eHealth Exchange

2016 Consolidated CDA (C-CDA) Content Testing

Specification and Testing Documentation v0.5

eHealth Exchange Testing Workgroup
11/15/2016

Change Log

Date	Version	Description
11/2/2015	Initial Draft v0.1	Initial rough draft
11/5/2015	Version 0.2	Added comments and fixed formatting and font issues found and updated table of contents
02/29/2016	Version 0.3	Comments received since 11/5/2015 incorporated. Added HL7 C-CDA CCD v2.1 requirements & additional clarification based on implementation FAQs tracked by the testing workgroup
4/11/2016	Version 0.4	Updated Test Methods to align with MU 2015 Edition Test Procedures and Test Data leveraged by Authorized Testing Labs
11/15/2016	Version 0.5	Updated Test Methods, test data, clinical document guidance to address pain points documented by the Testing Workgroup and findings from the April – July 2016 Pilot testing.

Table of Contents

1 INTRODUCTION

This Testing Documentation will replace the existing Content Test Cases used by the Product and Participant Testing Programs. The eHealth Exchange continues to support the content requirements and specifications defined within the 2011 and 2014 Edition Meaningful Use programs. In addition, the Testing Workgroup recommends the addition of testing compliance to the 2015 Edition Meaningful Use (MU3) Program Certification requirements that reference the latest Draft Standard for Trial Use (DSTU) HL7® C-CDA version 2.1 standards. These standards were published in August 2015 and are referenced in the standards and implementation guides chapter 3 of this document. This content testing documentation builds upon the Bridge C32 content requirements previously published by the eHealth Exchange. eHealth Exchange participants should strive to support the appropriate document for their various use cases. The reality today, is that 90% or more of the eHealth Exchange participants create on-demand documents when queried and respond with a Continuity of Care Document (CCD) document type. However, there are 12 document templates in the HL7® C-CDA standards and the eHealth Exchange will begin more rigorous conformance testing for the various versions of clinical content being exchanged.

This content testing documentation adds the additional content requirements from the Transitions of Care Implementation guidance published by HL7. The HL7 implementation guide provides meaningful use and additional clinical guidance for information that may be exchanged by nodes among eHealth Exchange participants to address particular use cases or business needs. The eHealth Exchange participants act as nodes on the eHealth Exchange network and enable their connected stakeholders to exchange clinical document content to make use of the discovery and information exchange capabilities and rest upon a foundational set of messaging, security, and privacy services.

This document provides the testing methodology and scenarios that will be required for interoperability testing and exchange of content documents between eHealth Exchange participants. The outcome from the content testing program will provide a feedback loop from real world deployments to HL7 and is expected to continue to inform future documentation under development by the Structured Documents and other Workgroups within HL7.

2 USE CASE SCENARIOS

The eHealth Exchange supports various transports and clinical content as required to enable the transitions of care and continuity of care process between clinicians and their patients. These testing requirements are meant to enable participants to exchange robust and meaningful clinical information with their connected stakeholders. The expectation is that all clinical document types will be tested for conformance so participants and their vendors can test for any innovative combination of constrained document templates, or sections or entries to support their identified use cases for the exchange of clinical data. The following provides information that can be leveraged by participants and their vendors during use case development for their organizational implementation.

What is a use case?

A use case is an easy to understand description detailing the interaction between an actor (human, organization, system) and a system under consideration. It identifies a set of 'trading partners' as source and consumer systems and describes how they intend to use the eHealth Exchange. The use case should describe the actors and clinical data to be exchanged.

Why do we use them?

Use cases are developed with a goal in mind, that makes them a valuable planning tool. A well-crafted use case communicates the functional requirements that may then inform technical planning. Having the use case available prior to technical discussions helps scope the technical solution and accelerates the technical evaluation process to elaborate on the policy and procedural requirements necessary.

How they should help you?

Use case development requires an understanding of the business need – the issue your organization seeks to resolve or opportunity on which you intend to capitalize. Defining your need early in the process will accelerate later development efforts and provide a basis for evaluating success.

Examples:

- I need to join the eHealth Exchange
  - Not detailed enough
- Our practice/organization needs to generate and securely send summary of care records to patients' specialists to meet meaningful use transition of care criteria within this region and across care delivery locations.
  - Provides initial needed details to guide plan development, scope the effort and establish priorities.

Use Case Benefits

- Identifies the clinical/business need before solution development…mitigating rework and delays
- Facilitates initial scoping, project planning and effort prioritization
- Supports 'marketing and selling' your request to management – you have done your due diligence to articulate value, not just functionality
- Supports identifying the project team/stakeholders involved

Use Case Elements

- Use case name: a brief summary of your use case
  - Patient referral from PCP to Specialist
- Goal: what is your end goal?
  - To attest to meaningful use, transition of care criteria
- Story: How do you intend to use the eHealth Exchange?
  - Perspective: a provider referring a patient to a specialist
  - Context: the referring provider has made the determination that it is clinically and legally appropriate to send a referral and summary of care to a specialist.
  - Story:

        - Dr. Jones (the referring provider) searches for a patient in the practice EHR and initiates a referral message. The referral reason is described in the message. In some cases, the referral is directed to a specific specialist, and in other case to a specialist practice. Dr. Jones attaches a summary of care for reference, and then sends the referral.
        - Dr. Smith (the specialist) sees the new referral in his/her local practice EHR. If this is a new patient for the practice, a new patient is created in the EHR. The core referral and the various documents are imported into the new patient's chart.
            - *Reference: The Direct Project, User Stories*
                - http://wiki.directproject.org/Primary+care+provider+refers+patient+to+specialist+including+summary+care+record
    - Actors: who are the sources and consumers, e.g. people, roles, organizations?
    - People = Dr. John, Nurse Thompson
    - Roles = Case Manager, Triage Nurse
    - Organizations = Hospital ABC, Medical Associates of XYZ
        - When describing the organization include size indicators, e.g. number of beds, providers, visits per month
- **Actors:** What are the source and intermediary systems and consumers?
    - When describing systems include vendor names and system versions
        - The eHealth Exchange gateway is typically an intermediary system
- **Data to exchange:** What data do you intend to exchange?
    - Common Meaningful Use data set (all data that may be required for exchange as part of MU2/2014 Edition or MU3/2015 Edition)
        - Patient name
        - Sex
        - Date of birth
        - Race**
        - Ethnicity**
        - Preferred language
        - Care team member(s)
        - Allergies**
        - Medications**
        - Care plan
        - Problems**
        - Laboratory test(s)**
        - Laboratory value(s)/result(s)**
        - Procedures**
        - Smoking status**
        - Vital signs

NOTE: Data requirements marked with a double asterisk (**) also have a defined vocabulary which must be used.

Use Case Guidance:

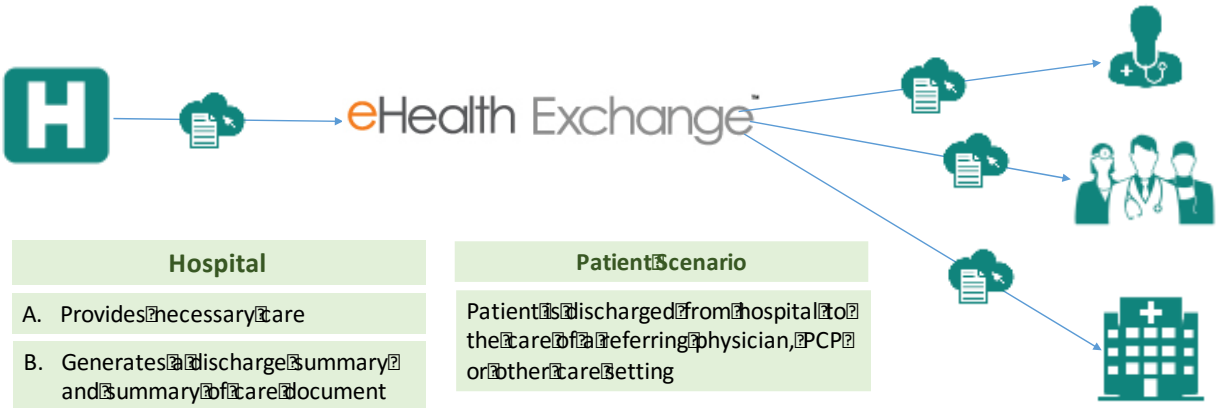
- Limit the use case to 1-2 page(s)
- Engage your clinical and business leaders early
- Align to business objectives, e.g. meaningful use criteria
- Complete all identified elements, but in 2 phases:
    - Part 1 – Name, Perspective, Context, Story
    - Part 2 – Actors, Data to Exchange
- Do not describe technical connectivity (i.e. S/MIME vs. XDS vs. XCA), rather tell the story of how you will use the solution once built
- Do not make the use case too general – select a well-defined area of focus and add in appropriate data

Some examples use cases can be found in the tables and diagrams below:

Table 1: Hospital Discharge Use Cases

Use Case	Type of Transaction	Care Setting	To Care Setting
1.1	Hospital discharge summary	Hospital	Referring physician and/or PCP
1.2	Hospital discharge summary	Hospital	Other care settings (i.e. Skilled Nursing Facility (SNF)
1.3	Hospital discharge summary	Hospital	Hospital
1.4	Hospital ED visit summary	Hospital	Referring physician and/or PCP

SAMPLE USE CASE 1: HOSPITAL DISCHARGE



Hospital	Patient Scenario
A. Provides necessary care	Patient is discharged from hospital to the care of a referring physician, PCP or other care setting
B. Generates a discharge summary and summary of care document	
C. Discharge summary sent via eHealth Exchange to referring physician, PCP, and/or other care setting	

This use case describes the situation where a patient's care is transitioned or referred to another care provider. The health information systems of the two provider organizations should be able to successfully transfer a notification of the patient discharge. The notification may include important patient data elements that facilitate the effective transfer of the patient's care from the first provider organization to the second.

1. Communicate a patient discharge to an external organization
2. Similar to a transition of care
3. Transport is tested separately from content requirements

Goals:

To be able to electronically send a discharge for a patient from a hospital encounter from a care provider Sender to care provider Receiver with the appropriate patient demographic, administrative and clinical data to ensure a smooth transition of care.

