

**Concise Consolidated CDA:
*Deploying Encounter Summary CDA
Documents with Clinical Notes***

June 2018



Executive Summary

In the Fall of 2017, the independent Carequality and CommonWell Content Work Groups were attempting to solve a set of common issues: unacceptably large C-CDA documents, an absence of clinical notes in exchanged documents, support for encounter summary documents, and the need for document version management. The initiatives agreed to launch a Joint Document Content Work Group (JDCWG) in January 2018 with participants that included clinicians, vendor representatives, and standards development representatives.

This white paper defines a path to improve the content in C-CDA exchange, while acknowledging the realities of present day documentation and exchange practices. The intended audience of this guidance is C-CDA implementers, product development teams, and software developers.

The recommendations resulting from this joint effort include the following:

- Implementers should support Encounter Summary Documents in addition to Patient Summary Documents
- Encounter Summary Documents should be based upon the C-CDA template for Progress Note (Outpatient/Ambulatory) or Discharge Summary (Inpatient/Hospital)
- Implementers should incorporate Clinical Notes in C-CDA implementations
- Content in Encounter Summary Documents should only reflect information at the time of the encounter
- Implementers should only include a subset of the ONC Common Clinical Data Set by default in an Encounter Summary Document, and only if that data was validated during the encounter
- Implementers should include a Section Time Range Observation for each section in an Encounter Summary Document
- Implementers should construct C-CDAs that reflect the scope of document query parameters

The next steps related to these recommendations are for Carequality and CommonWell representatives to present them to their respective Steering Divisions to determine how to encourage implementation. Additionally, these recommendations will be shared with HL7 for possible inclusion in a future version of C-CDA.

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1 Introduction

Carequality and the CommonWell Health Alliance are two industry initiatives committed to the seamless exchange of healthcare information. This guide is the result of a joint development effort of the Content Workgroups within each initiative to improve the content of Consolidated CDA exchange.

1.1 Purpose

This document provides guidance for including Clinical Notes, and guidance for exchanging Encounter Summary CDA Documents. A Clinical Note is narrative text a clinician wrote, dictated, or copied from other portions of the patient's chart. An Encounter Summary CDA document will include this Clinical Note (required) plus other relevant sections with discrete data as generated by the system and/or included per clinician instructions.

This document complements the Health Level Seven (HL7) CDA® R2 IG: C-CDA Templates for Clinical Notes STU Release 2.1. It is also not a replacement for the C-CDA Templates for Clinical Notes R1 Companion Guide, which primarily supports the requirements of the ONC 2015 Edition Certification Criteria (2015 Edition) Certified Electronic Health Record Technology requirements. The guidance provided here will be considered in a future update to C-CDA.

1.2 Audience

The primary audience of this guide is C-CDA implementers, product development teams, and software developers. This guide provides detailed guidance for placement of clinical information in C-CDA and best practices for system generators and receivers. Software architects, business analysts, and policy managers can also benefit from understanding the preferred approach of supporting Encounter Summary documents in addition to Patient Summary documents.

1.3 Background and Development Approach

In the fall of 2017, independent Carequality and CommonWell Content Work Groups were attempting to solve a set of common issues: unacceptably large C-CDA documents, an absence of clinical notes in exchanged documents, support for encounter summary documents, and the need for document version management. Participants from both content work groups approached the Directors of Carequality and CommonWell to consider a single joint effort to tackle these common issues. The Joint Work Group launched in January 2018. Participants in the Joint Content Work Group included clinicians, vendor representatives and participants involved in standards development.

The principles of the Joint Content Work Group were as follows:

1. Maintain an initiative agnostic perspective
2. The product of the work group should be a best practices document
 1. Exact format to be determined
 2. Carequality and CommonWell may reference document or incorporate into their material

3. All final material will have joint branding or none
3. Development will occur in single content work group
4. Initiatives will independently review and approve guidance
5. Any guidance developed may be transitioned over to HL7 for balloting and maintenance

The Joint Work Group set clinical and technical priorities in the first call as follows:

Clinical

1. Require Encounter specific document support
 1. Outpatient/Ambulatory Summary (Progress Note Document) with defined sections
 2. Inpatient/Hospital Summary (Discharge Summary Document) with defined sections
2. Determine most frequently used Clinical Note types¹ - develop examples for each to include in encounter specific documents
3. Develop guidance on Note placement within documents for generator and consumer
4. Require Patient Summary
 1. Define patient-level (not encounter specific) sections to always include
 2. Future – Define default time ranges for each section

Technical

1. Develop guidance for document versioning

Prior to the launch of the Joint Content Work Group each individual content work group discussed tackling the size of exchanged CCDs by discussing appropriate content restriction by section. It became clear, that even improved filtering of a single patient CCD wouldn't solve the information overload for clinicians reviewing documents that could sometimes be over 1,000 pages in length.

The group focused on the importance of providing focused information to the clinician at the time they need it. The group identified encounter specific document support, including clinical notes, as the top priority. Members felt that the information provided by clinical notes would provide critical supplemental context to the discrete data they were currently getting in Patient Summary CCD documents. They also felt that these notes should not be added to the already long Patient Summary CCD documents they were receiving.

After the Joint Content Work Group finalized priorities, weekly calls were scheduled to develop and review design approaches. Decisions were made through discussion and consensus without the implementation of formal voting.

1.3.1 Sources and Process

The Joint Content Work Group considered the C-CDA R2.1, and Companion Guide as the baseline for all discussions. As a guiding principle, the Joint Content Work Group focused on providing complementary,

¹ With support from our Argonaut colleagues!

not conflicting guidance. Starting in January 2018, the Joint Content Work Group met weekly to develop solutions to the identified priorities. The presentations from each week reside in a shared [google drive](#).

Other standard or guides referenced through the development:

- Health Level Seven (HL7) CDA® R2 IG: C-CDA Templates for Clinical Notes STU [Release 2.1](#)
- HL7 CDA R2 IG: C-CDA Templates for Clinical Notes R1 Companion Guide, [Release 1](#)
- Draft ONC U.S. Core Data for Interoperability ([USCDI](#))

2 Encounter Summary Documents

An encounter summary document is primarily a clinician authored collection of information specific to a single patient interaction with a clinician, care team or hospitalization. The document may be provided to a patient immediately upon, or soon after, the conclusion of their visit even if all the information related to that visit is not yet available. For example, an encounter may have pending laboratory results or may lack a finalized clinician note or discharge summary when a patient departs. However, an encounter summary document may be updated when additional encounter specific data is available (i.e. finalized). A complete encounter summary includes any information that may have been updated after the conclusion of the encounter. See [Document Versioning](#) section for guidance on how to manage documents versions and updates.

