNOMED CT Quantity Measurement Observation Codes Code System OID 2.16.840.1.113883.6.96		
Concept ID	**Original SNOMED ID**	**Display Name**
439932008	F-00721	Length of structure
440357003	F-0072A	Width of structure
439934009	F-00723	Depth of structure
439984002	F-00726	Diameter of structure
439933003	F-00722	Long axis length of structure
439428006	F-00719	Short axis length of structure
439982003	F-00724	Major axis length of structure
439983008	F-00725	Minor axis length of structure
440356007	F-00729	Perpendicular axis length of structure
439429003	F-0071A	Radius of structure
440433004	F-0072B	Perimeter of non-circular structure
439747008	F-0071E	Circumference of circular structure
439748003	F-0071F	Diameter of circular structure
439746004	F-0071D	Area of structure
439985001	F-00727	Area of body region
439749006	F-00720	Volume of structure

Table 10: DICOM Quantity Measurement Type Codes (DIR Table 8)

DICOM (DCM) Quantity Measurement Observation Codes Code System OID 1.2.840.10008.2.16.4			
Code	**Display Name**	**DICOM Context Group ID (CID)**	**Description**
121211	Path length	7470	Linear Measurements
121206	Distance	7470	Linear Measurements
121207	Height	7470	Linear Measurements
121216	Volume estimated from single 2D region	7472	Volume Measurements
121218	Volume estimated from two non-coplanar 2D regions	7472	Volume Measurements
121217	Volume estimated from three or more non-coplanar 2D regions	7472	Volume Measurements
121222	Volume of sphere	7472	Volume Measurements
121221	Volume of ellipsoid	7472	Volume Measurements
121220	Volume of circumscribed sphere	7472	Volume Measurements
121219	Volume of bounding three dimensional region	7472	Volume Measurements

SopInstance Observation (Template ID: 2.16.840.1.113883.10.20.6.2.8)

A SopInstance Observation contains the DICOM Service Object Pair (SOP) Instance information for referenced DICOM composite objects. The SopInstance act class is used to reference both image and non-image DICOM instances. The text attribute contains the DICOM WADO reference.

CONF-DIR-126: The templateId for a SopInstance Observation **SHALL** be 2.16.840.1.113883.10.20.6.2.8.

CONF-DIR-127: A SopInstance observation **SHALL** be represented with an observation element where @classCode is DGIMG and @moodCode is EVN.

CONF-DIR-128: An id element **SHALL** be present where @root contains an OID representing the DICOM SOP Instance UID.

CONF-DIR-129: A code element **SHALL** be present where @codeSystem is 1.2.840.10008.2.6.1 DCMUID and @code is an OID for a valid SOP class name UID.

CONF-DIR-130: A text element **SHOULD** be present where @mediaType is application/dicom.

CONF-DIR-131: If a text element is present, it **SHALL** contain a reference element where @value contains a WADO reference as a URI.

CONF-DIR-132: An effectiveTime element **SHOULD** be present containing the content creation time.

CONF-DIR-133: If effectiveTime is present, it **SHALL** contain a value attribute and **SHALL NOT** contain low and high elements.

CONF-DIR-134: Zero or more entryRelationship elements where @typeCode is SUBJ **MAY** be present containing additional SopInstance Observations.

CONF-DIR-135: An entryRelationship element where @typeCode is RSON **MAY** be present containing a Purpose of Reference Observation (templateId 2.16.840.1.113883.10.20.6.2.9).

CONF-DIR-136: If the referenced DICOM object is a multiframe object and the reference does not apply to all frames, a component element where @typeCode is COMP **SHALL** be present containing a Referenced Frames Observation (templateId 2.16.840.1.113883.10.20.6.2.10).

Text Observation (Template ID: 2.16.840.1.113883.10.20.6.2.12)

Imaging Report Observations that consist of image references and measurements (linear, area, volume, and numeric). Text DICOM Imaging Report Elements in this context are mapped to CDA text observations that are section components and are related to the SopInstance Observations (templateId 2.16.840.1.113883.10.20.6.2.8) or Quantity Measurement Observations (templateId 2.16.840.1.113883.10.20.6.2.14) by the SPRT (Support) act relationship.

A Text Observation is required if the findings in the section text are represented as inferred from SopInstance Observations.

CONF-DIR-150: The templateId for a Text Observation **SHALL** be 2.16.840.1.113883.10.20.6.2.12.

CONF-DIR-151: Text observations **SHALL** be represented with the observation element where @classCode is OBS and @moodCode is EVN.

CONF-DIR-152: A code element **SHALL** be present.

CONF-DIR-153: A value element **SHALL** be present where @xsi:type **SHALL** be ED.

CONF-DIR-154: An effectiveTime element **SHOULD** be present.

CONF-DIR-155: The text element **MAY** contain a reference element pointing to the equivalent content in section/text, or it **MAY** simply duplicate the appropriate text.

CONF-DIR-156: Zero or more entryRelationship elements where @typeCode is SPRT **MAY** be present, each containing a SopInstance Observation (templateId 2.16.840.1.113883.10.20.6.2.8), or a Quantity Measurement Observation (templateId 2.16.840.1.113883.10.20.6.2.14).

H&P Note Constraints

The following constraints are from the final publication of the History and Physical (H&P) Note dated July 16, 2008. Any discrepancy between this and the original is inadvertent and in all cases, the H&P source takes precedence.

History of Present Illness Section (Template ID: 1.3.6.1.4.1.19376.1.5.3.1.3.4)

H&P-CONF-76: All constraints in this section were derived from CRS. This section **SHALL** include the template identifier for the History of Present Illness section (1.3.6.1.4.1.19376.1.5.3.1.3.4, as defined in the IHE PCC Technical Framework – XDS-MS). A H&P Note **SHALL** contain exactly one and **SHALL NOT** contain more than one History of Present Illness section (templateId 1.3.6.1.4.1.19376.1.5.3.1.3.4). The History of Present Illness section **SHALL** contain a narrative block and **SHOULD** contain clinical statements.

This section describes the history related to the chief complaint. It contains the historical details leading up to and pertaining to the patient's current complaint or reason for seeking medical care.

General Status Section (Template ID: 2.16.840.1.113883.10.20.2.5)

The General Status section describes general observations and readily observable attributes of the patient, including affect and demeanor, apparent age compared to actual age, gender, ethnicity, nutritional status based on appearance, body build and habitus (e.g., muscular, cachectic, obese), developmental or other deformities, gait and mobility, personal hygiene, evidence of distress, and voice quality and speech. These observations may be nested under this heading or directly under the Physical Exam heading.

H&P-CONF-88: A History and Physical Examination section **MAY** contain exactly one General Status section (templateId 2.16.840.1.113883.10.20.2.5).

H&P-CONF-89: The section code for the section describing General Status **SHALL** be `10210-3 [GENERAL STATUS, PHYSICAL FINDINGS)`.