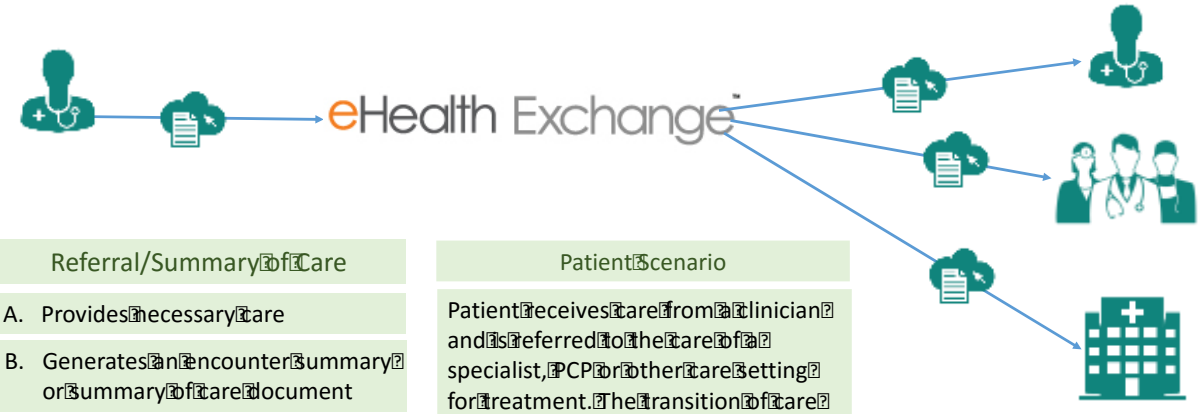
Documents templates that can be leveraged:

- Continuity of Care Document (CCD)
- Hospital Discharge Summary

SAMPLE USE CASE 2: PATIENT REFERRAL/TRANSITION OF CARE

Table 2: Patient Referral/Transition of Care Use Cases

Use Case	Type of Transaction	Care Setting	To Care Setting
2.1	Referral – Summary of care record	PCP	Specialist
2.2	Consult note – Summary of care record	Specialist	PCP
2.3	Referral – Summary of care record	PCP or specialist	Hospital



This use case describes the situation where a patient's care is transitioned or referred to another care provider. The health information systems of the two provider organizations should be able to successfully transfer a notification of the patient referral. The notification may include important patient data elements that facilitate the effective transfer of the patient's care from the first provider organization to the second.

1. Communicate a patient referral to an external organization
2. Similar to a transition of care
3. Transport is tested separately from content requirements but can Include provider to provider referral

Goals:

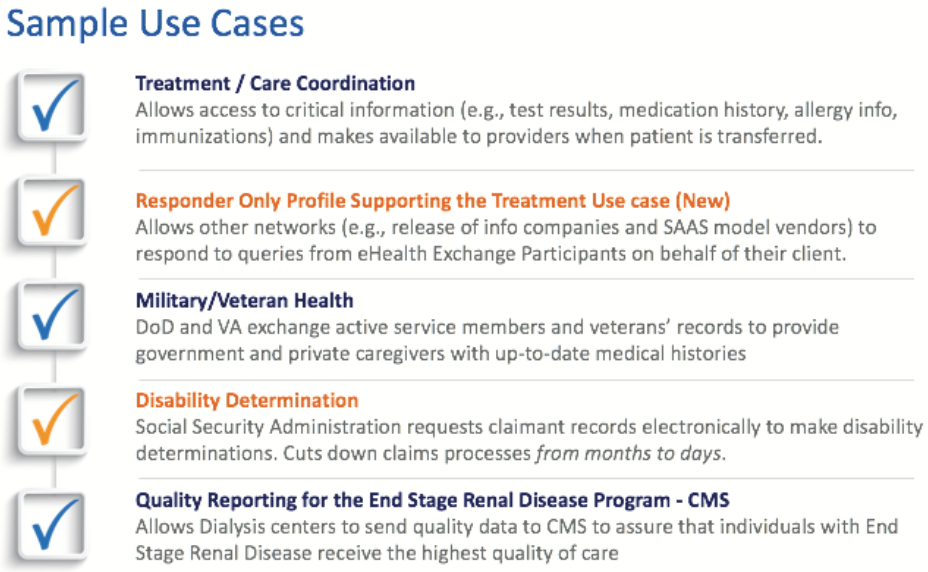
To be able to electronically send a referral for a patient from a care provider Sender to a care provider Receiver with the appropriate patient demographic, administrative and clinical data to ensure a smooth transition of care.

Documents templates that can be leveraged:

- Care Plan
- Consultation Note
- Continuity of Care Document (CCD)
- Progress Note
- Referral Note
- Transfer Summary

2.1 EXISTING EHEALTH EXCHANGE USE CASES

The eHealth Exchange has various use cases in production today that include the following:



3 REFERENCED STANDARDS AND IMPLEMENTATION GUIDES

HL7 Standard or Implementation Guide	URL
HITSP Summary Documents Using HL7 Continuity of Care Document	http://www.hitsp.org/Handlers/HitspFileServer.aspx?FileGuid=e1b99525-a1a5-48f6-a958-4b2fc6d7a5c7
HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use (July 2012)	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258
HL7 Implementation Guide: S&I Framework Transitions of Care Companion Guide to Consolidated-CDA for Meaningful Use Stage 2, Release 1 – US Realm (September 2014)	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=374
HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1 – Volume 1 – Introductory Material (August 2015)	http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=168 **Volume 1** provides narrative introductory and background material pertinent to this implementation guide, including information on how to understand and use the templates in Volume 2.
HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1- Volume 2 – Templates and Supporting Materials (August 2015)	http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=168 **Volume 2** contains the normative Clinical Document Architecture (CDA) templates for this guide along with lists of all templates, code systems, value sets, and changes from the previous version
Companion Guide to HL7 Consolidated CDA R2.1 for ONC 2015 Health IT Certification Criteria	http://wiki.hl7.org/index.php?title=C-CDA_2.1_Companion_Guide_Project HL7 is developing a Companion Guide for C-CDA Release 2.1 and the Testing Workgroup intends to update this document once it becomes publicly available. In the meantime, we recommend developers follow the guidance provided by the HL7 CDA Example Task Force for implementation of the C-CDA Release 2.1 standard.
HL7Implementation Guide for CDA® Release 2: Clinical Guidance on Relevant and Pertinent Data to Include Automatically Generated Patient Summaries	http://wiki.hl7.org/index.php?title=Relevant_and_Pertinent http://wiki.hl7.org/index.php?title=File:Relevant_and_Pertinent_Implementation_Guide.docx
HL7® Example Task Force Library	http://hl7-c-cda-examples.herokuapp.com/
Best Practices and Quantitative Scoring Criteria (Scorecard)	http://www.hl7.org/documentcenter/public/wg/structure/C-CDA%20Scorecard%20Rubrics%203.pptx

Following is a non-exhaustive list of third-party terminologies that may require a separate license: Terminology	Owner/Contact
Current Procedures Terminology (CPT) code set	American Medical Association http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/cpt-products-services/licensing.page?
SNOMED CT	International Healthcare Terminology Standards Developing Organization (IHTSDO) http://www.ihtsdo.org/snomed-ct/get-snomed-ct or info@ihtsdo.org
Logical Observation Identifiers Names & Codes (LOINC)	Regenstrief Institute
International Classification of Diseases (ICD) codes	World Health Organization (WHO)

Clarifications:

Data elements may have a value set assigned, that specifies the set of allowed values for the codes. Simple value sets specify a list of possible codes. When value sets are usually based on a single coding system (which is usually the case) a reference to the code system and value set are the same and usually reference the code system. However, more complicated value sets are possible that control how complex coded expressions are used.

In order to facilitate the translation of SNOMED CT® codes to ICD-10-CM in administrative systems, developers are encouraged to reference the publicly available mapping that the National Library of Medicine provides.
https://www.nlm.nih.gov/research/umls/mapping_projects/snomedct_to_icd10cm.html

The following OIDs **SHALL** be used to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.

- ICD-10 Procedure Coding System OID: 2.16.840.1.113883.6.4
- SNOMED CT® OID: 2.16.840.1.113883.6.96

Health IT Modules can present for validation to a more recent version of SNOMED CT®, U.S. Edition than the September 2015 Release per ONC's policy that permits certification to a more recent version of certain vocabulary standards.

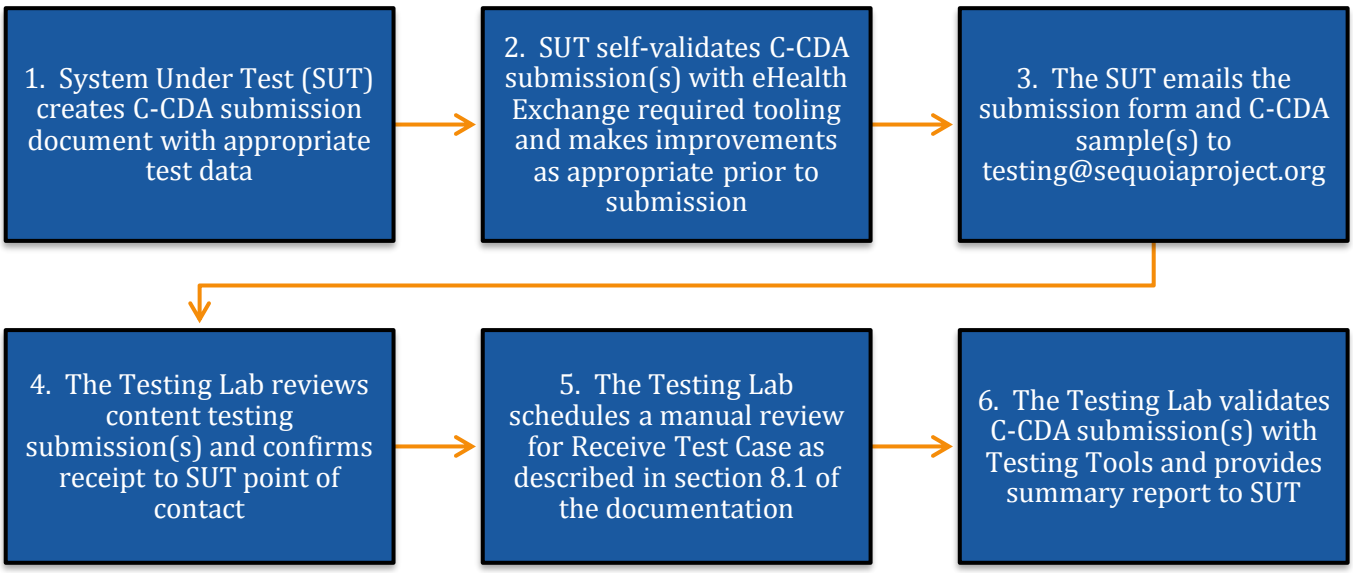
4 TESTING APPROACH

The testing approach will include a business process and technical process to facilitate the onboarding of eHealth Exchange participants. The general process is outlined below but it is expected that the existing process documentation and participant testing applications will need to be updated before this is formalized and required by all participants.