For the purposes of document exchange, this guide focuses on two Encounter Summary Document types:

- Outpatient/Ambulatory Encounter Summary
- Inpatient/Hospital Encounter Summary

It is important to note these two broad categories may not perfectly align with patient billing classes. This guide does not define exact scenarios of when to use each type of encounter summary. The group consensus was to use the outpatient/ambulatory encounter summary for office visits, and use the inpatient/hospital encounter summary for overnight stays in hospitals. For hospital outpatient services (ambulatory surgery, etc.) or inpatient rehabilitation the provider/organization may need to determine which encounter summary document type is most appropriate.

This supplement provides guidance for generating the C-CDA Progress Note Document to exchange information associated with an Outpatient/Ambulatory Encounter, and the C-CDA Discharge Summary Document to exchange information associated with an Inpatient/Hospital Encounter. The Joint Content Work Group selected these information exchange documents because they were designed to support the most generic, encounter level documents currently available. After systems support the Progress Note Document, and the Discharge Summary Document, implementers are encouraged to implement additional document types that support specific use cases, for example Consultation Note Document.

Implementation of the Encounter Summary Documents complements the existing [Patient Summary](#) document exchanged by systems today. Encounter Summary Documents provide information about the patient used or generated during the encounter. Patient Summary Documents provide the current and historical information about a patient. The Joint Content Work Group decided that in order for systems to provide a complete picture of a patient's history, they **SHALL** provide access to, at a minimum, one Encounter Summary Document for each available encounter and a current Patient Summary Document.

To help understand this decision, the Joint Content Work Group considered the following scenario:

1. A clinician requests a patient's historical visits from 9/1/2017-12/1/2017.

2. The patient had 3 visits during this time, so the system returns 3 individual Encounter Summary Documents.
3. Each Encounter Summary Document includes the information (e.g. Medication List) at the conclusion of the encounter.

Systems that are unable to report information that is accurate to the time of the encounter **SHALL NOT** include current information instead. If a system provided the current Medication list with each Encounter Summary, rather than the encounter specific list, all of the documents would have the same information making it impossible for the clinician to determine the state of the patient at the time of the encounter. Thus, systems without the ability to produce a Medication list that accurately reflected the Medications at the end of the encounter, **SHALL NOT** include a Medication list in the Encounter Summary Document.

2.1 Document Body Guidance

The CDA document body communicates clinical content through sections. C-CDA R2.1 includes robust recommendations for required and optional sections for the C-CDA Progress Note Document and the C-CDA Discharge Document which were determined by the review of thousands of clinical documents. The additional guidance here complements this prior work. When HL7 considers a new ballot, members of the Joint Content Work Group will submit these recommendations for inclusion.

The content work group selected sections for the [Progress Note Document](#) and [Discharge Summary Document](#) using these guidelines:

1. Include all sections required in the base C-CDA document template
2. Include a priority subset of clinical data drawn from the ONC Common Clinical Data Set (CCDS) and draft US Core Data for Interoperability (USCDI).
3. Systems **SHOULD** send a 'No information' assertion template if nothing is available² for one of the priority subset data elements.
4. Systems **MAY** send additional data elements, beyond the priority subset, if relevant to the encounter. For these additional data elements, systems should not send a 'No information' template if nothing is available.

Many systems include the data required in the Common Clinical Data Set (CCDS) in every C-CDA document even if that data is not updated, or relevant, to an encounter. The participants in the Joint Content Work Group recommended that only a priority subset of such data elements always be included (listed below), and only if they were reviewed or reconciled during an encounter. This approach is consistent with ONC's requirement that systems must support sending all CCDS for certification purposes, but also allows the clinician to determine what is relevant for a particular encounter document. The Joint Content Work Group recognizes that reconciliation does not occur the same way in

² See HL7 Approved C-CDA Example [No Information](#)

every system and provides no guidance on this activity. A goal of the Joint Content Work Group is for systems to only include information which is relevant and current at the time of the encounter.

Data elements that require review **SHALL NOT** be included in the Encounter Summary Document if the clinician did not review or reconcile this data at the time of the encounter.

Guidance for key sections:

- Problems - Include those addressed during the encounter as Encounter Diagnoses
- Allergies - Include only if the system can recreate the active Allergy list at the time of encounter, including those recorded in prior encounters.
- Medications - Include only if the system can recreate Medications at time of encounter.
- Immunizations - Include immunizations given during the encounter.

Systems **SHALL NOT** auto-populate the latest information (i.e. current active medications) in a historical Encounter Summary Document.³

Additionally, every section must comply with the following guidance:

- Each section must include the Section Time Range Observation to communicate the date and time range of the information included in the section. See [Section Time Range](#) section for more detail.
- If the section is required (see [Progress Note Document](#) and [Discharge Summary Document](#)) it must include a 'No information'⁴ assertion if no information is included for a section.

2.1.1 Section Time Range

In current exchanges, sending systems include varying amount of information in sections. For example, one sender might include immunizations for the current encounter, while another might include all immunizations on record for the patient. When an end-user reviews a section they may not know what portion of the available data the sender included. HL7 introduced a new observation, the Section time range observation⁵, to communicate what is included in a section. It was balloted with the C-CDA Companion Guide and is available for use in any existing C-CDA section.

The purpose statement from the Companion Guide: This observation represents the date and time range of the information contained in a section. It is an optional entry and may be used in any section.

³ An exception to this rule is if the last encounter is recent and does contain current information.