Past Medical History Section (Template ID: 2.16.840.1.113883.10.20.2.9)

This section describes the past medical history for the patient. It may contain information about past procedures or other illnesses that might have a bearing on the patient's current illness. Since past medical history can include past surgical history and other procedures, the Procedure History section may be included under the Past Medical History section or it may stand alone as its own section. By the same token, problems can be recorded in a standalone Problems section or in a nested Problems section. Wherever used, procedures and problems should conform to the CCD template for CDA entries cited in the Problems section.

H&P-CONF-77: A History and Physical **SHALL** contain exactly one and **SHALL NOT** contain more than one Past Medical History section (templateId 2.16.840.1.113883.10.20.2.9). The Past Medical History section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements.

H&P-CONF-78: The section code for the section describing Past Medical History **SHALL** be *11348-0* (HISTORY OF PAST ILLNESS).

Review of Systems Section (Template ID: 1.3.6.1.4.1.19376.1.5.3.1.3.18)

H&P-CONF-83: All constraints from this section were derived from CRS. This section **SHALL** include the template identifier for the Review of Systems section (1.3.6.1.4.1.19376.1.5.3.1.3.18, as defined in the IHE PCC Technical Framework – XDS-MS). A History and Physical **SHALL** contain exactly one and **SHALL NOT** contain more than one Review of Systems section (templateId 3.6.1.4.1.19376.1.5.3.1.3.18). The Review of Systems section **SHALL** contain a narrative block and **SHOULD** contain clinical statements.

The review of systems is a relevant collection of symptoms and function systematically gathered by a clinician. It includes symptoms the patient is currently experiencing, some of which were not elicited during the history of present illness, as well as a potentially large number of pertinent negatives, e.g., symptoms that the patient was specifically asked if they had experienced or were currently experiencing, but had denied experiencing.

Vital Signs Section (Template ID: 2.16.840.1.113883.10.20.2.4)

The Vital Signs section contains measured vital signs at the time of the examination. Measurements may include some or all of the following: blood pressure, heart rate, respiratory rate, body temperature, and pulse oximetry. Comments on relative trends may be appropriate, but not required. This section can be a first-level section or nested under Physical Exam.

H&P-CONF-86: A History and Physical **SHALL** contain exactly one Vital Signs section (`templateId 2.16.840.1.113883.10.20.2.4`). The Vital Signs section **MAY** be contained within a History and Physical Examination section or **MAY** stand alone in a first level section.

H&P-CONF-87: The section code for the section describing vital signs in a conforming History and Physical **SHALL** be `8716-3 (VITAL SIGNS)`.

The Vital Signs section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Level 3 clinical statements **SHOULD** include one or more CCD vital signs organizers (templateId 2.16.840.1.113883.10.20.1.35), each of which **SHALL** contain one or more CCD result observations (templateId 2.16.840.1.113883.10.20.1.31).

PHCR Constraints

The following constraints are from the Public Health Case Reports (PHCR) informative guide. Any discrepancy between this and the final document is inadvertent and in all cases, the final PHCR document takes precedence.

Imaging Observation (Template ID: 2.16.840.1.113883.10.20.15.3.5)

This clinical statement represents radiologic image findings. It may be a simple coded value of an overall impression of a study, such as "radiologic infiltrates" and a statement of the procedure method that was used, such as "standard chest x-ray". Or, it could be an assertion of a finding with a narrative text explanation similar to the "Impression" section of a radiology report. It may also reference an external diagnostic image or the entire external document radiology report. The code/value can be coded (e.g., assertion: nodule) or it can be largely narrative (e.g., finding: A complete white out of left lung seen. The chest tube is dislodged.).

1. Conforms to CCD Problem observation Template (templateId: 2.16.840.1.113883.10.20.1.28).
2. SHALL contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) STATIC (CONF:829).
3. SHALL contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) STATIC (CONF:830).
4. SHALL contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.3.5" (CONF:849).
5. SHALL contain [1..*] **id** (CONF:821).
6. SHALL contain [1..1] **code** (CONF:822).
7. SHALL contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) STATIC (CONF:823).
8. SHOULD contain [0..1] **effectiveTime** (CONF:824).
9. SHALL contain [1..1] **value** (CONF:825).
10. MAY contain [0..1] **methodCode** (CONF:826).
11. MAY contain [0..*] **reference** (CONF:827).
    a. Such references, if present, SHALL contain [1..1] **@typeCode**="SBJ" *Subject* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) STATIC (CONF:828).
    b. Such references, if present, SHALL contain [1..1] **externalObservation** (CONF:831).
        i. This externalObservation SHALL contain [1..1] **@classCode**="DGIMG" *Diagnostic image* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) STATIC (CONF:832).

ii. This externalObservation SHALL contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) STATIC (CONF:833).
iii. This externalObservation SHALL contain [1..1] **id** (CONF:834).
iv. This externalObservation SHALL contain [1..1] **code** (CONF:835).

12. MAY contain [0..1] **reference** (CONF:842).
    a. This reference, if present, SHALL contain **@typeCode** (CONF:843).
    b. This reference, if present, SHALL contain [1..1] **externalDocument** (CONF:844).
        i. This externalDocument SHALL contain [1..1] **@classCode**="DOCCLIN" *Clinical document* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) STATIC (CONF:845).
        ii. This externalDocument SHALL contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) STATIC (CONF:846).
        iii. This externalDocument SHALL contain [1..1] **id** (CONF:847).
        iv. This externalDocument SHALL contain [1..1] **code** (CONF:848).

APPENDIX E — PARTICIPANT SCENARIO XML EXAMPLES

This appendix contains XML examples of the document participants found the Participant Scenarios table.

In the colonoscopy participant scenario, a surgeon refers a patient to an endoscopist. A colonoscopy is performed at an outpatient surgery center. The endoscopist inputs information into an EHR. The outpatient surgery center EHR generates a Procedure Note to send to the Hospital EHR.