4.1 TESTING PROCESS

1. Submission Form Completion (describes the participant's content, data limits included in each section, terminology coding, reports inclusion, etc.
2. Testing
    - Focus is on HITSP C32, HL7 C-CDA Release 1.1 and HL7 C-CDA Release 2 document templates
    - Product Vendors create samples based on Test Procedure test data referenced in Appendix D or Participants SUT will provide sample(s) with self-created testing data.

The testing process will proceed as follows:



1. System Under Test (SUT) submits C-CDA document with appropriate test data.
    a. See test cases in chapter 8 for appropriate test procedures and test data for Inpatient and Ambulatory
2. SUT self-tests with prescribed testing tooling and makes improvements as appropriate prior to submission
    a. Repeat until all Errors reported by the testing tool(s) are eliminated
    b. Warnings from the tooling should be reviewed by SUT for potential improvement
    c. If SUT finds inappropriate error(s) or warning(s), please provide details in an email to testing@sequoiaproject.org
3. The SUT emails the survey/submission form (see appendix C) and the C-CDA sample(s) to testing@sequoiaproject.org
4. The Testing Lab reviews submission form and content testing C-CDA submission(s) for completeness
    a. If submission is complete, the testing lab confirms receipt
5. The Testing Lab schedules a manual review for the Receive Test Case as described in Section 8.1 in this document.
6. The Testing Lab validates the C-CDA submission(s) with testing tools as prescribed by the testing program.

4.2 OUTSTANDING QUESTIONS

1. How do we ensure the tested systems are realistic? (similar to what is implemented in production and include fully populated C-CDA document?
2. How do we measure value gained to ensure improvements and that the content is good and drives data sharing, usage, and patient outcomes?
3. What should be required for each Participant on the eHealth Exchange to ensure data quality monitoring once moved into production as new stakeholders are connected to their exchange gateways?
    - inside the organization?
    - using real patient data, during production?

4. Additional FAQs and Pain Points are being tracked as a separate Appendix to this document as collaboration with HL7 for suggested improvements to documentation and standards continue. (See Appendix A).

5 CONSOLIDATED CLINICAL DOCUMENT ARCHITECTURE (C-CDA) BACKGROUND AND CONFORMANCE REQUIREMENTS

This document type was derived from HITSP C32 and CCD Release 1.0 and is defined in both the HL7 C-CDA Release 1.1 and Release 2.1 Implementation and Companion Guides. The C-CDA represents a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another to support the continuity of care.

5.1 CONFORMANCE VERBS

The keywords **SHALL, SHOULD, MAY, NEED NOT, SHOULD NOT**, and **SHALL NOT** in this documentation are to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide (HL7, *Version 3 Publishing Facilitator's Guide.* http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm). To determine constraints for the recommended approach, applications of conformance verbs from C-CDA were determined as follows:

- **SHALL:** an absolute requirement.
  - Required in the Consolidated CDA document template specification(s)
  - Testing Fails/Errors will be reported for non-compliance
- **SHALL NOT:** an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT:** best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course.
  - Testing Warnings will be report for non-compliance
- **MAY/NEED NOT:** truly optional; can be included or omitted as the author decides with no implications in testing reports.

Conformance verbs, when used in the Consolidated CDA implementation guide, are written in all capital letters and bolded within a conformance statement.

The keyword "**SHALL**" allows the use of `nullFlavor` unless the requirement is on an attribute or the use of `nullFlavor` is explicitly precluded.

When conformance statements are nested (or have subordinate clauses) the conformance statements are to be read and interpreted in hierarchical order. These hierarchical clauses can be interpreted as "if then, else" clauses. Thus...

a. This structured Body **SHOULD** contain zero or one [0..1] **component** (CONF:1098-29066) such that it
   i. **SHALL** contain exactly one [1..1] **Plan of Treatment Section (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.10:2014-06-09) (CONF:1098-29067).

...is understood as:

a. It is recommended (**SHOULD**) that the structureBody contains a component.
   i. **If** the component exists, **then** it must contain a Plan of Treatment Section (V2),

   ii. **else** the component does not exist, and the conformance statement about the Plan of Treatment Section (V2) should be skipped.

In the case where the higher level conformance statement is a **SHALL,** there is no conditional clause. Thus...

b. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:1098-29086) such that it
   i. **SHALL** contain exactly one [1..1] **Problem Section (entries required) (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.5.1:2014-06-09) (CONF:1098-29087).

...means that the structuredBody is always required to have a component.

5.2 CARDINALITY

The cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators are interpreted with the following format "m…n" where m represents the least and n the most:

- 0..1 zero or one
- 1..1 exactly one
- 1..* at least one
- 0..* zero or more
- 1..n at least one and not more than n

When a constraint has subordinate clauses, the scope of the cardinality of the parent constraint must be clear. In the next figure, the constraint says exactly one participant is to be present. The subordinate constraint specifies some additional characteristics of that participant.

OPTIONAL AND REQUIRED WITH CARDINALITY

The terms *optional* and *required* describe the *lower* bound of cardinality as follows:

Optional means that the number of allowable occurrences of an element may be 0; the cardinality will be expressed as [0..1] or [0..*] or similar. In these cases, the element may not be present in the instance. Conformances formulated with **MAY** or **SHOULD** are both considered "optional" conformances.

Required means that the number of allowable occurrences of an element must be at least 1; the cardinality will be expressed as [m..n], where m >=1 and n >=1 (for example, [1..1] or [1..*]). In these cases, the element must be present in the instance. Conformance statements formulated with SHALL are required conformances. If an element is required but it is not known, the @nullFlavor attribute must be used. See Unknown and No Known Information.

Figure 1: Sample Representation of CDA Conformance

1. Conforms to **Allergies Section (entries optional)** template (2.16.840.1.113883.10.20.22.2.6).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:7527) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.6.1" (CONF:10379).
3. **SHALL** contain exactly one [1..1] **code** (CONF:15349).
4. This code **SHALL** contain exactly one [1..1] **@code**="48765-2" Allergies, adverse reactions, alerts (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:15350).

5.3 TEMPLATE – DRIVEN APPROACH

HL7 templates are used to constrain and verify conformance to profiled HL7 C-CDA. A template is an expression of a set of constraints on the RIM which is used to apply additional constraints to a portion of an instance of data expressed in terms of some other Static Model. Templates are used to further define and refine these existing models within a narrower and more focused scope. Each template is identified with a templateID, a globally unique identifier. CDA is the most widely adopted implementation of HL7 v3. It is used for exchanging information in the form of documents. CDA has three levels: level 1 is a single human-readable document, level 2 can include multiple documents and level 3 can included structured information. Each CDA document has a common header and a variable body part. Templates are used widely in HL7 CDA to constrain the generic CDA model. Conformance statements within the referenced HL7 guides are presented as constraints from Trifolia Workbench, a template repository. An algorithm converts constraints recorded in Trifolia to a printable presentation within the HL7 C-CDA standards specifications. An algorithm converts constraints recorded in Trifolia to a printable presentation. Each constraint is uniquely identified by an identifier at or near the end of the constraint (e.g., CONF:86-7345). The digits in the conformance number before the hyphen identify which implementation guide the template belongs to and the number after the hyphen is unique to the owning implementation guide. Together, these two numbers uniquely identify each constraint. These identifiers are persistent but not sequential.

Templates are declared at the document, section, and entry level of CDA documents. The C-CDA Implementation Guide defines an initial set of commonly used clinical documents whose contents are harmonized, thus ensuring semantic interoperability across current and future document models. Templates capture specific uses and can represent professional society recommendations, national clinical practice guidelines, and standardized data sets. Templates are designed to create standardized clinical documents that are specifically intended to support clinical workflows in various use cases.

Document-level templates: These templates constrain fields in the CDA header, and define containment relationships to CDA sections. For example, the Continuity of Care Document (CCD) template contains patient summary data defined by the ASTM Continuity of Care Record (CCR) represented in the C-CDA XML format. Understanding the purpose of a template helps to ensure that implementations support the inclusion of clinical information that is relevant to the intended use. In the case of the CCD, the clinical content is limited to the most relevant patient data captured during one or more encounters to ensure continuity of patient care. Similarly, the Problem Observation entry template captures a single problem or diagnosis for the patient and is limited to information about the problem or diagnosis, such as the diagnosis or observation date and the code representing the diagnosis or observation.

Templates are available in different types that reflect levels of a CDA document. Starting at the top of a document, the **header template** describes the scope and intended use of the document. The header includes the metadata, or data about the document data, that details contextual information, such as who created the document, encounter or event time and location, and patient demographics. In the broadest sense, header templates are documents with no defined body content.