⁴HL7 example for sending '[No Information](#)'

⁵ C-CDA R2.1 Companion Guide Section Time Range Observation (2.16.840.1.113883.10.20.22.4.201:2016-06-01)

The Joint Content Work Group recommends all sections include this observation and corresponding text. The text should be included underneath the section header and state either:

- The section includes all information for this encounter
- Or, the section includes information corresponding to a time range with a low and a high value

[-] Procedures for the Encounter					
This section includes all Surgical Procedures and Surgical Procedure Notes associated to the Encounter.					
Surgical Procedures					
This section includes all Surgical Procedures associated to the Encounter.					
Date/Time	Procedure Type	Procedure Qualifiers	Procedure	Provider	Source
Sep 20, 2017	SIMPLE REPAIR OF SUPERFICIAL WOUNDS OF FACE, EARS, EYELIDS, NOSE, LIPS AND/OR MUCOUS MEMBRANES; 2.5 CM OR LESS		RHINOPLASTY (Non-OR)	SULLIVAN,DANIELLE H	CHEYENNE VAMC

Figure 1 – Sample display of Section Time Range

2.2 Outpatient/Ambulatory Summary (Progress Note Document)

The content work group selected the C-CDA Progress Note document template⁶ to support Outpatient/Ambulatory Encounter Summary Document exchange. The Progress Note is a generic document which supports any outpatient visit. It is a first step towards systems exchanging more specific document types per encounter type.

The preferred LOINC document type code is 11506-3, Provider-unspecified Progress note, although systems may send more specific codes from the `ProgressNoteDocumentTypeCode` urn:oid:2.16.840.1.113883.11.20.8.1 value set.

Figure 2 – Progress Note Document Section Requirements, below, identifies the sections the Joint Content Work Group recommends be required for implementations of the Progress Note document type intended to serve as an Outpatient/Ambulatory Summary.

⁶C-CDA R2.1 Progress Note templateId: 2.16.840.1.113883.10.20.22.1.9:2015-08-01

	Required	Required if Reviewed ⁷
Outpatient/Ambulatory Summary (Progress Note Document)	Assessment and Plan Section (V2)	Allergies and Intolerances Section (entries required) (V3)
	Clinical Notes ⁸ (may include Subjective)	Medications Section (entries required) (V2)
	Encounter Section (V3) with encounter diagnoses for the <u>specific encounter</u>	Immunizations Section (entries required) (V3)

Figure 2 – Progress Note Document Section Requirements

The Progress Note Document is not restricted to these sections. Clinicians, or specific sites, may choose to include other sections relevant to the encounter (Results, Vital Signs, etc.).

2.3 Inpatient/Hospital Summary (Discharge Summary Document)

The content work group selected the C-CDA Discharge Summary document template⁹ to support Inpatient/Hospital Encounter Summary Document exchange. The Discharge Summary is a key document for patients transitioning from the hospital to a new care setting.

The preferred LOINC document type code is 18842-5, Discharge Summary note, although systems may send more specific codes from the `DischargeSummaryDocumentTypeCode` value set `urn:oid:2.16.840.1.113883.11.20.4.1`.

Figure 3 – Discharge Summary Document Section Requirements, below, identifies the sections the Joint Content Work Group recommends be required for implementations of the Discharge Summary document type intended to serve as an Inpatient/Hospital Summary.

⁷Only include if the system is confident a user has reviewed or reconciled the list and is current to the Encounter Summary Document. On generation, systems may include the [IHE Reconciliation](#) template to record an explicit reconciliation act.

⁸C-CDA R2.1 Companion Guide Notes Section 2.16.840.1.113883.10.20.22.2.65:2016-11-01

⁹C-CDA R2.1 Discharge Summary templateId: 2.16.840.1.113883.10.20.22.1.8:2015-08-01

	Required	Required if Reviewed
Inpatient/Hospital Summary (Discharge Summary Document)	Allergies and Intolerances Section (entries required) (V3)	Problem Section (entries required) (V3)(not covered by Discharge Diagnosis)
	Hospital Course (C-CDA) = Discharge Note ¹⁰	Medications <ul style="list-style-type: none"> - Admission medications list (patient reported/home medications)¹¹ - Facility Administered¹² (Given during admission) - Discharge Medications list¹³
	Clinical Notes ¹⁴ (may include Subjective)	Immunizations Section (entries required) (V3)
	Discharge Diagnosis Section (V3)	
	Plan of Treatment Section (V2)	

Figure 3 – Discharge Summary Document Section Requirements

The Discharge Summary Document is not restricted to these sections. Clinicians, or specific sites, MAY choose to include other sections relevant to the encounter (Results, Vital Signs, etc.).

2.4 Clinical Notes

Clinician authored Clinical Notes capture the health story of a patient – this may include their past and current health as well as planned next steps to improve their health. Clinical Notes are a critical part of the patient record. Prior to the formation of the Joint Content Work Group the independent Carequality and CommonWell content work groups were discussing methods to exchange Clinical Notes in C-CDA. Additionally, in response to requirements within the 21st Century Cures Act to identify a common set of data for exchange, the Office of the National Coordinator (ONC) proposed the U.S. Core Data for Interoperability (USCDI) include Clinical Notes. The exchange of Clinical Notes is also a high priority for the further development of the Fast Healthcare Interoperability Resources (FHIR) specification as supported through the Argonaut Project. Fortunately, for all activities HL7 drafted an initial approach for

¹⁰ If discharge note summarizes what occurred in the hospital - include Note Activity, label text as 'Discharge Note'.

¹¹Admission Medications Section (entries optional) (V3) (2.16.840.1.113883.10.20.22.2.44:2015-08-01)

¹²Medications Administered Section (V2) (2.16.840.1.113883.10.20.22.2.38:2014-06-09)

¹³Discharge Medication (V3) (2.16.840.1.113883.10.20.22.4.35:2016-03-01)

¹⁴ C-CDA R2.1 Companion Guide Notes Section 2.16.840.1.113883.10.20.22.2.65:2016-11-01

exchanging in the HL7 C-CDA companion guide¹⁵ using the new Notes Section¹⁶ and Notes Activity¹⁷. The HL7 guidance provided a baseline for the additional guidance here.

2.4.1 Common Clinical Note Types

The LOINC terminology includes thousands of different note types. To focus the industry, the Argonaut participants and the Department of Veterans Affairs contributed their most commonly used note types to develop the following list of top notes:

- Discharge documentation (8648-8 and/or 18842-5)
- Consultation (11488-4)
- Imaging narrative (18726-0)
- Lab/path narrative
- History & Physical (34117-2)
- Progress note
- Procedures note (28570-0)

The list is not in a priority order, nor does it represent the exclusive list of what systems can and will support. All systems are encouraged to support this list and additional notes from the [Note Types](#) value set. Any future standards publications should not be restricted to this list.