Figure 37: Colonoscopy participant scenario

```
<component>
       <author>
              <time value="20100329224411+0500" />
              <assignedAuthor>
                     <id extension="IO00017" root="2.16.840.1.113883.19.5"
/>
                     <addr>
     ...
                     </addr>
      ...
                     <assignedPerson>
                            <name>
       <prefix>Dr.</prefix>
                                   <given>Tony</given>
                                   <family>Tum</family>
                            </name>
                     </assignedPerson>
              </assignedAuthor>
       </author>
       <custodian>
              <assignedCustodian>
                     <representedCustodianOrganization>
                            <id extension="12344"
root="2.16.840.1.113883.19.5" />
                            <name>Good Health clinic</name>
      ...
                     </representedCustodianOrganization>
              </assignedCustodian>
       </custodian>
       <informationRecipient>
              <intendedRecipient>
     ...
                     <receivedOrganization>
                            <id extension="12345"
root="2.16.840.1.113883.19.5" />
                            <name>Good Health Hospital</name>
                       ...
                     </receivedOrganization>
              </intendedRecipient>
       </informationRecipient>
```

```
       <legalAuthenticator>
              <time value="20100329224411+0600" />
              <signatureCode code="S" />
              <assignedEntity>
                     <id extension="IO00017" root="2.16.840.1.113883.19.5"
/>
                     <addr>
       ...
                     <assignedPerson>
                            <name>
       <prefix>Dr.</prefix>
                                   <given>Tony</given>
                                   <family>Tum</family>
                            </name>
                     </assignedPerson>
              </assignedEntity>
       </legalAuthenticator>
       <documentationOf>
              <serviceEvent classCode="PROC">
                     <code codeSystem="2.16.840.1.113883.6.12"
codeSystemName="CPT-4"
      code="45385" displayName="Colonoscopy with snare polypectomy" />
                     <effectiveTime>
                            <low value="201003291400" />
                            <width value="15" unit="m" />
                     </effectiveTime>
                     <performer typeCode="PRF">
                            <assignedEntity>
                                   <id extension="IO00017"
root="2.16.840.1.113883.19.5" />
                                   <code code="207RG0100X"
codeSystem="2.16.840.1.113883.11.19465"
                                    codeSystemName="NUCC"
displayName="Gastroenterologist" />
        ...
                                   <assignedPerson>
                                          <name>
       <prefix>Dr.</prefix>
                                   <given>Tony</given>
                                   <family>Tum</family>
                                          </name>
                                   </assignedPerson>
                            </assignedEntity>
                     </performer>
              </serviceEvent>
       </documentationOf>
     ...
              <componentOf>
              <encompassingEncounter>
                     <id root="4ac71514-6a10-4164-9715-f8d96af48e6d"/>
                                   <effectiveTime>
                            <low value="201003291200" />
                            <high value="201003291600" />
                     </effectiveTime>
                     <encounterParticipant typeCode="REF">
                            <time value="20100326"/>
                            <assignedEntity>
                                   <id extension="12343"
```

```
root="2.16.840.1.113883.19.5"/>
                                    <code code="208600000X"
codeSystem="2.16.840.1.113883.11.19465"
                              codeSystemName="NUCC" displayName="Surgeon"/>
                                 <assignedPerson>
                                             <name>
                                                    <given>Harold</given>

       <family>Hippocrates</family>
                                                    <suffix>MD</suffix>
                                             </name>
                                       </assignedPerson>
                                       <representedOrganization>
                                             <id
root="2.16.840.1.113883.19.5"/>
                                       </representedOrganization>
                                 </assignedEntity>
                           </encounterParticipant>
                     </encompassingEncounter>
       </componentOf>
<componentOf>
    <encompassingEncounter>
    <location>
        <healthCareFacility classCode="SDLOC">>
          <!-- Facility ID -->
          <id root="2.16.840.1.113883.3.117.1.1.5.1.1"/>
          <code codeSystem="2.16.840.1.113883.6.259"
                codeSystemName="HL7 HealthcareServiceLocation"
                code="1118-9"
                displayName=" Gastroenterology clinic"/>
        </healthCareFacility>
      </location>
    </encompassingEncounter>
  </componentOf>
 </component>
```

In the following scenario, a wart is removed during an office visit. The PCP dictates the procedure into the local transcription system. The transcription system generates a CDA Procedure Note to the EHR.

Figure 38: Office removal of wart participation scenario

```
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 <author>
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             <assignedAuthor>
                    <id extension="IO00018" root="2.16.840.1.113883.19.5"
/>
                    <addr>
     ...
                    </addr>
                    <assignedPerson>
                          <name>
       <prefix>Dr.</prefix>
                                <given>Sophie</given>
                                <family>Scratch</family>
                          </name>
```

```
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              </assignedAuthor>
       </author>
       <dataEnterer>
              <time value="20100329224411+0600" />
              <assignedEntity>
                    <id extension="IO00019" root="2.16.840.1.113883.19.5"
/>
                    ...
                    <assignedPerson>
                          <name>
                                <prefix>Mrs.</prefix>
                                <given>Ellen</given>
                                <family>Enter</family>
                          </name>
                    </assignedPerson>
              </assignedEntity>
       </dataEnterer>
       <custodian>
              <assignedCustodian>
                    <representedCustodianOrganization>
                          <id root="2.16.840.1.113883.19.5" />
                          <name>Lone Tree Island Clinic</name>
      ...
                          </addr>
                    </representedCustodianOrganization>
              </assignedCustodian>
       </custodian>
       <legalAuthenticator>
              <time value="20100329224411+0600" />
              <signatureCode code="S" />
              <assignedEntity>
                    <id extension="IO00018" root="2.16.840.1.113883.19.5"
/>
                    <addr>
        ...
                    </addr>
                    <telecom value="tel:(555)555-1002" use="WP" />
                    <assignedPerson>
                          <name>
                                <prefix>Dr.</prefix>
       <given>Sophie</given>
       <family>Scratch</family>
                          </name>
                    </assignedPerson>
              </assignedEntity>
       </legalAuthenticator>
       <documentationOf>
              <serviceEvent classCode="PROC">
                    <code codeSystem="2.16.840.1.113883.6.12"
codeSystemName="CPT-4"
        code="17110" displayName="Office Removal of Wart" />
                    <effectiveTime>
                          <low value="200906251400" />
                          <width value="15" unit="m" />
                    </effectiveTime>
                    <performer typeCode="PRF">
                          <assignedEntity>
```

```
                                    <id extension="IO00018"
root="2.16.840.1.113883.19.5" />
                                    <code code="207Q00000X"
codeSystem="2.16.840.1.113883.11.19465"
          codeSystemName="NUCC" displayName="Family Medicine" />
                                    <addr>
        ...
                                    </addr>
                                    <telecom value="tel:(999)555-1212" />
                                    <assignedPerson>
                                           <name>
                                    <prefix>Dr.</prefix>
       <given>Sophie</given>
       <family>Scratch</family>
                                           </name>
                                    </assignedPerson>
                             </assignedEntity>
                      </performer>
               </serviceEvent>
       </documentationOf>
   ...
 </component>
```

In the dental procedure scenario, a dentist extracts a tooth after the patient has a cleaning by the hygienist. He enters the information into his Dental EHR.