Content comprising the document body and additional constraints on the header are expressed within **document templates** that define the clinical information contained based on the purpose for the document. Document templates include constraints on the CDA header and indicate contained section-level templates.
Each document-level template contains the following information:

- Scope and intended use of the document type
- Description and explanatory narrative
- Template metadata (e.g., templateId)
- Header constraints (e.g., document type, template id, participants)
- Required and optional section-level templates

Contents of the document body are comprised of **section and entry templates**. These templates specify

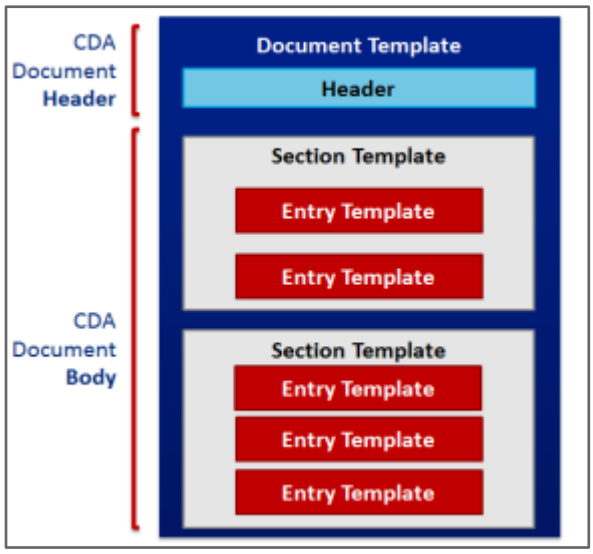
standardized patterns used to express clinical concepts and provide the basis for reusability of CDA documents. Document templates include section and entry templates as needed, but the section and entry templates are not limited to a certain document. For example, the same Medications section may be used in more than one type of document, as in the case of the CCD and Consultation Note.

The Section-level templates constrain fields in the CDA section, and define containment relationships to CDA entries that revolve around a common clinical concept, such as Procedures or Encounters. The Procedures section template captures information relative to patient procedures detailed in the entry templates that specify the procedure.

The **entry-level templates** constrain the CDA clinical statement model in accordance with real-world observations and acts. The **entry-level templates** represent individual clinical statements through coded data elements, such as a specific medication or procedure. Entries are very specific templates intended to capture an event, action, or observation relative to the clinical concept captured in the Section. Each **document template** defines a collection of required and optional sections as well as the entries within sections. Figure 2 depicts the template types in the CDA document.

Lastly, there are also **Other templates** that exist to establish a set of constraints that are reused in the CDA document. These other templates are only used within another template, rather than on their own as a complete clinical statement. For example, US Realm Date and Time (DTM.US.FIELDED) includes a set of common constraints for recording time. This template is referenced several times with other templates used in the testing documentation.

Figure 2: CDA Template Types



TEMPLATE VERSIONING

In HL7 implementation guides a new version of an existing implementation guide reuses templates from the previous version. During the ballot phase or update phase, templates carry the designation “Published” to indicate the template is unchanged from the previous version or “Draft” to indicate a new or revised template. Substantial revisions to previously published templates are indicated by the version number (V2, V3, etc.) in all phases: ballot, update, and published guides.

If there are no substantive changes to a template that has been successfully published, the template will carry the same templateId/@root (identifier oid) and templateId/@extension as in the previous implementation guide. (In the case of older templates, the @extension attribute will not be present.) During a new ballot or update phase, "Published" is appended to the main heading for the template to indicate that the template cannot be commented on in the ballot or update. The "Published" designation is removed in the final publication versions.

A revised version of a previously published template keeps the same templateId/@root as the previous version but is assigned a new templateId/@extension. The notation "(Vn)" (V2, V3, etc.) is also added to the template name. Versions are not necessarily forward or backward compatible. A versioning may be due to substantive changes in the template or because a contained template has changed. The "(Vn)" designation is persistent; it appears with that template when it is used in subsequent guides. During a new ballot or update phase, "Draft" is appended to the main heading for the template to indicate that it may be voted on in the ballot or commented on in the update; the "Draft" designation is removed in the final publication versions.

Structured Documents Working Group collaborated with Templates Working Group to establish template versioning recommendations, recently published in the following specification: HL7 Templates Standard: Specification and Use of Reusable Information Constraint Templates, Release 1. SDWG will leverage that specification to create guidance for template IDs and template versioning for future CDA implementation guides, including future versions of C-CDA, but that work is still in progress. The versioning approach used in this version of C-CDA is likely to be close to the final guidance, but has not been formally approved by SDWG for all implementation guides at this time.

Use of Deprecated Template Versions

Several templates used in C-CDA 1.1 were deprecated as of C-CDA R2. The status for these templates remains deprecated in the Release 2.1 guide. Deprecation of a template version does not prohibit its use in a document, rather, it is a signal to implementers this version of the template may be permanently retired (terminated) in the future, which will end the lifecycle of the template. (For more about deprecated templates, see the section titled *Use of Deprecated Template Versions*). In C-CDA R2.1, the "status" observation templates remain deprecated. The list of deprecated templates appears below:

- Discharge Diet Section
- Implants Section
- Surgery Description Section
- Allergy Status Observation
- Cognitive Status Problem Observation
- Functional Status Problem Observation
- Pressure Ulcer Observation
- Problem Status

Status of a Template Version

Each version of a template has a status. For example, a template version can be draft, active, or deprecated, etc. The HL7 Templates DSTU describes the various status states that may apply to a template version over the course of its lifecycle. Each version of a template has an associated status. This, one version of a template may be deprecated, while a newer version of that template may be draft or active. To support backward compatibility, systems that consume CDA documents need to address the possibility that a "status" observation template may also be present. The following guidance should be followed if a CDA document includes a deprecated status observation:

Deprecated "status" observation template	Implementer Guidance
A status of "active"	If the parent Observation has an effectiveTime/high, the content contains conflicting information.
A status of "resolved"	If the parent Observation does not have an effectiveTime/high, the content contains conflicting information.
A status of "inactive"	If the parent Observation does not have an effectiveTime/high, the content has the potential to contain conflicting information.

Levels of Constraint

The CDA standard describes conformance requirements in terms of three general levels corresponding to three different, incremental types of conformance statements:

- Level 1 requirements impose constraints upon the CDA Header. The body of a Level 1 document may be XML or an alternate allowed format. If XML, it must be CDA-conformant markup.
- Level 2 requirements specify constraints at the section level of a CDA XML document: most critically, the section code and the cardinality of the sections themselves, whether optional or required.
- Level 3 requirements specify constraints at the entry level within a section. A specification is considered "Level 3" if it requires any entry-level templates.

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 levels of reusability could be defined. The contexts table for each document type lists the sections defined in the document template.

5.4 COMPATIBILITY PRINCIPLES

This testing documentation contains new versions of templates included in C-CDA Release 2.0. Systems under test may want to support compatible template versions in the HL7 C-CDA R1.1 Implementation Guide. The new compatible template versions contain constraint modifications which enable compatibility with C-CDA 1.1 and are identified in the updated C-CDA R2.1 Volume 2 Summary of Changes Appendix.

New systems that wish to support C-CDA R1.1, R2.0 and R2.1 should review all specifications. A system developed strictly to the R2.1 version might not automatically support receiving R1.1 documents without additional development. Support for R2.0 conformant documents will require additional generation and import effort since different vocabulary requirements apply in several places.

Compatibility Principles

The baseline for C-CDA Release 2.1 is C-CDA Release 2.0. HL7 has applied these principles against templates present in C-CDA Release 1.1 and C-CDA R2.0 to create compatible template versions:

1. When a SHALL constraint present in C-CDA R1.1 is relaxed to SHOULD or MAY in C-CDA R2.0, the C-CDA R2.1 specification will increase the strength of that constraint to SHALL when compatibility is asserted.
2. When a SHALL constraint present is C-CDA R1.1 is removed in C-CDA R2.0, the C-CDA R2.1 specification will add that constraint when supporting compatibility.
3. When a SHOULD or MAY constraint present in C-CDA R1.1 is relaxed or removed in C-CDA R2.0, the C-CDA R2.1 specification will remain silent. As these constraints are not strictly required in a C-CDA R1.1

instance, they are not necessary for backwards compatibility. Implementers who wish to continue to convey data elements with a SHOULD or MAY constraint in C-CDA R1.1 can still report this information as it was done in C-CDA R1.1, so long as these are also conformant with this specification.

4. A SHALL, SHOULD or MAY constraint added in C-CDA R2.0 that is not explicitly prohibited in C-CDA R1.1 will be added to C-CDA R2.1.
5. When a vocabulary or value set binding has changed for an element to a new coding system in C-CDA R2.0, C-CDA R2.1 will — when supporting backwards compatibility — require the use of the old value set or vocabulary in *element*/code, the new value set or vocabulary in *element*/translation, and otherwise require the use of the new value set or vocabulary in code as it was constrained (with the same strength appearing) in C-CDA R2.0.

HL7 C-CDA R2.1 ASSERTION OF COMPATIBILITY

The HL7 C-CDA R2.1 volume 2 guides includes a requirement that all C-CDA R2.1 conformant instances:

- Include a C-CDA R2.1 templateId,
- Additionally, when the C-CDA R2.1 templateId includes an extension, the C-CDA R1.1 templateId must also be included.

By including both templateIds the sending application is asserting conformance with C-CDA R2.1 and C-CDA R1.1. This requirement (CONF:32936) is included in the US Realm Header (V3):

SHALL contain exactly one [1..1] **templateId** (CONF:1198-5252) such that it

a. **SHALL** contain exactly one [1..1] @**root**="2.16.840.1.113883.10.20.22.1.1" (CONF:1198-10036).

b. **SHALL** contain exactly one [1..1] @**extension**="2015-08-01" (CONF:1198-32503).

c. When asserting this templateId, all document, section, and entry templates **SHALL** include a templateId root without an extension. See C-CDA R2.1 Volume 1 - Design Considerations for additional detail (CONF:1198-32936).

5.5 DETERMINING THE STATUS OF CLINICAL STATEMENT

A recipient must be able to determine whether the status of an entry — which can include a problem, a medication administration, etc. — is active, completed, or in some other state. Determination of the exact status is dependent on the interplay between an act's various components (such as statusCode and effectiveTime), and inconsistent modeling between different objects.