2.4.2 Sending Clinical Notes in C-CDA

The introduction of the Notes Section and Notes Activity entry templates in the HL7 C-CDA companion guide provided structure and guidance for sending notes. Depending on the clinician workflow, and the discrete information available at time of document creation, the participants agreed on three potential approaches in priority order:

1. Include Note(s) directly attached to the associated act
2. Include Note(s) in an appropriate standard section
3. Include Note(s) in a stand-alone notes section

2.4.2.1 Note directly attached to the associated act

When a note is specifically about an action a clinician performed, the note should reference that action. For example, a Procedure Note is linked, or nested within, the procedure it documents. When direct attribution is possible (as an entryRelationship), the clinical note should be included in the appropriate section where the act is included. Receiving systems should be prepared for Clinical Notes directly embedded in an act and provide a control to display, at minimum, and be able to expand or collapse the note. For example, if the Procedure section had 5 procedures, it is preferable to display the 5 procedures in a flat list or table, with an option, possibly a '+' sign, to allow the user to expand and read each individual Procedure note.

¹⁵ HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R1 Companion Guide, Release 1

¹⁶ C-CDA R2.1 Companion Guide Notes Section 2.16.840.1.113883.10.20.22.2.65:2016-11-01

¹⁷ C-CDA R2.1 Companion Guide Note Activity 2.16.840.1.113883.10.20.22.4.202:2016-11-01

```

<section>
  <templateId root="2.16.840.1.113883.10.20.22.2.7" extension="2014-06-09"/>
  <!-- Procedures section template -->
  <code code="47519-4" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC" displayName="PROCEDURES" />
  <title>Procedures</title>
  <text>
    <table>
      <thead><tr><th>Procedure</th><th>Date</th></tr></thead>
      <tbody>
        <tr><td ID="Procl">Appendectomy</td><td>January 25, 2018</td></tr>
        <tr>
          <td ID="ProclNote" colspan="2">
            <paragraph>Operative Note - Dr. Surgeon - 01/25/2018</paragraph>
            <paragraph>Patient repositioned with arms extended on arm
              boards...</paragraph>
          </td>
        </tr>
      </tbody>
    </table>
  </text>
  <entry typeCode="DRIV">
    <!-- C-CDA Procedure Activity Procedure entry -->
    <procedure classCode="PROC" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.14"
        extension="2014-06-09"/>
      <templateId root="2.16.840.1.113883.10.20.22.4.14"/>
      <code code="80146002" codeSystem="2.16.840.1.113883.6.96"
        displayName="Appendectomy" />
      ...
      <!-- Start of Note Activity as related to an existing procedure -->
      <entryRelationship typeCode="COMP">
        <act classCode="ACT" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.22.4.202"
            extension="2016-11-01"/>
          <code code="34109-9" codeSystem="2.16.840.1.113883.6.1"
            displayName="Note">
            <translation code="28570-0" codeSystem="2.16.840.1.113883.6.1"
              displayName="Procedure note" />
          </code>
          <text><reference value="#ProclNote" /></text>
          ...
        </act>
      </entryRelationship>
    </procedure>
  </entry>
</section>

```

Figure 4 – Example of Note Attached to an Act

2.4.2.2 Note is in an appropriate section

In some situations, the generating system may only be able to place the Note in an appropriate section, and not the specific creation action. For example, when a system is unable to nest the Procedure Note within a procedure act (as an entryRelationship) but is able to place the Note Activity in the Procedure Section. Alternatively, the system may place the Note Activity in an otherwise text-only section, such as the Hospital Course section as demonstrated below in Figure 5.

```
<section>
  <!-- C-CDA Hospital Course Section -->
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.5"/>
  <code code="8648-8" displayName="HOSPITAL COURSE"
        codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title>Hospital Course</title>
  <text>
    <list styleCode="TOC">
      <item ID="DischargeSummary">
        <caption>Chung, Anthony - 09/13/2016 2:46 PM CDT</caption>
        <paragraph>The patient was admitted and started on Lovenox and
          nitroglycerin paste...
        </paragraph>
      </item>
    </list>
  </text>
  <entry>
    <!-- Note Activity Entry -->
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.202"
                extension="2016-11-01"/>
      <code code="34109-9" codeSystem="2.16.840.1.113883.6.1"
            displayName="Note">
        <translation code="8648-8" codeSystem="2.16.840.1.113883.6.1"
                    displayName="Discharge Summary" />
      </code>
      <text><reference value="#DischargeSummary" /></text>
      ...
    </act>
  </entry>
</section>
```

Figure 5 – Example of Note Added to an Appropriate Section

2.4.2.3 Note in stand-alone Notes Section

When a system only knows the Note Type, and the Note Activity doesn't align to an existing C-CDA section, the Note Activity may be sent in the generic Notes Section with an appropriate LOINC code indicating the type of note. Some systems may choose this approach over inserting into existing section and potentially creating clutter for the end user. For example, a system creating an Encounter Summary

for which there are many consultation notes, may choose to put those notes in a standalone Notes Section to avoid cluttering up the Encounter Section.

```
<section>
  <!-- Notes Section -->
  <templateId root="2.16.840.1.113883.10.20.22.2.65" extension="2016-11-01"/>
  <code code="11488-4" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC" displayName="Consultation note"/>
  <title>Consultation Notes</title>
  <text>
    <list>
      <item ID="ConsultNote1">
        <paragraph>Dr. Specialist - September 8, 2016</paragraph>
        <paragraph>Dear Dr. Henry Leven: Thank you for referring Ms. Everywoman
          for evaluation. As you know...</paragraph>
      </item>
    </list>
  </text>
  <!-- Note Activity entry -->
  <entry>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.202"
        extension="2016-11-01"/>
      <code code="34109-9" codeSystem="2.16.840.1.113883.6.1"
        displayName="Note">
        <translation code="11488-4" codeSystem="2.16.840.1.113883.6.1"
          displayName="Consultation note"/>
      </code>
      <text><reference value="#ConsultNote1"/></text>
      ...
    </act>
  </entry>
</section>
```

Figure 6 – Example of Stand-alone Notes Section

2.4.3 Encounter Linking for Clinical Notes

Clinical Notes are written by a clinician in the context of an encounter. Every Clinical Note must have an Author and should be linked to an Encounter, whether a short telephone encounter or a lengthy Hospital Encounter. Encounter linking is important since some systems parse entries and may not properly retrieve header information.