Figure 39:Dental procedure participation scenario

```
<component>
       <author>
              <time value="20100329224411+0500" />
              <assignedAuthor>
                     <id extension="IO00013" root="2.16.840.1.113883.19.5"
/>
                     <addr>
     ...
                     </addr>
    ...
                     <assignedPerson>
                            <name>
                                   <prefix>Dr.</prefix>
                                   <given>Charlie</given>
                                   <family>Chopper</family>
                            </name>
                     </assignedPerson>
              </assignedAuthor>
       </author>
       <custodian>
              <assignedCustodian>
                     <representedCustodianOrganization>
                            <id root="2.16.840.1.113883.19.5"/>
                            <name>Good Health Dental Clinic</name>
                            ...
                            <addr>
       ...
                            </addr>
                     </representedCustodianOrganization>
```

```
            </assignedCustodian>
      </custodian>
      <legalAuthenticator>
            <time value="20100329224411+0500" />
            <signatureCode code="S" />
            <assignedEntity>
                  <id extension="IO00013" root="2.16.840.1.113883.19.5"
/>
                  <addr>
     ...
                  </addr>
                  <telecom value="tel:(555)555-1002" use="WP" />
                  <assignedPerson>
                        <name>
                              <prefix>Dr.</prefix>
                  <given>Charlie</given>
            <family>Chopper</family>
                        </name>
                  </assignedPerson>
            </assignedEntity>
      </legalAuthenticator>
      <documentationOf>
            <serviceEvent classCode="PROC">
                  <code codeSystem="2.16.840.1.113883.6.12"
codeSystemName="CPT-4"
        code="XXXXX" displayName="Tooth Extraction" />
                  <effectiveTime>
                        <low value="201003291400" />
                        <width value="15" unit="m" />
                  </effectiveTime>
                  <performer typeCode="PRF">
                        <assignedEntity>
                              <id extension="IO00012"
root="2.16.840.1.113883.19.5" />
                              <code code="122300000X"
codeSystem="2.16.840.1.113883.11.19465"
            codeSystemName="NUCC" displayName="Dentist" />
                              <addr>
         ...
                              </addr>
                              <telecom value="tel:(999)555-1212" />
                              <assignedPerson>
                                    <name>
                              <prefix>Dr.</prefix>
                  <given>Charlie</given>
            <family>Chopper</family>
                                    </name>
                              </assignedPerson>
                        </assignedEntity>
                  </performer>
            </serviceEvent>
      </documentationOf>
      <documentationOf>
            <serviceEvent classCode="PROC">
                  <code codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT"
       code="87189000" displayName="Dental debridement"/>
```

```
      <effectiveTime>
                        <low value="201003291400" />
                        <width value="15" unit="m" />
                  </effectiveTime>
                  <performer typeCode="PRF">
                        <assignedEntity>
                              <id extension="1"
root="2.16.840.1.113883.10.20.18.7" />
                              <code code=" 124Q00000X"
codeSystem="2.16.840.1.113883.11.19465"
           codeSystemName="NUCC" displayName="Dental Hygienist" />
                              <addr>
       ...
                              </addr>
                              <telecom value="tel:(999)555-1212" />
                              <assignedPerson>
                                    <name>
                                          <prefix>Ms.</prefix>
                                          <given>Charlene</given>
                                          <family>Chopper</family>
                                    </name>
                              </assignedPerson>
                        </assignedEntity>
                  </performer>
            </serviceEvent>
      </documentationOf>
  ...
      </authorization>
 </component>
```

At a university hospital, a transjugular intrahepatic portosystemic shunt (TIPS) procedure is performed by the interventional radiology fellow, with the help of an interventional radiology nurse, under the supervision of an attending interventional radiologist. The radiology technician enters the data into the EMR. The patient was referred to the university hospital by his oncologist. The patient is insured by Cigna.

Figure 40: TIPS procedure (interventional radiology) participant scenario

```
<component>
      <author>
            <time value="20100329224411+0500" />
            <assignedAuthor>
                  <id extension="IO00013"
root="2.16.840.1.113883.19.5"/>
    <code code="390200000X" codeSystem="2.16.840.1.113883.11.19465"
    codeSystemName="NUCC" displayName="Health Care Fellow"/>
                  <assignedPerson>
                        <name>
       <prefix>Dr.</prefix>
                              <given>Horace</given>
                              <family>Helper</family>
                        </name>
                  </assignedPerson>
            </assignedAuthor>
      </author>
```

```
       <dataEnterer>
              <time value="20100329224411+0500" />
              <assignedEntity>
                     <id extension="IO00014"
root="2.16.840.1.113883.19.5"/>
              ...
                     <assignedPerson>
                            <name>
                                   <given>Ellen</given>
                                   <family>Enter</family>
                            </name>
                     </assignedPerson>
              </assignedEntity>
       </dataEnterer>
       <custodian>
              <assignedCustodian>
                     <representedCustodianOrganization>
                            <id root="2.16.840.1.113883.19.5" />
                            <name>Good Health University Hospital</name>
      ...
                     </representedCustodianOrganization>
              </assignedCustodian>
       </custodian>
       <legalAuthenticator>
              <time value="20100329224411+0500" />
              <signatureCode code="S" />
              <assignedEntity>
    <id extension="IO00016" root="2.16.840.1.113883.19.5"/>
                                   <code code="2085R0204X"
codeSystem="2.16.840.1.113883.11.19465"
              codeSystemName="NUCC"
              displayName="Vascular and Interventional Radiologist" />
     ...
                     <assignedPerson>
                            <name>
                                                 <prefix>Dr.</prefix>
                                                 <given>Christine</given>
                                                 <family>Curie</family>
                            </name>
                     </assignedPerson>
              </assignedEntity>
       </legalAuthenticator>
       <participant typeCode="IND">
              <associatedEntity classCode="UNDWRT">
                     <id root="4ff51570-83a9-47b7-91f2-93ba30373141"/>
         <addr>
                                   <streetAddressLine>5555 Insurers
Circle.</streetAddressLine>
                                   <city>Ann Arobor</city>
                                   <state>MI</state>
                                   <postalCode>99999</postalCode>
                      </addr>
                      <telecom value="555-555-3002"/>
                      <scopingOrganization>
                                <name> Cigna Healthcare </name>
                      </scopingOrganization>
              </associatedEntity>
       </participant>
```

```
       <documentationOf>
              <serviceEvent classCode="PROC">
                     <code codeSystem="2.16.840.1.113883.6.12"
codeSystemName="CPT-4"
    code="37182" displayName="Transjugular Intrahepatic Portosystemic
Shunt" />
                     <effectiveTime>
                            <low value="201003291400" />
                            <width value="15" unit="m" />
                     </effectiveTime>
                     <performer typeCode="PRF">
                            <assignedEntity>
                                   <id extension="IO00016"
root="2.16.840.1.113883.19.5"/>
                                   <code code="2085R0204X"
codeSystem="2.16.840.1.113883.11.19465"
              codeSystemName="NUCC"
              displayName="Vascular and Interventional Radiologist" />
                                   <addr>
          ...
                                   <assignedPerson>
                                          <name>
                                                 <prefix>Dr.</prefix>
                                                 <given>Christine</given>
                                                 <family>Curie</family>
                                          </name>
                                   </assignedPerson>
                            </assignedEntity>
                     </performer>
                     <performer typeCode="SPRF">
                            <assignedEntity>
                                   <id extension="RN1121"
root="2.16.840.1.113883.19.5"/>
                                   <code code="163WM0705X"
codeSystem="2.16.840.1.113883.11.19465"
                                          codeSystemName="NUCC"
displayName=" Medical-Surgical Nurse"/>
          ...
                                   <assignedPerson>
                                          <name>
                                                 <prefix>Ms.</prefix>
                                                 <given>Florence</given>

       <family>Nightengale</family>
                                          </name>
                                   </assignedPerson>
                            </assignedEntity>
                     </performer>
                     <performer typeCode="ATND">
                            <assignedEntity>
                                   <id extension="IO00017"
root="2.16.840.1.113883.19.5" />
              <code code="2085R0204X"
codeSystem="2.16.840.1.113883.11.19465"
                                          codeSystemName="NUCC"
displayName= "Vascular and Interventional
               Radiologist"/>
             ...
```

```
                                        <assignedPerson>
                                              <name>

      <prefix>Dr.</prefix>

      <given>Carol</given>

      <family>Cranium</family>
                                              </name>
                                        </assignedPerson>
                           </assignedEntity>
                     </performer>
                     <performer typeCode="REF">
                           <assignedEntity>
                                 <id extension="IO00020"
root="2.16.840.1.113883.19.5" />
                                 <code code="2085R0204X"
codeSystem="2.16.840.1.113883.11.19465"
                                        codeSystemName="NUCC"
displayName= "Oncologist"/>
          ...
                                        <assignedPerson>
                                              <name>

      <prefix>Dr.</prefix>

      <given>Trudy</given>

      <family>Tumor</family>
                                              </name>
                                        </assignedPerson>
                           </assignedEntity>
                     </performer>
            </serviceEvent>
      </documentationOf>
 </component>
```

At a university hospital, a lumbar puncture is performed by a medical student, with the help of an intern, under the supervisory authority of an attending neurologist. The student performs the procedure and dictates the note. The note is signed by the intern and attending. The patient has a family doctor that is not participating in the procedure, did not refer the patient, and does not have privileges at the providing organization but is recorded in the note.