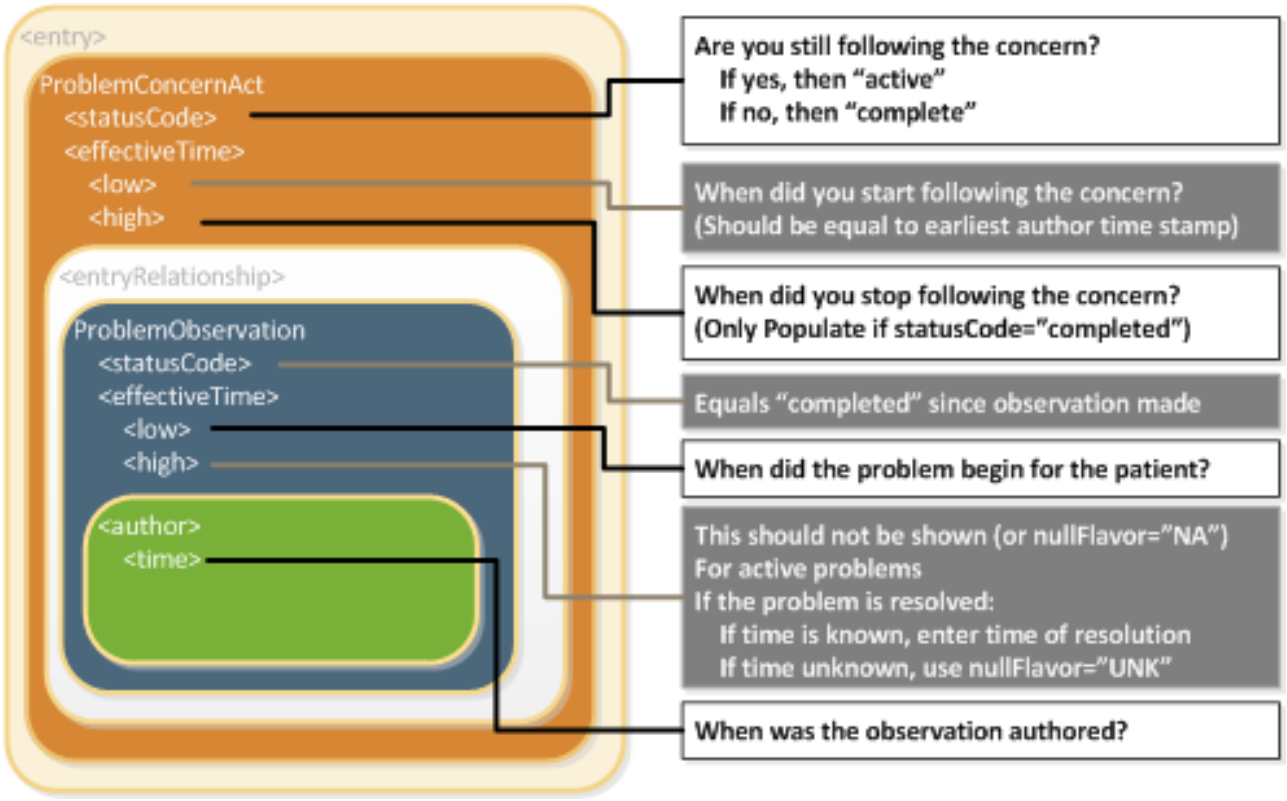
The following principles apply when representing or interpreting a clinical statement's status.

- **The Act.statusCode of the clinical statement specifies the state of the entry**: Per the RIM, the statusCode "reflects the state of the activity. In the case of an Observation, this is the status of the activity of observing, not the status of what is being observed."
- **Act.statusCode and Act.moodCode are inter-related**: Generally, an act in EVN (event) mood is a discrete event (a user looks, listens, measures; records what was done or observed), so generally an act in EVN mood will have a statusCode of "completed." A prolonged period of observation is an exception, in which a user would potentially have an observation in EVN mood that is "active." For an Observation in RQO (request) mood, the statusCode generally remains "active" until the request is complete, at which time the statusCode changes to "completed." For an Observation in GOL (goal) mood, the statusCode generally remains "active" as long as the observation in question is still an active goal for the patient.
- **Act.statusCode and Act.effectiveTime are inter-related**: Per the RIM, the effectiveTime, also referred to as the "biologically relevant time," is the time at which the act holds for the patient. So, whereas the effectiveTime is the biologically relevant time, the statusCode is the state of the activity. For a provider seeing a patient in a clinic and observing a history of heart attack that occurred 5 years ago, the status of the observation is completed, and the effectiveTime is five years ago.

The Problem Concern Act (V2) (templateId 2.16.840.1.113883.10.20.22.4.3:2014-06-09) reflects an ongoing concern on behalf of the provider who placed the concern on a patient's problem list. So long as the provider has an ongoing concern — meaning that the provider is monitoring the condition, whether it includes problems that have resolved or not — the statusCode of the Problem Concern Act is "active." When the underlying condition is no longer an active concern, the statusCode of the Problem Concern Act is set to "completed." The effectiveTime of a Problem Concern Act reflects the time that the concern about an underlying condition — as such, the effectiveTime of the concern may not correspond to the effectiveTime of the condition. For example, a patient may have suffered a heart attack 5 years ago, but a physician may continue to have an active concern about the patient's cardiac condition.

A Problem Concern Act can contain one or more Problem Observations (templateId 2.16.840.1.113883.10.20.22.4.4:2014-06-09). Each Problem Observation is a discrete observation of a condition and therefore has a statusCode of "completed." The statusCode of the Problem Concern Act is the definitive indication of the status of the concern. The effectiveTime of the Problem Observation is the definitive indication of whether the underlying condition is resolved. This is shown graphically in the following figure.

Figure 3: componentOf/encompassingEncounter Header Element



5.6 NARRATIVE REFERENCE

The C-CDA R1.1 release recommends that clinical statements include a link between the narrative (section.text) and coded clinical data (entry). Rather than repeat these constraints in every applicable entry, SDWG agreed in R2.0 to apply the following constraint to all entry templates, unless explicitly prohibited.

SHOULD contain zero or one [0..1] **text** (CONF:XXXX).

a. The text, if present, **SHOULD** contain zero or one [0..1] **reference/@value** (CONF: XXXX).

i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA R2.0, section 4.3.5.1) (CONF: XXXX).

MAY contain zero or one [0..1] original**Text** (CONF:XXXX).

a. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value** (CONF:XXXX).
    i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA R2.0, section 4.3.5.1) (CONF:XXXX).

5.7 OVERALL DOCUMENT TESTABLE ASSERTIONS:

Please provide your suggested edit/additions/deletions to testing@sequoiaproject.org.

Testable Assertion 5.7.1; Systems receiving CDA documents **SHALL** be capable of rendering all human-readable content of CDA documents received. Inclusion of additional sections or content does not affect validation as long as conformance to the specified template is maintained.

Testable Assertion 5.7.2; While some systems **MAY** create C-CDAs with only the required sections,

Testable Assertion 5.7.3; others **MAY** include additional optional sections if the Template is Open.

Testable Assertion 5.7.4; Still, others **MAY** include additional templates not included in the C-CDA document template definition.

Testable Assertion 5.7.5; The **receiving system** is not required to parse the structured entries (machine-readable fields) in the additional sections,

Testable Assertion 5.7.6; but it **SHALL** be able to display the entire CDA document, including narrative blocks, in human-readable form.

Testable Assertion 5.7.7; CDA R2 requirements affecting design[1] are provided directly from the standard for reference below: There **SHALL** be a deterministic way for a recipient of an arbitrary CDA document to render the attested content.

Testable Assertion 5.7.8; Human readability **SHALL NOT** require a sender to transmit a special style sheet along with a CDA document. It must be possible to render all CDA documents with a single style sheet and general-market display tools.

Testable Assertion 5.7.9; Human readability applies to the authenticated content. There **MAY** be additional information conveyed in the document that is there primarily for machine processing that is not authenticated and need not be rendered.

Testable Assertion 5.7.10; When structured content is derived from narrative, there **SHALL** be a mechanism to describe the process (e.g. by author, by human coder, by natural language processing algorithm, by specific software) by which machine-processable portions were derived from a block of narrative.

[1] Taken from section 1.2.3 of the CDA R2 specification available through HL7.

Testable Assertions 5.7.11; When narrative is derived from structured content, there **SHALL** be a mechanism to identify the process by which narrative was generated from structured data.

Testable Assertion 5.7.12; Document Sources **SHALL** provide the capability to send all data for Meaningful Use Requirements,

Testable Assertion 5.7.13; but **SHOULD** also provide flexibility for clinicians to select the pertinent information to send for a transition of care and/or clinical summary for a patient.

Testable Assertion 5.7.16; There **MAY** be certain tests that can be completed to validate that vendors can properly express the absence of information, however. For example, a vendor may include a flavor of null to indicate that there are no known medications, or no known allergies, which are Meaningful Use requirements, rather than leave these sections blank.

Testable Assertion 5.7.17; Providers **SHOULD** use certified document source modular capabilities, where available, to select or deselect information such that the clinical document is relevant for the receiving clinician and/or the patient. The following guidance for providers assumes that they are using certified Document Source technology from vendors that are capable of providing all required Meaningful Use data. Furthermore, it assumes that the Document Source offers the selectability features recommended above. In the ONC S&I ToC Initiative, consensus was obtained on the importance of including information relevant to the specific transition of care circumstance, and warned against the risks, to adoption and quality of care provided, of sending the recipient clinician too much data (e.g. all of the information in the EHR on the patient) rather than a tailored message. There are concerns that if too much information is included, the recipient clinician may miss the relevant key data on the patient. Using the example of the closed-loop referral, current clinical practice involves the sending clinician composing a referral letter with pertinent positive and negative clinical information about the patient pertaining to the question that the clinician is asking of the consultant.

Testable Assertion 5.7.18; Therefore, any given instance of a CDA document, produced for a real patient in the context of a specific transition of care, **MAY** not contain all data that is available.

Testable Assertion 5.7.19; Data **MAY** exist but cannot be obtained (e.g. patient was unconscious so birth date and other demographic information was not obtained even though they are required, or the patient was asked about medications and did not know them).

- The data was not generated for this instance (e.g. patient had a visit with the physician, but there were no tests performed so there are no results in the Results Section, even though that section is required).

- The author exercised clinical judgment to limit the summary to information deemed by the sender to be pertinent to the receiver (e.g. PCP has captured the patient's smoking status and vital signs (weight, blood pressure and temperature which were unremarkable), but knows that those are not relevant to the Podiatrist to whom the patient is being referred for an ingrown toenail). The author should have the ability through the EHR to select for inclusion in the document only those results that are relevant to the care transition.