When the C-CDA is an 'Encounter Summary' the Clinical Note should use an `entryReference` to the

encompassingEncounter/id¹⁸. Figure 7 below provides an XML example for how this should be done.

```
<!-- Reference to encounter nested within Note Activity -->
...
<entryRelationship typeCode="COMP" inversionInd="true">
  <encounter>
    <!-- Encounter ID matches an encounter in the Encounters Section or
         encompassingEncounter/id -->
    <id root="1.2.3.4" />
  </encounter>
</entryRelationship>
...

```

Figure 7 – Example of Encounter Linking with entryRelationship reference

When C-CDA is ‘Patient Summary’ each Note must have explicit encounter reference within the entry. If the document contains an Encounters section with the associated encounter, the Note Activity can reference the encounter ID as demonstrated in Figure 7. Otherwise, the entire encounter should be included in the Note Activity as demonstrated in Figure 8 below.

```
<!-- Reference to encounter nested within Note Activity -->
...
<entryRelationship typeCode="COMP" inversionInd="true">
  <encounter>
    <!-- ** If ID doesn't match an encounter/id from the Encounters Section,
         then this entry SHALL conform to Encounter Activity (V3) ** -->
    <templateId root="2.16.840.1.113883.10.20.22.4.49" extension="2015-08-01" />
    <id root="1.2.3.4" />
    <code code="99213" codeSystemName="CPT-4" />
    <effectiveTime value="201209271300+0500" />
  </encounter>
</entryRelationship>
...

```

Figure 8 – Example of Encounter Linking with encounter nested

2.4.3.1 Clinical Note Best Practices

The best practices for clinical note exchange will evolve as exchange of this type of information becomes more common. For a start, these are suggested best practices:

1. Prioritize human authored content. Text generated from structured entries are not considered ‘Notes’

¹⁸ The companion guide published in March 2017 restricted to only encounters in the encounter section. SDWG approved [errata 1522](#) on 1/29/2018 to additionally allow linking to encompassingEncounter/id.

2. Notes documenting an act should be associated/nested/linked to the corresponding act (e.g. Procedure Note links to Procedure) and the associated encounter
3. All Note Activity entries should have an Author (The author may be inferred from the author of the section) or the corresponding act
4. All Note Activities should link to an encounter
5. Multiple Note Activities, and Note types, can be sent in their appropriate sections in a single C-CDA instance

While this is not an exhaustive list of best practices, it reflects the recurring themes discussed in the Joint Content Work Group.

3 Patient Summary Documents

With the advent of ONC Certified Electronic Health Record Technology (CEHRT) and the CMS EHR Meaningful Use Program came an increase in the adoption of CDA documents. First, in the form of the HITSP C32 and in latter stages, the HL7 Consolidated-CDA (C-CDA). Each new CEHRT rule and C-CDA version added additional data requirements. In the latest ONC certification rule, the 2015 Edition Health IT Certification Criteria, the requirement to support the Common Clinical Dataset (CCDS) again increased the amount of data reported in these documents, much of it in codified form. While this has been a positive development it has also had some unintended side effects.

In the 2014 and 2015 Editions of the ONC Certification Criteria, patient health summary requirements primarily referenced the CCD (Continuity of Care Document) template within the HL7 C-CDA standard. As data requirements have increased, many vendors have taken to creating only CCDs and including as much information as possible. This has led to the issue of unnecessarily large CCDs that may span dozens of pages, which include information of limited value to the document recipient, and which most providers do not have the time to review. This was a driving force behind the efforts of this workgroup to improve the quality and focus of data being included.

An Encounter Summary provides a snapshot of the patient's condition at the time of the encounter as authored by the clinician. A Patient summary on the other hand provides the most current information available from the sending system across multiple encounters. While the workgroup primarily focused on the importance of creating Encounter Summary Documents to complement Patient Summary Documents, the work group does believe honoring query parameters from the requester will improve the clinical relevance of the CCD documents systems are currently producing in response to those requests. Adding support for time range parameters is a CCD is an interim step to support for Encounter Summary Documents.

3.1 Honor time parameters in Query for Documents

The Carequality and CommonWell content work groups joined forces to tackle the problem of bloated C-CDA documents. The Joint Content Work Group agreed to emphasize the importance of using existing IHE start and stop time elements to limit, at the request of the Query Initiator, the amount of information returned.

If you generate documents at the time you receive the request (on-demand) a way of managing this is to support the query parameters passed in the IHE Query (XCA, XDS.b) transactions. As a Query Responder, respecting the IHE Query `serviceStartTime` and IHE Query `serviceStopTime` parameters will reduce the size of the C-CDA's created and provide the scope of information the requester wants.

When the IHE Query `serviceStartTime` and IHE query `serviceStopTime` span multiple encounters, it is expected that the responding system will provide a document for each encounter with information

about the patient used or generated during the encounter.

In each Encounter Summary Document, the `encompassingEncounter` will record the time of the encounter.

If the responding system also provides a Patient Summary Document, it **SHALL** record the time range provided in the IHE Query `serviceStartTime` and IHE query `serviceStopTime` parameters in the `serviceEvent/effectiveTime` and **SHALL NOT** include an `encompassingEncounter`.

Below are the relevant elements in the IHE Query transaction that indicate the span of time the requestor is interested in.

```
<rim:Slot name="serviceStartTime">
  <rim:ValueList>
    <rim:Value>201501010800</rim:Value>
  </rim:ValueList>
</rim:Slot>
<rim:Slot name="serviceStopTime">
  <rim:ValueList>
    <rim:Value>201712310800</rim:Value>
  </rim:ValueList>
</rim:Slot>
```

Figure 9 – Timespan Elements in the Query Transaction

The Joint Content Work Group participants strongly encourage all systems to implement support for query parameters.

3.2 Missing Time parameters

Not every system will immediately support sending, or processing, the query parameters in the IHE request. The Joint Content Work Group declined to define default behaviors for each section when query parameters aren't provided, as it is impossible to predict the information needs of the requestor. Systems should therefore prioritize support of query parameters over implementing new defaults.