Figure 41: Lumbar puncture (spinal tap) procedure participant scenario

```
<component>
      <author>
            <time value="20100329224411+0500" />
            <assignedAuthor>
                  <id extension="IO00011"
root="2.16.840.1.113883.19.5"/>
    <code code="390200000X" codeSystem="2.16.840.1.113883.11.19465"
```

```
    codeSystemName="NUCC" displayName="Health Care Student"/>
     ...
                    <assignedPerson>
                           <name>
                                  <given>Barry</given>
                                  <family>Brain</family>
                           </name>
                    </assignedPerson>
             </assignedAuthor>
       </author>
       <dataEnterer>
             <time value="20100329224352"/>
             <assignedEntity>
                    <id extension="IO00014"
root="2.16.840.1.113883.19.5"/>
     ...
                    <assignedPerson>
                           <name>
                                  <given>Ellen</given>
                                  <family>Enter</family>
                           </name>
                    </assignedPerson>
             </assignedEntity>
       </dataEnterer>
       <custodian>
             <assignedCustodian>
                    <representedCustodianOrganization>
                           <id root="2.16.840.1.113883.19.5" />
                           <name>Good Health University Hospital</name>
    ...
                    </representedCustodianOrganization>
             </assignedCustodian>
       </custodian>
       <informationRecipient>
             <intendedRecipient>
                    <id extension="IO00014"
root="2.16.840.1.113883.19.5"/>
      ...
                    <informationRecipient>
                           <name>
                                  <prefix>Dr.</prefix>
                                  <given>Fay</given>
                                  <family>Family</family>
                           </name>
                    </informationRecipient>
                    <receivedOrganization>
                           <id root="2.16.840.1.113883.19.51"/>
                           <name>Good Health Clinic #2</name>
                      ...
                    </receivedOrganization>
             </intendedRecipient>
       </informationRecipient>
       <Authenticator>
             <time value="20100329224411+0500" />
             <signatureCode code="S" />
             <assignedEntity>
                    <id extension="IO00027"
root="2.16.840.1.113883.19.5"/>
```

```
    <code code=”390200000X”
    codeSystem="2.16.840.1.113883.11.19465"
    displayName=”Healthcare Student”/>
                    <assignedPerson>
                           <name>
                                  <given>Iving</given>
                                  <family>Intern</family>
                           </name>
                    </assignedPerson>
             </assignedEntity>
       </Authenticator>
       <legalAuthenticator>
             <time value="20100329224411+0500" />
             <signatureCode code="S" />
             <assignedEntity>
                        <id extension="IO00016"
root="2.16.840.1.113883.19.5"/>
                                  <code code="207T00000X"
codeSystem="2.16.840.1.113883.11.19465"
             codeSystemName="NUCC"
             displayName="Neurological Surgeon" />
     ...
                    <assignedPerson>
                           <name>
       <prefix>Dr.</prefix>
                                  <given>Sally</given>
                                  <family>Sleeper</family>
                           </name>
                    </assignedPerson>
             </assignedEntity>
       </legalAuthenticator>
       <documentationOf>
             <serviceEvent classCode="PROC">
                    <code codeSystem="2.16.840.1.113883.6.12"
codeSystemName="CPT-4"
       code="62272" displayName="Lumbar Puncture" />
                    <effectiveTime>
                           <low value="201003291400" />
                           <width value="15" unit="m" />
                    </effectiveTime>
                    <performer typeCode="PRF">
                           <assignedEntity>
                    <id extension="IO00011"
root="2.16.840.1.113883.19.5"/>
    <code code="390200000X" codeSystem="2.16.840.1.113883.11.19465"
    codeSystemName="NUCC" displayName="Health Care Student"/>
             ...
                                  <assignedPerson>
                                         <name>
                                     <given>Barry</given>
                                     <family>Brain</family>
                                         </name>
                                  </assignedPerson>
                           </assignedEntity>
                    </performer>
             </serviceEvent>
       </documentationOf>
...
```

Appendix III.