Testable Assertion 5.7.20; Chapter 1.8.8 of the Consolidated CDA implementation guide details how to handle unavailable and unknown information. **In HL7 V3, unavailable, unknown or incomplete data are handled with 'flavors of null' representing coded values that communicate the reasoning for missing information. Asserting a value for missing data is necessary where entries are required to meet validation.** In addition, communicating reasons for missing data is important in other circumstances as good practice. Indicating null flavors at the appropriate level of precision to convey reasoning for missing required or expected data is encouraged. **The null flavor vocabulary domain within the CDA R2 details the complete hierarchy of null flavor values.**

Testable Assertion 5.7.21; Problems, medications, and medication allergies sections **SHALL NOT** be "left blank", but must include the section and a null value describing the unknown data.

Testable Assertion 5.7.22; Creators of CDA documents **SHALL** be mindful of the purpose of the document as well as the intended use so that only clinically relevant data is sent.

- A circumstance where too much information or irrelevant data is provided presents opportunity for information overload and may have an undesirable impact on patient care. For example, MU 2014 EDITION requires the inclusion of medications. All current and active medications must be clear to the recipient, so detailing all historical medications is not recommended.

5.8 ASSESSING C-CDA DOCUMENTS FOR MEANINGFUL USE

The majority of eHealth Exchange participants provide some form of the Continuity of Care Document (CCD) type when exchanging clinical data.

This section details the body constraints for select CDA documents and results of the assessment. The US Realm Clinical Document Header **SHALL** be required for all document templates.

Considerations are provided below for implementations of the Consolidated CDA General Header, Section and Entry template requirements for encounter and care team information.

ONC TOC CONSOLIDATED CDA IG CHAPTER REFERENCES

Table 3: Initiative Consensus Recommendations and Consolidated CDA(C-CDA) IG Chapters

MU Data Requirement	Consensus Recommendations	C-CDA IG (Release 1.1) Chapter	C-CDA IG (Release 2.1) Chapter
Patient Name; Sex; Date of Birth; Race; Ethnicity; Preferred Language	**Header element:** Record Target	2.2.1	Volume 2 Section 1.1
Provider Name & Contact Information [participating in the encounter]; Date and Location of Visit or Hospitalization; Care Team Members [participating in the encounter]	**Header element:** Component Of Encompassing Encounter	2.2.13	Volume 2 Section 1.1
Provider Name & Contact Information [performing the service event]; Care Team Members [performing the service event]	**Header element:** Documentation Of Service Event	2.2.11	Volume 2 Section 1.1
Medication Allergies	Allergies Section	4.2	Volume 2 Section 2.4.1
Functional Status; Cognitive Status	Functional Status Section	4.14	Volume 2 Section 2.20
Discharge Instructions or Clinical Instructions	Hospital Discharge Instructions Section (inpatient settings) or Instructions Section	4.23 or 4.28	Volume 2 Section 3.4

MU Data Requirement	Consensus Recommendations	C-CDA IG (Release 1.1) Chapter	C-CDA IG (Release 2.1) Chapter
Immunizations	Immunizations Section	4.27	Volume 2 Section 2.32.1
Medications	Medications Section (entries required) or Hospital Discharge Medications (inpatient settings)	4.33 or 4.24	Volume 2 Section 2.38
Care Plan, including goals and instructions; Future Scheduled Tests and Appointments; Referrals to Other Providers; Diagnostic Test(s) Pending	Plan of Care Section or Assessment and Plan Section	4.39 and/or 4.4	Volume 2 Section 2.48
Problems	Problems Section (entries required)	4.44	Volume 2 Section 2.53.1
Procedures	Procedures Section (entries required)	4.52	Volume 2 Section 2.61.1
Reason for Referral	Reason for Referral Section	4.53	Volume 2 Section 2.62
Reason for Visit or Hospitalization	Reason for Visit or Chief Complaint or Chief Complaint and Reason for Visit	4.54 and/or 4.7	Volume 2 Section 2.63
Laboratory Test(s); Results of Laboratory Test(s)	Results Section (entries required)	4.55	Volume 2 Section 2.64.1
Smoking Status	Social History Section	4.57	Volume 2 Section 2.66
Vital Signs	Vital Signs Section	4.60	Volume 2 Section 2.70.1

5.9 HEADER CONSTRAINTS SPECIFIC TO C-CDA

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. An example of this would be a doctor using an EHR that already contains the patient's name, date of birth, 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.

The eHealth Exchange recommends that the following **SHALL** be present whenever the document is viewed:

- Document title and document dates

- Service and encounter types, and date ranges as appropriate
- Names of all persons along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Names of selected organizations along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Date of birth for recordTarget(s)
- Patient identifying information

In addition, Operative and Procedure Notes, the following information is typically displayed in the EHR and/or rendered directly in the document:

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

DOCUMENT META DATA CARE TEAM MEMBERS AND PROVIDER NAMES AND CONTACT INFORMATION CONSIDERATIONS

A CDA participant (i.e., Author, Informant), per the Reference Information Model (RIM) is "an association between an Act and a Role with an Entity playing that Role. Each Entity (in a Role) involved in an Act in a certain way is linked to the Act by one Participation-instance. The kind of involvement in the act is specified by the Participation.typeCode."

CDA principles when asserting participations include:

- Participation persistence: An object's participations (and participation time stamps) don't change just because that object is reused. For instance, authorship of an object doesn't change just because that object is not included in a summary document.
- Participation evolution: Additional participations (and participation time stamps) can be ascribed to an object over its lifetime. (In some cases, an electronic health record (EHR) system will create a new object instead of adding participants to an existing object, such as when an EHR has imported a C-CDA and the receiving clinician chooses to create a local problem list entry corresponding to a problem in the C-CDA).
- Device participation: Devices do not participate as legally responsible entities, but can participate as authors in some scenarios.

Meaningful Use 2014 Edition criterion §170.314(b)(4) Clinical Information Reconciliation requires a system to "simultaneously display (i.e., in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the **source** and **last modification date**."

CDA addresses this requirement via the Author Participation and its time stamp. CDA requires that Author and Author time stamp be asserted in the document header. From there, authorship propagates to contained sections and contained entries, unless explicitly overridden. Thus, all entries in CDA implicitly include Author and Author time stamp.

The HL7 C-CDA 2.1 version added a new Author Participation template (templateId 2.16.840.1.113883.10.20.22.4.119) to better ensure consistent representation. This template should be used to explicitly assert authorship and author time stamps, unless the values propagated from the document header hold true.

Care team members, including providers, are participants in the care of a patient. A patient's care team may include individuals providing support to the patient, such as family members or caregivers, as well as providers and non-physician providers, including nurses, technicians, and assistants. When capturing care team member information, it is recommended to capture the name, identification number, and contact information along with

codes to indicate the type of provider and role in the patient's care. Detailing the type of provider and role helps to distinguish care team members across care settings so that participants in the patient's care are clear to recipients of the document.

Within CDA, care team members are represented as participants in elements of the document header associated with the patient, the clinical encounter and/or service event detailed in the document, and the document itself. Applicable header elements for capturing care team members from Section 2.2 of the Consolidated CDA implementation guide are described in the following table.

Table 4: Participants in the Header

Participant	Description
author	Care team member who generates content contained in the document. *Examples: PCP, nurse practitioner, admitting physician*
dataEnterer	Care team member who enters information into the document by transferring content from another source, such as a paper chart. *Examples: transcriptionist, technician*
informant	Care team member providing information about a patient contained in the document. *Examples: PCP, family member, caregiver*
informationRecipient	Care team member who the document is intended for. *Examples: PCP, caregiver, consulting physician*
legalAuthenticator	Care team member who authenticates content contained in the document and accepts legal responsibility. *Examples: PCP, consulting physician, attending physician*
authenticator	Care team member who authenticates content contained in the document. *Examples: PCP, consulting physician, attending physician*
participant	Other supporting care team members associated with the patient. *Examples: Caregiver, family member, emergency contact*
documentationOf/ serviceEvent/ performer	Care team member who performs the service event detailed in the document. *Examples: PCP, surgeon, consulting physician*
componentOf/ encompassingEncounter/ encounterParticipant	Care team member who participates in the encounter detailed in the document. *Examples: PCP, consulting physician, attending physician*

In most cases, multiple participants will be the same care team member. For example, a consulting physician may see a patient in a clinical encounter, dictate a note, and legally authenticate the document. In this example, the consulting physician is participating as the encounterParticipant, author, and legalAuthenticator. In support of Meaningful Use goals to provide complete and accurate information, it is recommended to capture care team member and provider name and contact information data requirements within participants associated with the clinical encounter or service event detailed in the document. This practice ensures that the recipient of the document knows the care team member who participated in the clinical encounter or performed the service event for any follow-up communications.

Generally, service events, such as procedures, occur as part of a clinical encounter associated with a visit or hospitalization. For example, a patient may be referred by a general surgeon to a surgical specialist in an outpatient surgery center for a specific procedure. In this example, the general surgeon who referred the patient is associated with the clinical encounter that represents the setting during which the procedure occurred. The surgical specialist is then associated with the procedure, or service event, that happened as part of the clinical encounter and is listed as a performer in the documentationOf/serviceEvent header element. Within the document detailing the procedure, these care team members would be captured as participants in distinct header elements associated with the clinical encounter from which the patient was referred or the procedure service

event that transpired.

The C-CDA serves as a summary for a provision of care service event. The provision of care occurs over a specified period of time that may include multiple clinical encounters. For the provision of care, key care team members like the PCP and consulting physicians perform the provision of care over time. Other clinical encounters relevant to communicate for continuity of care purposes would be captured in the Encounters section in the document body along with associated care team members. The C-CDA **MAY** also be used to detail a single encounter within the provision of care. For single encounters, key care team members are still performers of the provision of care captured in the documentationOf/serviceEvent header element while care team members participating in the specific clinical encounter are the encounterParticipants within the componentOf/encompassingEncounter header element. To help demonstrate care team member participants for the C-CDA, example scenarios are provided below.