In addition to implementing query parameters, the Joint Content Work Group recommends the Section Time Range be present in every section. Including this observation will help receiving systems be confident in the range of information received.

The VA EHR currently supports the query parameters, but exchanges documents with systems that don't provide query parameters. While not an endorsement, the Joint Content Work Group agreed it is helpful to see an example of the decisions the VA made when query parameters weren't provided.

Figure 10 below summarizes the key sections and corresponding time defaults the VA currently applies when no date and time parameters are included in the query. Each organization may develop and document/share (think Capabilities Statement) their own decisions in this area.

Section	Default Time Range
Allergies	All Allergies or “no known allergies” and “no assessment done” when appropriate
Clinical Notes (new USCDI requirement) other notes	<p>Discharge Summaries with complete text includes all summaries within the requested date range. If no date range was provided, the list of Discharge Summaries includes the 2 most recent summaries within the last 18 months. <u>The data comes from all VA treatment facilities</u></p> <p>RADIOLOGY STUDIES This section includes all Radiology Reports within the requested date range. If no date range was provided, includes the 5 most recent reports within the last 24 months. <u>The data comes from all VA treatment facilities</u></p> <p>PATHOLOGY STUDIES This section includes all Pathology Reports within the requested date range. If no date range provided, include the 5 most recent reports within the last 24 months. <u>The data comes from all VA treatment facilities</u></p> <p>SURGICAL PROCEDURE NOTE Max of 5 Surgery Notes per Surgical Procedure.</p> <p>Clinical Procedure Notes, with complete text, that have procedure dates within the requested date range. If no date range was provided, the section contains the 10 most recent Clinical Procedure notes, with complete text, that have procedure dates within the last 18 months. <u>The data comes from all VA treatment facilities.</u></p>
Encounters	All Outpatient Encounters within the requested date range. If no date range was provided, the list of VA Outpatient Encounters shows all Encounter dates within the last 18 months
Immunizations	All Immunizations
Problems	All Problems

Procedures	All Surgical Procedures within the requested date range. If no date range provided, includes the 5 most recent procedures within the last 18 months.
Plan of Care/Treatment	Future Outpatient Appointments with appointment date within the next 6 months, max of 20 appointments
Assessment	This section includes the notes associated to the Encounter. The notes may include assessment information.
Medications	Outpatient Meds dispensed in the last 15 months All Non-VA Meds on record at VA

Figure 10 – VA Section Timespan Filters

3.3 USCDI within TEFCA

A recent proposed change in federal requirements is the proposed [Draft U.S. Core Data for Interoperability \(USCDI\)](#) within the Trusted Exchange Framework and Common Agreement (TEFCA). Clinical Notes and Provenance are two data elements identified in the Draft USCDI for immediate inclusion in exchanged documents beyond the required CCDS data elements. These are valuable data elements and should be exchanged to improve patient care. However, participants in the Joint Work Group are concerned systems will dump Clinical Notes in their existing Patient Summary documents making them even larger. The Joint Content Work Group believes Clinical Notes will serve the clinician best by providing them in the context of the encounter where they were created. When systems add support for Clinical Notes they should also add support for Encounter Summary documents.

A future Joint Content Work Group will consider data provenance when ONC provides more guidance on which elements they are consider important. More guidance on representing Care Team Members also is needed.

Data classes outlined in red represent the current ONC CEHRT- Common Clinical Data Set (CCDS).

Draft USCDI Version 1 Data Classes	
1. Patient name	2. Sex (birth sex)
3. Date of Birth	4. Preferred Language
5. Race	6. Ethnicity
7. Smoking Status	8. Laboratory tests
9. Laboratory values/results	10. Vital signs
11. Problems	12. Medications
13. Medication Allergies	14. Health concerns
15. Care Team members	16. Assessment and plan of treatment
17. Immunizations	18. Procedures
19. Unique device identifier(s) for a patient's implantable device(s)	20. Goals
21. Provenance	22. Clinical Notes

Figure 11 – ONC Draft USCDI

4 Smart Senders and Resilient Receivers

Successful document exchange relies on layers of rules from CDA document specifications, C-CDA 2.1 specification, and the C-CDA 2.1 companion guide. Despite every effort by implementers, and the HL7 community, to document all the important topics for successful exchange, the Joint Content Work Group discussed many other areas that would benefit from additional guidance. The Smart Senders and Resilient Receivers sections are not an exhaustive list of best practices, but instead is a list of the best practices that captured the group's attention. Other topics that would benefit from additional guidance are listed in the future work appendix.

4.1 Smart Senders

4.1.1 Maintain proper references between coded values and narrative

Narrative text linking is extremely important for processing and validating CDA documents that include machine-processable entries. The narrative text linkages are the mechanism that associate human-readable information in the narrative text of each section to the entries carrying that information for machine processing. Without proper narrative text linking, it is impossible to accurately validate if the machine-readable entries and the human-readable representation of that information accurately reflect the same semantic meaning.

Resources for more information:

- [How to create narrative text linking in sections that contain machine-processable entries](#)
- See narrative reference examples in the [General section](#) of HL7 Example Task Force

4.1.2 Maintain act/observation IDs across documents

Most entries in C-CDA require an identifier¹⁹ (ID) on every entry. The best practice is to keep those IDs consistent whether sending the data in an Encounter Summary Document, a Patient Summary document or any other CDA document types. This enables receivers who machine-process the documents and de-duplicate the information to accurately identify data that has been previously reported.

```
<act classCode="ACT" moodCode="EVN">  
  <id root="36e3e930-7b14-11db-9fe1-0800200c9a66"/>  
  ...
```

Figure 12 – Example id root only

¹⁹C-CDA R2.1 Companion 4.1.10 Generating Unique Identifiers

```
<observation classCode="OBS" moodCode="EVN">  
  <templateId root="2.16.840.1.113883.10.20.22.4.7" extension="2014-06-09" />  
  <id root="2.16.840.1.113883.5555.34567.12" extension="4398764"/>  
  ...
```

Figure 13 – Example id root + extension

4.1.3 Document Versioning

There are many situations where a document may be updated. For example, a pending lab result or a missing note may trigger an update. The base CDA standard provides a mechanism to replace or append a previously sent document through the `parentDocument` relationship. Since senders will not know what a receiver stored, it is preferable to always send a complete document that replaces the prior document, then indicate the parent document being replaced by including it with the `replace` relationship (`typeCode="RPLC"`). The C-CDA R2.1 Companion Guide describes this scenario in the section: 4.1.4.1 *Options for data that is temporarily unavailable*.