Colonoscopy Note Example of Procedure Note Standard

Colonoscopy Note Example of Procedure Note Standard

```
<?xml version="1.0" encoding="utf-8"?>
<?xml-stylesheet type="text/xsl" href="cda.xsl"?>
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:voc="urn:hl7-org:v3/voc" xmlns:xsi="http://www.w3.org/2001/XMLSchema-
instance" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">

        <!--
Title: Procedure Note
Original Filename: Procedure_Note.xml
Version: 1.0
Revision History: 12/03/2009 TC created for 2009 winter ballot
        4/2010 Edits based on ballot comments for publishing
Specification: CDAR2_PROCNOTE_R1D1_2010MAY

This sample document was created by Thomas A. Carr, MD Oregon Health & Science University and Alschuler Associates, LLC, on
behalf of a project called Health Story founded by M*Modal, the American Health Information Management Association (AHIMA),
and the Association for Healthcare Documentation Integrity (AHDI).

For more information on Health Story please see www.healthstory.com
For more information on the "HL7 Implementation Guide for CDA Release 2: Procedure Note" see www.hl7.org, Structured
Documents Working Group
-->
        <!--
**********************************************************
 CDA Header
**********************************************************
        -->
        <realmCode code="UV" />
        <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040" />
        <!-- Conforms to the DSTU -->
        <templateId root="2.16.840.1.113883.10.20.18.1" />
        <!-- Fake document id for sample -->
        <id root="cefab940-52f4-11df-9879-0800200c9a66" />
        <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
        code="28570-0" displayName="Procedure Note" />
        <title>Procedure Note</title>
        <effectiveTime value="20100329224411+0500" />
        <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25" />
        <languageCode code="en-US" />
        <versionNumber value="1" />
        <recordTarget>
                <patientRole>
                        <id extension="12345" root="2.16.840.1.113883.19.5" />
                        <addr>
                            <streetAddressLine>555 Residential Lane</streetAddressLine>
                            <city>Ann Arbor</city>
                            <state>MI</state>
                            <postalCode>99999</postalCode>
                            <country>USA</country>
                        </addr>
                        <telecom value="tel:(555)555-1212" use="HP" />
                        <patient>
                                <name>
                                        <given>Adam</given>
                                        <family>Everyman</family>
                                </name>
                                <administrativeGenderCode code="M"
                                codeSystem="2.16.840.1.113883.5.1"
                                displayName="Male" />
                                <birthTime value="19541125" />
                                <!-- Guardian if patient is a minor -->
                                <guardian>
                                        <id extension="23456"
                                        root="2.16.840.1.113883.19.5" />
                                    <addr>
                                                <streetAddressLine>4444 Home
                                        Street</streetAddressLine>
                                                <city>Ann Arbor</city>
```

```
                        <state>MI</state>
                            <postalCode>99999</postalCode>
                        <country>USA</country>
                    </addr>
                            <telecom value="tel:(555)555-2004"
                            use="HP" />
                            <guardianPerson>
                                    <name>
                                            <given>Ralph</given>
                                            <family>Relative</family>
                                    </name>
                            </guardianPerson>
                    </guardian>
            </patient>
            <!--Providing Organization -->
            <providerOrganization>
                    <id root="2.16.840.1.113883.19.5" />
                    <name>Good Health Hospitals and Community
                    <telecom value="tel:(555)555-5000" use="WP" />
                    <addr>
                            <streetAddressLine>1000 Enterprise
                                    Blvd</streetAddressLine>
                            <city>Ann Arbor</city>
                            <state>MI</state>
                            <postalCode>99999</postalCode>
                            <country>USA</country>
                    </addr>
            </providerOrganization>
    </patientRole>
</recordTarget>
<!--Author -->
<author>
    <time value="20100329224411+0500" />
    <assignedAuthor>
            <id extension="IO00017"

                    <addr>
                            <streetAddressLine>1001 Hospital
                            Lane</streetAddressLine>
                            <city>Ann Arbor</city>
                            <state>MI</state>
                            <postalCode>99999</postalCode>
                            <country>USA</country>
                    </addr>
                    <telecom value="tel:(555)555-3101"
                    use="WP" />
                    <assignedPerson>
                            <name>
                                    <prefix>Dr.</prefix>
                                    <given>Tony</given>
                                    <family>Tum</family>
                            </name>
                    </assignedPerson>
            </assignedAuthor>
    </author>
    <!-- Custodian -->
    <custodian>
            <assignedCustodian>
                    <representedCustodianOrganization>
                            <id root="2.16.840.1.113883.19.5"
                            extension="1234" />
                            <name>Good Health clinic</name>
                            <telecom value="tel:(555)555-1002"
                            use="WP" />
                            <addr>
                        <streetAddressLine>103

                            <city>Ann Arbor</city>
                            <state>MI</state>
                        <postalCode>99999</postalCode>
```

```
                                                <country>USA</country>
                                        </addr>
                                </representedCustodianOrganization>
                        </assignedCustodian>
                </custodian>
                <informationRecipient>
                        <intendedRecipient>
                                <id extension="12345"
                                root="2.16.840.1.113883.19.5" />
                                <addr>
                                        <streetAddressLine>1030 Healthcare
                                        Drive</streetAddressLine>
                                        <city>Ann Arbor</city>
                                        <state>MI</state>
                                        <postalCode>99999</postalCode>
                                        <country>USA</country>
                                </addr>
                                <telecom value="tel:(555)555-1032"
                                use="WP" />
                                <informationRecipient>
                                        <name>
                                                <prefix>Dr.</prefix>
                                                <given>Fay</given>
                                                <family>Family</family>
                                        </name>
                                </informationRecipient>
                                <receivedOrganization>
                                        <id root="2.16.840.1.113883.19.5" />
                                        <name>Good Health Clinic</name>
                                        <telecom nullFlavor="NI" />
                                        <addr nullFlavor="NI" />
                                </receivedOrganization>
                        </intendedRecipient>
                </informationRecipient>
                <!-- Legal Authenticator -->
                <legalAuthenticator>
                        <time value="20100329224411+0600" />
                        <signatureCode code="S" />
                        <assignedEntity>
                                <id extension="IO00017"
                                root="2.16.840.1.113883.19.5" />

                                <addr>
                                        <streetAddressLine>1001 Hospital
                                        Lane</streetAddressLine>
                                        <city>Ann Arbor</city>
                                        <state>MI</state>
                                        <postalCode>99999</postalCode>
                                        <country>USA</country>
                                </addr>
                                <telecom value="tel:(555)555-1002"
                                use="WP" />

                        <assignedPerson>
                                <name>
                                        <prefix>Dr.</prefix>
                                        <given>Tony</given>
                                        <family>Tum</family>
                                </name>
                        </assignedPerson>
                </assignedEntity>
        </legalAuthenticator>
        <!-- Service event -->
        <documentationOf>
                <serviceEvent classCode="PROC">
                        <code codeSystem="2.16.840.1.113883.6.12"    codeSystemName="CPT-4" code="45385"
                        displayName="Colonoscopy with snare polypectomy" />
                        <effectiveTime>
                                <low value="201003292240" />
                                <width value="15" unit="m" />
```

```
                    </effectiveTime>
                    <!-- performer-->
                    <performer typeCode="PRF">
                        <assignedEntity>
                            <id extension="IO00017" root="2.16.840.1.113883.19.5" />
                            <code code="207RG0100X" codeSystem="2.16.840.1.113883.6.96"
                            codeSystemName="NUCC" displayName="Gastroenterologist" />
                            <addr>
                                <streetAddressLine>1001 Hospital Lane</streetAddressLine>
                                <city>Ann Arbor</city>
                                <state>MI</state>
                                <postalCode>99999</postalCode>
                                <country>USA</country>
                            </addr>
                            <telecom value="tel:(999)555-1212" />
                            <assignedPerson>
                                <name>
                                    <prefix>Dr.</prefix>
                                    <given>Tony</given>
                                    <family>Tum</family>
                                </name>
                            </assignedPerson>
                        </assignedEntity>
                    </performer>
                    <performer typeCode="SPRF">
                        <assignedEntity>
                            <id extension="RN1121" root="2.16.840.1.113883.19.5" />
                            <code code="163WM0705X" codeSystem="2.16.840.1.113883.11.19465"
                            codeSystemName="NUCC" displayName=" Medical-Surgical Nurse" />
                            <addr>
                                <streetAddressLine>1013 Healthcare Drive</streetAddressLine>
                                <city>Ann Arbor</city>
                                <state>MI</state>
                                <postalCode>99999</postalCode>
                                <country>USA</country>
                            </addr>
                            <telecom value="tel:(555)555-1013" />
                            <assignedPerson>
                                <name>
                                    <prefix>Ms.</prefix>
                                    <given>Florence</given>
                                    <family>Nightengale</family>
                                </name>
                            </assignedPerson>
                        </assignedEntity>
                    </performer>
            </serviceEvent>
    </documentationOf>
    <!-- consent example with fake LOINC code-->
    <authorization typeCode="AUTH">
            <consent classCode="CONS" moodCode="EVN">