Tables 5: Sample C-CDA Participant Scenarios

The PCP in an ambulatory setting generates a CCD to summarize a patient's healthcare for transmission to the PHR (*View/Download/Transmit Objective*).	
documentationOf/serviceEvent	Captures names and contact information for key care team members including the PCP and other active care providers, such as the patient's physical therapist or dietician
Encounters section	Captures relevant encounters and associated care team members

The consulting physician in an ambulatory setting generates a C-CDA detailing an encounter to provide to the patient and the patient's caregiver (*Clinical Summary Objective*).	
participant/	Captures the names and contact information of supporting participants, including the patient's caregiver
documentationOf/serviceEvent	Captures the names and contact information for any known key care team members, such as the PCP, who may not be participating in the encounter
componentOf/encompassingEncounter	Captures the names and contact information of the consulting provider as the responsible party for the clinical encounter and the nurse practitioner as an encounterParticipant

The discharging physician in an inpatient setting generates a C-CDA to detail the hospitalization to send to the patient's PCP (*Transition of Care Objective*).	
documentationOf/serviceEvent	Captures the names and contact information for any known key care team members, including the PCP
componentOf/encompassingEncounter	Captures the names and contact information of the attending physician as the responsible party for the clinical encounter and the discharging physician and rounding physician as encounterParticipants

The Consolidated CDA implementation guide includes specific guidance on participants for each document, with example participant scenarios provided in Section 3.7.1.5.

Location of Visit or Hospitalization and Date of Visit or Admission and Discharge

Dates and locations for visits and hospitalizations are captured as the clinical encounter setting detailed within the componentOf/encompassingEncounter header element. The date of the visit is captured in the effectiveTime for the clinical encounter and specific dates for hospitalizations can be specified using effectiveTime/low for the admission date and effectiveTime/high for the discharge date. Within the componentOf/encompassingEncounter,

the location for the visit or hospitalization is captured as the healthcareFacility/location. When the location of the visit or hospitalization is part of an organization, such as an emergency department within a hospital, the healthcareFacility/location would describe the emergency department and the hospital would be the healthcareFacility/serviceProviderOrganization.

COMPONENTOF/ENCOMPASSINGENCOUNTER HEADER ELEMENT

The componentOf/encompassingEncounter element captures **care team member and provider information**, **date of visit or admission and discharge**, and **location of visit or hospitalization** when the document is detailing an encounter. If the document is detailing a service event, care team members or providers performing the service event are captured in the documentationOf/serviceEvent header element.

Through analysis of Consolidated CDA, the ToC Initiative has determined the following elements within the componentOf/encompassingEncounter header element are recommended to capture **Care Team Members, Provider Names and Contact Information**, **Date of Visit** or **Hospitalization Admission and Discharge Dates**, and **Location of Visit or Hospitalization** MU 2014 EDITION data requirements. The structure of the componentOf/encompassingEncounter header element is described hierarchically with corresponding constraints (e.g., SHALL, SHOULD, MAY) as specified in Section 2.2.13 of the Consolidated CDA implementation guide. Elements without a constraint are not specified within the General Header template, but guidance may be found within Sections 3.2 and 3.4 of the Consolidated CDA implementation guide for the Consultation Note and Discharge Summary document templates. Descriptions of select elements are provided in [brackets] and elements representing MU 2014 EDITION data requirements are shaded in red.

Figure 4: componentOf/encompassingEncounter Header Element

componentOf/encompassingEncounter
SHALL **id**
SHALL **effectiveTime** [date of visit or hospitalization]
low [admission date]
high [discharge date]
location
healthcareFacility
id
code
location [location of visit or hospitalization]
name
addr
serviceProviderOrganization [provider's organization]
id
name
telecom
addr
standardIndustryClassCode [type of facility]
responsibleParty [care team member or provider responsible for the encounter]
assignedEntity
assignedPerson or representedOrganization
name [care team member or provider name]
addr [care team member or provider contact information]
telecom [care team member or provider contact information]
encounterParticipant [care team member or provider participating in the encounter]
typeCode [type of care team member or provider]
effectiveTime [time of participation in the encounter]
assignedEntity

assignedPerson or representedOrganization
name [care team member or provider name]
addr [care team member or provider contact information]
telecom [care team member or provider contact information]

DOCUMENTATIONOF/SERVICEEVENT HEADER ELEMENT

The documentationOf/serviceEvent element captures **care team member and provider information**, **date of visit or admission and discharge**, and **location of visit or hospitalization** when the document is detailing a service event.

Through analysis of Consolidated CDA, the ToC Initiative has determined the following elements within the documentationOf/serviceEvent header element are recommended to capture service event **Care Team Members** and **Provider Names and Contact Information** MU 2014 EDITION data requirements. The structure of the documentationOf/serviceEvent header element is described hierarchically with corresponding constraints as specified in Section 2.2.11 of the Consolidated CDA implementation guide. Elements without a constraint are not specified within the General Header template, but guidance may be found within Section 3.1 of the Consolidated CDA implementation guide for the C-CDA document template. Descriptions of select elements are provided in [brackets] and elements representing MU 2014 EDITION data requirements are shaded in red.

Figure 5: documentationOf/serviceEvent Header Element

documentationOf/serviceEvent
SHALL **effectiveTime** [date of visit or hospitalization]
SHALL **low** [admission date]
high [discharge date]
SHOULD **performer** [care team member or provider performing the service event]
SHALL **typeCode** [type of care team member or provider participation in service event]
MAY **functionCode** [care team member or provider role in service event]
SHALL **assignedEntity**
SHALL **id**
SHOULD **code** [care team member or provider type]
addr [care team member or provider contact information]
telecom [care team member or provider contact information]
assignedPerson
name [care team member or provider name]

AUTHORIZATION/CONSENT

The header can record information about the patient's consent.

The type of consent (e.g., a consent to perform the related serviceEvent) is conveyed in consent/code. Consents in the header have been finalized (consent/statusCode must equal Completed) and should be on file. The HL7 specifications do not address how Privacy Consent is represented, but does not preclude the inclusion of 'Privacy Consent'.

PATIENT INFORMATION

This category captures MU 2014 EDITION requirements pertaining to patient information and elements within the General Header template that meet the requirement for an MU 2014 EDITION Objective.

Considerations for implementations of the Consolidated CDA general header template to achieve MU 2014 EDITION requirements for patient information within the Record Target header element are provided below.

Patient Name, Sex, and Date of Birth

No further considerations are needed for implementing these MU 2014 EDITION data requirements in the header.

Patient Preferred Language

Consolidated CDA specifies RFC 4646 SHALL be used for the language value set. RFC 4646, which is maintained by The Internet Society, describes the structure, content, construction, and semantics of language tags. The RFC 4646 specifies how the MU 2014 EDITION-required ISO 639-2 alpha-3 codes are used, so it is allowable in Consolidated CDA. For situations where the patient language is unknown or declined to provide, the ability to capture these details within the EHR is required by the 2014 Ed. CEHRT. Allowable representations for the MU 2014 EDITION summary types include null values (e.g., ASKU) or special codes "undetermined" (UND) or "missing" (MIS) from ISO 639-2.

Patient Race and Ethnicity

These data elements require the use of the Office of Management and Budget (OMB) Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997. Consolidated CDA specifies a CDC Race and Ethnicity value set containing applicable codes reflecting the OMB standard for the requirement. In instances where the patient declines to provide their race or ethnicity or it is unknown, HL7 null values may be used.

For indicating multiple race codes for a patient, a CDA R2 extension is specified: sdtc:raceCode. Additional information on CDA R2 extensions and their use is available in Appendix G of the Consolidated CDA implementation guide.

recordTarget Header Element

Through analysis of Consolidated CDA, the ToC Initiative has determined the following elements within the recordTarget header element are recommended to capture Patient Name, Sex, Date of Birth, Preferred Language, Race, and Ethnicity MU 2014 EDITION data requirements. The structure of the recordTarget header element is described hierarchically with corresponding constraints as specified in Section 2.2.1 of the Consolidated CDA implementation guide. Descriptions of select elements are provided in [brackets] and elements representing MU 2014 EDITION data requirements are shaded in red.

Figure 6: recordTarget Header Element

recordTarget
SHALL **patientRole**
SHALL **id**
SHALL **addr**
SHALL **telecom**
SHALL **patient**
SHALL **name** [patient name]
SHOULD **administrativeGenderCode** [sex]
SHALL **birthTime** [date of birth]
SHOULD **maritalStatusCode**
MAY **religiousAffiliationCode**
MAY **raceCode** [race]
MAY **sdtc:raceCode** [additional race]
MAY **ethnicGroupCode** [ethnicity]
MAY **guardian**

MAY **birthPlace**
SHOULD **languageCommunication** [preferred language]
SHALL **languageCode**
MAY **preferenceInd**
MAY **providerOrganization**

6 CONSOLIDATED HL7 C-CDA® SECTION REQUIREMENTS & MEANINGFUL USE REQUIREMENTS

6.1 SECTION-LEVEL TESTABLE ASSERTIONS

A requirement and function of sections, per the base CDA standard, is that section templates **SHALL** contain human-readable content and **MAY** contain machine-readable data. At a minimum, CDA requires human-readability, meaning that the CDA document can be displayed on a standard web browser and be understood when read. Therefore, even when the document is sent to an organization without an electronic health record (EHR), the recipient clinician can still read the content and provide care accordingly. At a higher degree, machine-readable data in entry templates can be "consumed" by an information system and integrated for applications such as medication reconciliation or clinical decision support.