4.1.3.1 Encounter Summary Document Version Management Guidance

Systems either generate documents at the conclusion of an encounter or on-demand at the request of a querying system. CDA provides a mechanism to link documents together through a `relatedDocument/ParentDocument/id`. For additional detail, see Figure 14 and Figure 15 below.

Some systems cannot link to prior versions using `relatedDocument/ParentDocument/id`. Due to this inconsistent implementation of linking to parent documents, the best method for receiving systems to link prior versions is by using `encompassingEncounter/id`.

```
<ClinicalDocument>
  <realmCode code="US">
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <templateId root="2.16.840.1.113883.10.20.22.1.1" extension="2015-08-01">
  <templateId root="2.16.840.1.113883.10.20.22.1.8" extension="2015-08-01">
  <id root="2.16.840.1.113883.19.5.99999.1" extension="20160414014447">
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
    code="18842-5" displayName="Discharge Summary" />
  <title>Health Summary</title>
  <effectiveTime value="20160414014447-0500">
  <confidentialityCode codeSystem="2.16.840.1.113883.5.25" code="N">
  <languageCode code="en-US">
  <setId extension="20160414014447" root="2.16.840.1.113883.19.5.99999.19">
  <versionNumber value="1">
  ...
  <section nullFlavor="NI">
    <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.5"/>
    <code code="8648-8" displayName="HOSPITAL COURSE"
      codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <title>Hospital Course</title>
    <text>No Information</text>
```

Figure 14 – Discharge Summary with no Hospital Course information

```
<ClinicalDocument>
  <realmCode code="US">
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <templateId root="2.16.840.1.113883.10.20.22.1.1" extension="2015-08-01">
  <templateId root="2.16.840.1.113883.10.20.22.1.8" extension="2015-08-01">
  <id root="2.16.840.1.113883.19.5.99999.1" extension="20160414145050">
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
    code="18842-5" displayName="Discharge Summary" />
  <title>Health Summary</title>
  <effectiveTime value="20160414145050-0500">
  <confidentialityCode codeSystem="2.16.840.1.113883.5.25" code="N">
  <languageCode code="en-US">
  <setId extension="20160414014447" root="2.16.840.1.113883.19.5.99999.19" I>
  <versionNumber value="2">
  <relatedDocument typeCode="RPLC">
    <parentDocument>
      <id root="2.16.840.1.113883.19.5.99999.1" extension="20160414014447">
      <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
        code="18842-5" displayName="Discharge Summary" I>
      <setId extension="20160414014447" root="2.16.840.1.113883.19.5.99999.19">
      <versionNumber value="1">
    </parentDocument>
  </relatedDocument>
  ...
  <section>
    <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.5"/>
    <code code="8648-8" displayName="HOSPITAL COURSE"
      codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <title>Hospital Course</title>
    <text>The patient was admitted ...</text>
```

Figure 15 – Replacement Discharge Summary document with Hospital Course Information

4.1.4 Reconciliation flag

Sending systems may indicate that particular list was reconciled prior to sending using the [IHE Supplement](#). The Reconciliation Act Entry Content Module (1.3.6.1.4.1.19376.1.5.3.1.1.24.3.1) provides the structure to indicate the information in a section has been reconciled. While not required, systems should consider including this act, or a similar indicator, to explicitly state a list has been reconciled.

4.2 Resilient Receivers

4.2.1 Document Display Guidance

A clinician determines whether to retrieve or review a document based on a limited set of document metadata (e.g. Date, Title, etc.). The information available to display is slightly different depending on whether the user is reviewing the results of a query or reviewing a document previously retrieved and stored locally.

In a Document Query / Document Retrieve scenario the initial IHE Document Query transaction returns a set of information about the document(s) available from sources associated with the patient. The receiving system then displays this initial information to a user to select which documents to retrieve. Once the user selects which documents are to be retrieved, a subsequent Document Retrieve transaction prompts the document source to deliver the selected documents to be viewed by the user. To optimize performance, some systems pre-fetch a patient's available documents based on an upcoming encounter so the steps in Figure 16 and Figure 17 may be transparent to the user.

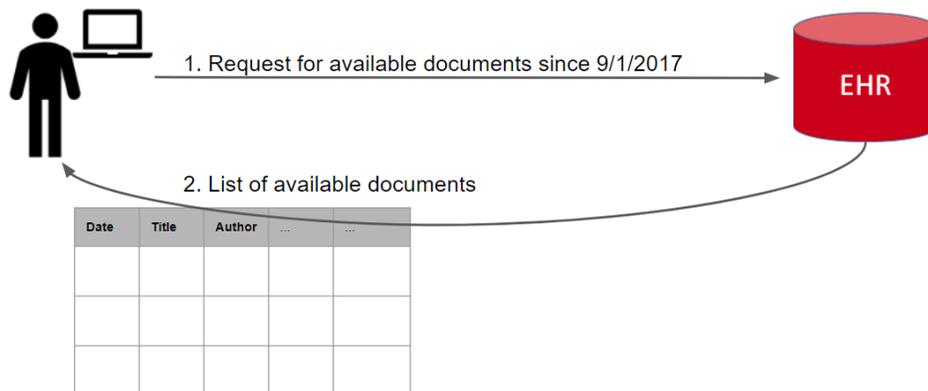


Figure 16 – Document Query

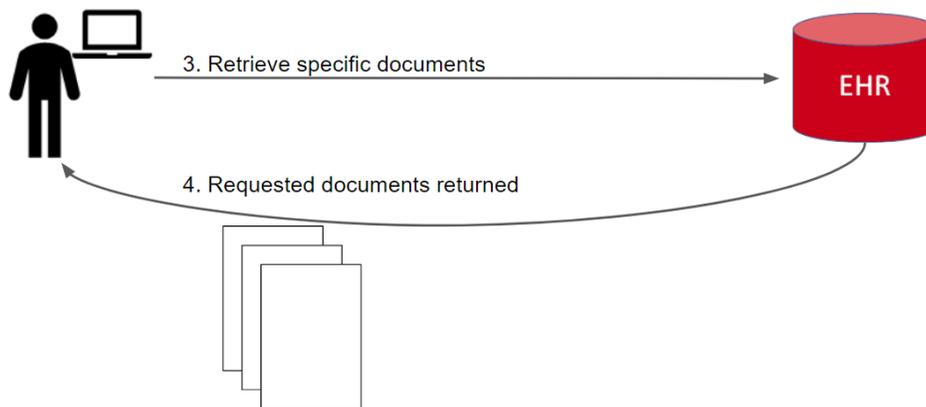


Figure 17 – Document Retrieval

Document Information display

When displaying available documents for retrieval or retrieved documents, systems should display corresponding document information. This information may be obtained from the IHE query/retrieve transaction (i.e., the same as what was displayed in the “list of available documents” during the query) or may be obtained (parsed) from within the C-CDA document header.