                    <id root="629deb70-5306-11df-9879-0800200c9a66" />
                    <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" code="CONSP-X"
                    displayName="Consent for Surgical Procedure" />
                    <statusCode code="completed" />
            </consent>
    </authorization>
    <componentOf>
            <encompassingEncounter>
                    <id extension="KPENC1332" root="2.16.840.1.113883.19.5" />
                    <effectiveTime value="20100329" />
                    <encounterParticipant typeCode="REF">
                        <time value="20100326" />
                        <assignedEntity>
                            <id extension="KP00017" root="2.16.840.1.113883.19.5" />
                            <code code="208600000X" codeSystem="2.16.840.1.113883.11.19465"
                            codeSystemName="NUCC" displayName="Surgeon" />
                            <assignedPerson>
                                <name>
                                    <given>Harold</given>
```

```
                                                <family>Hippocrates</family>
                                                <suffix>MD</suffix>
                                        </name>
                                </assignedPerson>
                                <representedOrganization>
                                        <id root="2.16.840.1.113883.19.5" />
                                </representedOrganization>
                        </assignedEntity>
                </encounterParticipant>
                <location>
                        <healthCareFacility classCode="SDLOC">
                                <id root="2.16.840.1.113883.19.5" extension="1234" />
                                <code codeSystem="2.16.840.1.113883.6.259" codeSystemName="HL7
                                HealthcareServiceLocation" code="1118-9" displayName=" Gastroenterology
                                clinic" />
                        </healthCareFacility>
                </location>
        </encompassingEncounter>
</componentOf>
<!--
*****************************************************
CDA Body
*****************************************************
-->
<component>
        <structuredBody>
<!-- ***********************************************
Required Sections
***********************************************-->
<!-- ************************************
Indications
************************************ -->
                <component>
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                                <code code=" IND-X" codeSystem="2.16.840.1.113883.6.1"
                                codeSystemName="LOINC" displayName="INDICATIONS" />
                                <title>Indications</title>
                                <text> The procedure is performed for screening in a low risk individual.
                                </text>
                        </section>
                </component>
<!-- ************************************
Procedure Description
************************************ -->
                <component>
                        <section>
                                <templateId root="2.16.840.1.113883.10.20.18.2.2" />
                                <code code="29554-3" codeSystem="2.16.840.1.113883.6.1"
                                codeSystemName="LOINC" displayName="PROCEDURE DESCRIPTION" />
                                <title>Procedure Description</title>
                                <text>The patient was taken to the endoscopy suite where …. </text>
                        </section>
                </component>
<!-- ************************************
Post-procedure Diagnosis
************************************ -->
                <component>
                        <section>
                                <templateId root="2.16.840.1.113883.10.20.18.2.3" />
                                <code code="POSTPR-X" codeSystem="2.16.840.1.113883.6.1"
                                codeSystemName="LOINC"
                                displayName="POSTPROCEDURE DIAGNOSIS" />
                                <title>Postprocedure Diagnosis</title>
                                <text>
                                        <list listType="ordered">
                                                <item> Sigmoid diverticulosis, moderate</item>
                                                <item> Internal hemorrhoids</item>
                                                <item> Colon polyp, 6mm, ascending colon</item>
                                        </list>
```

```
                                        </text>
                                    </section>
                                </component>
<!-- ************************************
    Complications
    ************************************ -->
                                <component>
                                    <section>
                                        <templateId root="2.16.840.1.113883.10.20.18.2.4" />
                                        <code code="55109-3" codeSystem="2.16.840.1.113883.6.1"
                                        codeSystemName="LOINC" displayName="COMPLICATIONS" />
                                        <title>Complications</title>
                                        <text>None</text>
                                    </section>
                                </component>
<!--************************************
Assessment & Plan
************************************ -->
                                <component>
                                    <section>
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                                        <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
                                         code="51847-2" displayName="ASSESSMENT AND PLAN" />
                                        <title>Assessment and Plan</title>
                                        <text>
                                          <list listType="ordered">
                                          <item> Sigmoid diverticulosis, moderate. High fiber diet</item>
                                          <item> Internal hemorrhoids. Treat conservatively with Canasa
                                           suppositories </item>
                                           <item> Colon polyp, 6mm, ascending colon, removed by snare. Patient to
                                            call for results </item>
                                           </list>
                                        </text>
                                    </section>
                                </component>
<!-- ************************************************
    Optional Sections
    ************************************************-->
<!-- ************************************
    Medical History
    ************************************ -->
                                <component>
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                                        <templateId root="2.16.840.1.113883.10.20.18.2.5" />
                                        <code code="11329-0" codeSystem="2.16.840.1.113883.6.1"
                                        codeSystemName="LOINC" displayName="MEDICAL HISTORY" />
                                        <title>Medical History</title>
                                        <text>The patient is a 55 year old Caucasian male with a history of non-
                                         insulin dependent diabetes.</text>
                                    </section>
                                </component>
<!-- ************************************
    Physical Examination
    ************************************ -->
                                <component>
                                    <section>
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                                        <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
                                        code="29545-1" displayName="PHYSICAL FINDINGS" />
                                        <title>Physical Examination</title>
<!-- ************************************
        Physical findings Vital Signs
    ************************************ -->
                                        <component>
                                            <section>
                                                <templateId root="2.16.840.1.113883.10.20.18.16" />
                                                <code codeSystem="2.16.840.1.113883.6.1"
                                                    codeSystemName="LOINC" code="8716-3"
                                                     displayName="VITAL SIGNS" />
                                                     <title>Physical Findings - Vital Signs</title>
```

```
                                        <text>
                                            <paragraph>Heart Rate: 78, Respiratory  Rate: 12, Temp (degF): 96.7,
                                                Oxygen Sat (%): 100.</paragraph>
                                            <paragraph>Non-invasive Blood Pressure: Systolic: 107, Diastolic:
                                                51, Mean: 64.</paragraph>
                                        </text>
                                    </section>
                                </component>
                <!-- ************************************
                        General Status
                    ************************************ -->
                                <component>
                                    <section>
                                    <templateId root="2.16.840.1.113883.10.20.2.5" />
                                    <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" code="10210-
                3" displayName="GENERAL STATUS " />
                                    <title>GENERAL STATUS</title>
                                <text>
                                    <paragraph>Alert and in good spirits, no acute distress.</paragraph>
                                </text>
                            </section>
                </component>
                <!-- ************************************
                        Physical Findings - HEENT
                    ************************************ -->
                                                <component>
                                                    <section>
                                                    <code codeSystem="2.16.840.1.113883.6.1"
                                                    codeSystemName="LOINC" code="51850-6"
                                                    displayName="Physical Findings - HEENT" />
                                                    <title>Physical Findings - HEENT</title
                                                    <text>
                                                    <content>All normal to examination.</content>
                                                    </text>
                                                    </section>
                                                </component>
                                                                                        <!--
                                                ************************************
                                                        Physical Findings - HEART
                                                ************************************ -->

                                                    <component>

                                                    <section>

                                                    <code codeSystem="2.16.840.1.113883.6.1"
                                                    codeSystemName="LOINC" code="10200-4"
                                                    displayName="PHYSICAL FINDINGS- HEART" />
                                                <title>Physical Findings - HEART</title>
                                                    <text>
                                                            <content> RRR, no murmur.</content>
                                                    </text>
                                                </section>
                                            </component>
                                    </section>
                                </component>
            <!-- ************************************
                Planned Procedure
                ************************************ -->
                                <component>
                                    <section>
                                        <templateId root="2.16.840.1.113883.10.20.18.2.6" />