Figure 18 below summarizes the data elements available in the IHE Query transaction vs the retrieved C-CDA Header²⁰:

Document Info	Availability	Location
Date range	IHE Query	serviceStartTime serviceStopTime
	Encounter Summary C-CDA Header	ClinicalDocument/componentOf/encompassingEncounter/effectiveTime/low ClinicalDocument/componentOf/encompassingEncounter/effectiveTime/high
	Patient Summary C-CDA Header	ClinicalDocument/documentationOf/serviceEvent/effectiveTime/low ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high
Title	IHE Query	Title
	C-CDA Header	ClinicalDocument/title
Document Type	IHE Query	typeCode
	C-CDA Header	ClinicalDocument/code

²⁰ This list came from The Sequoia Project - [eHealth Exchange Content Testing Program Guide](#) with the additions of Date and Title by the joint content work group.

Author	IHE Query	authorPerson
	C-CDA Header	ClinicalDocument/author/assignedAuthor/assignedPerson
Author Organization ²¹	IHE Query	authorInstitution
	C-CDA Header	ClinicalDocument/author/assignedAuthor/representedOrganization/name
List of Services	IHE Query	eventCode
	Encounter Summary C-CDA Header	ClinicalDocument/documentationOf/serviceEvent/code
	Patient Summary C-CDA Header	Not Applicable - the service event information in a patient summary is restricted to "Provision of Care". The document does not contain details about the services provided during the span of time covered by the document.
Practice Type	IHE Query	practiceSettingCode
	Encounter Summary C-CDA Header	ClinicalDocument/componentOf/encompassingEncounter/location/healthcareFacility
	Patient Summary C-CDA Header	Not Applicable - Patient Summary may multiple practice types
Format Code	IHE Query	formatCode
	C-CDA Header	Not Applicable - the formatCode is inferred by the templateIDs asserted in the Header

Figure 18 - Document Information Available during the IHE Query and in the stored C-CDA

See Figure 19 below for an example of how data elements from the IHE Query or C-CDA Header might be displayed to improve document selection.

Date	Title	Document Type	Author	Author Institution
4/5/2018	Patient Summary	CCD	Good Health	
4/5/2018	Office Visit Checkout	Progress Note	Dr. Johnson	Good Health Clinic
3/28/2018	Hospital Stay	Discharge Summary	Dr. Smith	Good Health Hospital
...				

Figure 19 - Sample Document List Display

²¹ eHealth exchange named this Service Location

4.2.2 Receive and display any valid CDA document

The base CDA standard is designed so that every section's `section.text` element is displayable in a basic browser using the base CDA stylesheet, `cda.xsl`. While receivers are allowed to implement complex processing to apply their own display styles to a section, a system **SHALL** never hide a section if it does not recognize the LOINC section code. Every properly formatted section **SHALL** be displayed, or an option given, to the user to view the full unrestricted document.

5 Appendix

5.1 Additional education material

- Refer to Section 5 in [Companion Guide to HL7 Consolidated CDA R2.1](#)
- [HL7 CDA Example Task Force](#)

5.2 Document Generation Timing and Content

The Joint Content Work Group struggled to agree on terms to describe document generation timing and content. On several work group calls we considered terms: on-demand, stable, static, dynamic and persistent. Within the discussions we considered both the clinical content and technical assembly of content.

Ultimately, we agreed on the following items:

- Encounter Summary Documents provide information about the patient used or generated during the encounter.
- Patient Summary Documents provide the current information about a patient.

During our discussion, we learned systems have different approaches to generate Encounter Summary Documents, and Patient Summary Documents.

Two common scenarios discussed on the work group for Encounter Summary Documents:

- Generation of the Encounter Summary Document immediately after the visit, or after all information has been filed to visit, and stored for future retrieval
- Generation of the Encounter Summary Document when requested

In both cases, the clinical content must be equivalent. However, some systems that generate when requested are unable to recreate certain items, such as the Medication or Problems at the time of the Encounter.

Systems **SHALL NOT** auto-populate the latest information (i.e. current active medications) in a historical Encounter Summary Document.²² (see [2.1 Document Body Guidance](#) for additional details)

IHE provides basic guidance²³ to describe this behavior. When discussing this additional layer, the content work group failed to reach a consensus recommendation. Clarifying the terms to use for both registry, repository, and clinical content stability is something the joint content work group believes

²² An exception to this rule is if the last encounter is recent and does contain current information.

²³ IHE ITI-TF3 http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol3.pdf

should continue in IHE.

5.3 Future Work

- Develop a prioritized list of laboratory results to be shared, similar to how Allergies and Intolerances developed a ‘most common allergens’ list.
- Develop best practices for rendering documents - stylesheets
- Provide guidance on sending Referral Notes, or Consultation Notes to complement encounter summaries as an example: Push vs Pull and timing of information
- Develop guidance for populating meaningful narratives.
 - The basic requirement of all CDA documents is they are human-readable. Future efforts may define guidance for the following issues:
 - Discussion about `section.text` is generated vs authored
 - Negative - what are we trying to solve?
 - Minimal narrative populated - systems are relying on entries (code information)
 - Bloat - generation is including meaningless content clinicians don’t want to see -- RIM Elements that don’t provide additional meaning.
 - Importance of narrative-only sections - Clinical Notes, Free Text SIG
 - Provide guidance on IHE On-demand transactions