                                        <code code="PLNPROC-X" codeSystem="2.16.840.1.113883.6.1"
                                        codeSystemName="LOINC" displayName="PLANNED PROCEDURE" />
                                        <title>Planned Procedure</title>
                                        <text>Colonoscopy</text>
                                    </section>
                                </component>
            <!-- ************************************
                Anesthesia
```

```
    ****************************************** -->
                        <component>
                            <section>
                                <templateId root="2.16.840.1.113883.10.20.18.2.7" />
                                <code code="ANES-X" codeSystem="2.16.840.1.113883.6.1"
                                codeSystemName="LOINC" displayName="ANESTHESIA" />
                                <title>Anesthesia</title>
                                <text> Conscious sedation with propofol 200 mg IV </text>
                            </section>
                        </component>
<!-- ****************************************
    Medications Administered
    ****************************************** -->
                        <component>
                            <section>
                                <templateId root="2.16.840.1.113883.10.20.18.2.8" />
                                <code code="29549-3" codeSystem="2.16.840.1.113883.6.1"
                                codeSystemName="LOINC"
                                displayName="MEDICATIONS ADMINISTERED" />
                                <title>Medications Administered</title>
                                <text>Secretin 100 IU administered IV</text>
                            </section>
                        </component>
<!-- ****************************************
Medications History
****************************************** -->
                        <component>
                            <section>
                                <templateId root="2.16.840.1.113883.10.20.1.8" />
                                <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
                                code="10160-0" displayName="HISTORY OF MEDICATION USE" />
                                <title>Current Medication History</title>
                                <text>
                                  <list listType="ordered">
                                      <item>
                                          <content ID="m1">Lisinopril 5 mg</content>
                                          1 tablet once a day
                                              </item>
                                              <item>
                                                  <content ID="m2">Atenolol 25 mg</content> 1 tablet
                                                  once a day
                                      </item>
                                        </list>
                                            </text>
                                            <entry>
                                             <substanceAdministration classCode="SBADM"
                                              moodCode="EVN">
                                                  <consumable>
                                                  <manufacturedProduct>
                                                  <manufacturedLabeledDrug>
                                                  <code codeSystem="2.16.840.1.113883.6.88"
                                                  codeSystemName="RxNorm" code="203644”

                                                  <originalText>

                                                  <reference value="#m1" />

        </originalText>
                                                                                                  </code>

                    </manufacturedLabeledDrug>
                                                                          </manufacturedProduct>
                                                                  </consumable>
                                                  </substanceAdministration>
                                            </entry>
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                    <manufacturedLabeledDrug>
                                                                                                    <code
codeSystem="2.16.840.1.113883.6.88" codeSystemName="RxNorm" code="197380" displayName="ATENOLOL--PO
25MG TAB">

                    <originalText>

                    <reference value="#m2" />

</originalText>
                                                                                                    </code>

                    </manufacturedLabeledDrug>
                                                                                                        </manufacturedProduct>
                                                                                                    </consumable>
                                                                                                </substanceAdministration>
                                                                                            </entry>
                                                                                        </section>
                                                                                    </component>
                <!-- ****************************************
                    Estimated Blood Loss
                    **************************************** -->
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                                                                                        <section>
                                                                                            <templateId root="2.16.840.1.113883.10.20.18.2.9" />
                                                                                            <code code=" EBL-X" codeSystem="2.16.840.1.113883.6.1"
                                                                                        codeSystemName="LOINC" displayName="ESTIMATED BLOOD LOSS" />
                                                                                            <title>Estimated Blood Loss</title>
                                                                                            <text>Minimal</text>
                                                                                        </section>
                                                                                    </component>
<!-- ****************************************
    Specimens Removed
    **************************************** -->
                                                                                    <component>
                                                                                        <section>
                                                                                            <templateId root="2.16.840.1.113883.10.20.18.2.10" />
                                                                                            <code code="SPECRE-X" codeSystem="2.16.840.1.113883.6.1"
                                                                                            codeSystemName="LOINC" displayName="SPECIMENS REMOVED" />
                                                                                            <title>Specimens Removed</title>
                                                                                            <text>
                                                                                                <list>
                                                                                                    <item>Ascending colon polyp</item>
                                                                                                </list>
                                                                                            </text>
                                                                                            <entry>
                                                                                                <procedure classCode="PROC" moodCode="EVN">
                                                                                                    <id root="d68b7e32-7810-4f5b-9cc2-acd54b0fd86d" />
                                                                                                    <code code="274025005" displayName="Colonic
                                                                                                    polypectomy" />
                                                                                                    <specimen typeCode="SPC">
                                                                                                        <specimenRole classCode="SPEC">
                                                                                                    <id root="c2ee9ee9-ae31-4628-a919-fec1cbb58683" />
                                                                                            <specimenPlayingEntity>
                                                                                                <code code="309226005"   codeSystem="2.16.840.1.113883.6.96"
                                                                                                    displayName="colon polyp sample" />
                                                                                            </specimenPlayingEntity>
                                                                                            </specimenRole>
                                                                                        </specimen>
                                                                                    </procedure>
                                                                                </entry>
                                                                            </section>
                                                                        </component>
<!-- ****************************************
    Implants
    **************************************** -->
                                                                        <component>
                                                                            <section>
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                                        <templateId root="2.16.840.1.113883.10.20.18.2.11" />
                                        <code code="IMPL-X" codeSystem="2.16.840.1.113883.6.1"
                                        codeSystemName="LOINC" displayName="IMPLANTS" />

                                        <title>Implants</title>
                                        <text>No implants were placed.</text>
                                    </section>
                                </component>
<!-- ************************************
    Findings
    ************************************ -->
                                <component>
                                    <section>
                                        <templateId root="2.16.840.1.113883.10.20.18.2.15" />
                                        <code code="FIND-X" codeSystem="2.16.840.1.113883.6.1"
                                        codeSystemName="LOINC" displayName="FINDINGS" />
                                        <title>Procedure Note Findings</title>
                                        <text>A 6 mm sessile polyp was found in the ascending colon and removedby
                                            snare, no cautery. Bleeding was controlled. Moderate diverticulosis and
                                                hemorrhoids were incidentally noted.</text>
                                    </section>
                                </component>
<!-- ************************************
    Dispostion
    ************************************ -->
                                <component>
                                    <section>
                                        <templateId root="2.16.840.1.113883.10.20.18.2.12" />
                                        <code code="DISPO-X" codeSystem="2.16.840.1.113883.6.1"
                                        codeSystemName="LOINC" displayName="DISPOSITION" />
                                        <title>Disposition</title>
                                        <text>The patient was taken to the Endoscopy Recovery Unit in stable
                                                condition.</text>
                                    </section>
                                </component>
                            </structuredBody>
                        </component>
</ClinicalDocument>
```