Table 6: MU Mapping to Consolidated CDA Sections & Requirements

MU Data Requirements	Consolidated CDA Section	C-CDA R1.1	C-CDA R R2.1
	Advance Directives (entries optional)	**O**	**O**
Medication allergies	Allergies and Intolerances (entries required)	**R**	**R**
	Encounters (entries optional)	**O**	**O**
	Family History	**O**	**O**
Functional Status; Cognitive Status	Functional Status	**O**	**O**
Discharge instructions (Inpatient setting)	Hospital Discharge Instructions	**O**	**O**
Immunizations	Immunizations (entries optional)	**O**	**O**
Clinical instructions; Recommended patient decision aids	Instructions		
	Medical Equipment	**O**	**O**
Medications	Medications (entries required)	**R**	**R**
	Mental Status		**O**
	Nutrition		**O**
	Payers	**O**	**O**
Care plan, including goals and instructions; Future appointments; Future scheduled tests; Referrals to other providers; Diagnostic tests pending	Plan of Care or Assessment and Plan of Treatment	**O**	**O**
Problems	Problem (entries required)	**R**	**R**
Procedures	Procedures (entries required)	**O**	**R**
Reason for Referral	Reason for Referral	**O**	**O**
Reason(s) for visit or Reason(s) for hospitalization (Inpatient setting)	Reason for Visit or Chief Complaint or Chief Complaint and Reason for Visit	**O**	**O**
Laboratory Tests; Values/results of laboratory tests	Results (entries required)	**R**	**R**

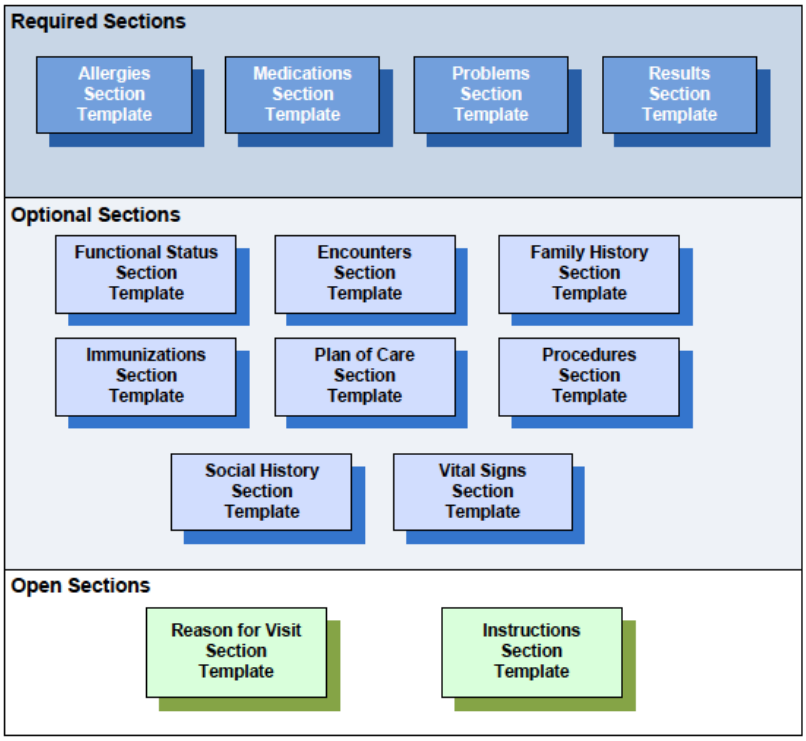
Smoking status	Social History	**O**	**R**
Vital signs	Vital Signs (entries optional)	**O**	**R**

Please note that the use of the unstructured document template for MU2 requirements is prohibited. However, the eHealth Exchange participants my leverage this document type for narrative documents without structured entries.

OPTIONS FOR SYSTEMS SENDING AND RECEIVING CDA DOCUMENTS

To meet the varying business needs of healthcare organizations, the ability to include additional content beyond the Consolidated CDA document template is allowable and maintains compliance with the underlying CDA R2 standard. This means that open document templates may be supplemented by additional CDA section or entry templates and remain a fully compliant CDA document, which is shown in Figure 7 below.

Figure 7: Example C-CDA with open sections



Systems receiving CDA documents **SHALL** be capable of rendering all human-readable content of CDA documents received. This ensures that any additional content beyond template definitions are at least displayable. As discussion in section 5.7 of this guide, inclusion of additional sections or content does not affect validation as long as conformance to the specific template is maintained.

Principles in Practice: While some systems may create C-CDAs with only the minimum required sections, others may include additional optional sections. Still, others may include additional templates not included in the C-CDA document type definition. The receiving system is not required to parse the structured entries (machine-readable fields) in the additional sections, but it **SHALL** be able to display the entire CDA document, including narrative blocks, in human-readable form.

7 USING CDA DOCUMENTS TO MEET THE NEEDS OF CARE TRANSITIONS

The goal of the approach is to address the needs of providers in a care transition, beyond Meaningful Use.

The approach is informed by the collective efforts of the Transitions of Care Initiative to identify and define the core clinical information that should be exchanged in every patient care transition. The core clinical information includes MU requirements as the minimum data set and a robust set of clinical information to meet the needs of clinicians and ensure continuity of care for a given clinical scenario. The ToC recommended approach is the representation of core clinical information in Consolidated CDA.

7.1 HANDLING MISSING OR IRRELEVANT CLINICAL DATA

Information technology solutions store and manage data, but sometimes data are not available. An item may be unknown, not relevant, or not computable or measureable, such as where a patient arrives at an emergency department unconscious and with no identification.

In many cases, the C-CDA standard will stipulate that a piece of information is required (e.g., via a SHALL conformance verb). However, in most of these cases, the standard provides an "out", allowing the sender to indicate that the information isn't known.

Many fields in C-CDA contain a "@nullFlavor" attribute, used to indicate an exceptional value. Some flavors of Null are used to indicate that the known information falls outside of value set binding constraints. Not all uses of the @nullFlavor attribute are associated with a case in which information is unknown.

Section 1.8.8 of the Consolidated CDA implementation guide details how to handle unavailable and unknown information. Further details can be found in the HL7 V3 Data Types Release 1 specification that accompanies the CDA R2 normative standards. However, it should be noted that the focus of Consolidated CDA is on the ambiguous representation of known data, and that in general, the often subtle nuances of unknown representation are less relevant to the recipient.

In HL7 V3, unavailable, unknown or incomplete data are handled with 'flavors of null' representing coded values that communicate the reasoning for missing information. Asserting a value for missing data is necessary where entries are required to meet validation. In addition, communicating reasons for missing data is important in other circumstances as good practice. Indicating null flavors at the appropriate level of precision to convey reasoning for missing required or expected data is encouraged. The null flavor vocabulary domain within the CDA R2 details the complete hierarchy of null flavor values.

OPTIONS FOR DATA THAT IS TEMPORARILY UNAVAILABLE

For information that is not available at the time a CDA document is sent, the incomplete document may be sent even though it is not fully compliant. When the information is available to complete the document, a new document with a new object identifier (OID) is created and marked to communicate that it supersedes the previous version of the document.

UNKNOWN DATA IN SECTIONS THAT REQUIRE ENTRIES

Asserting a null flavor at the section level for sections with entries required by the document template or MU2 data requirements is not permitted. These include sections detailing patient allergies, immunizations, medications, problems, procedures, and results. The machine-readable data required within these sections are specified for

clinical best practice and should not be completely omitted. In these instances, unknown information may be used on the specific act, such as a Procedure Activity.

Additionally, text describing any reasoning for the unknown information and a code indicating the precise unknown information are encouraged. The key is to describe any unknown information as explicitly as possible to ensure accurate communication. Further guidance and examples are provided in Section 1.8.9 of the Consolidated CDA implementation guide. The CMS Final Rule for EHR Incentive Program, Stage 2 also reinforces this concept, as quoted below.

"In our proposed rule we went further and said that if the provider does not have the information available to populate one or more of the fields listed, either because they can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, laboratory tests), the provider may leave the field(s) blank. The only exception to this is the problem list, medication list, and medication allergy list".

In other words, problems, medications, and medication allergies cannot simply be "left blank", but must include the section and a null value describing the unknown data.

NONE OR "NO KNOWN" DATA

In scenarios where the data reflects a value of 'none', negation indicators should be used. Examples include stating that a patient has no allergies or that administrating a certain immunization is inadvisable (contraindication). For scenarios like these, a negation indicator (negationInd) is used to flag the act as described in the third example within Section 1.8.9 of the R1.1 Consolidated CDA implementation guide. Explicit codes for no known information, such as "no known allergies" within an Allergy Observation, are not recommended within Consolidated CDA. Rather, a negation indicator is to be used on the act along with a text description along with a code indicating the data that has no value. For the purposes of this guide, emphasis is on distinguishing between statements of 'no known', which employ negation indicators, and 'I don't know', which employ null flavors.

IRRELEVANT (NOT PERTINENT) DATA

A circumstance where too much information or irrelevant data is provided presents opportunity for information overload and may have an undesirable impact on patient care. For example, MU2 requires the inclusion of medications. All current and active medications must be clear to the recipient, so detailing all historical medications is not recommended. Creators of CDA documents must be mindful of the purpose of the document as well as the intended use so that only clinically relevant data is sent.

7.2 USE OF NULL FLAVORS AND NEGATION INDICATORS

To communicate unknown, not relevant, or not computable or measurable data, the following practices are recommended for the approach.

1. Any **SHALL** conformance statement may use a null flavor to indicate unknown data, unless the attribute is required or the null flavor is explicitly disallowed.
2. **SHOULD** and **MAY** conformance statement may also use a null flavor.
3. Negation indicators **SHALL** be used for any required attribute reflecting the assertion of "no known" data (e.g., "no known allergies").

It is recommended to use the HL7 null flavor that most precisely describes the reason, e.g., ASKU (asked but unknown) is more precise than UNK (unknown), and NAV (temporarily unavailable) is more precise than ASKU (e.g., patient was asked and did not know, but will find out the answer). Additional guidance on null

flavors and negation indicators are provided in section 5 of this guide and Sections 1.8.8 and 1.8.9 of the Consolidated CDA implementation guide.

Section 3.6 of the C-CDA R2.1 Volume 1 guide provides further details on using null flavors for unknown, required, or optional attributes:

NI	No information. This is the most general and default null flavor.
NA	Not applicable. Known to have no proper value (e.g., last menstrual period for a male).
UNK	Unknown. A proper value is applicable, but is not known.
ASKU	Asked, but not known. Information was sought, but not found (e.g., the patient was asked but did not know).
NAV	Temporarily unavailable. The information is not available, but is expected to be available later.
NASK	Not asked. The patient was not asked.
MSK	There is information on this item available but it has not been provided by the sender due to security, privacy, or other reasons. There may be an alternate mechanism for gaining access to this information.
OTH	The actual value is not an element in the value domain of a variable. (e.g., concept not provided by required code system).

The list above contains those null flavors that are commonly used in clinical documents. For the full list and descriptions, see the nullFlavor vocabulary domain in the CDA R2 normative edition.10. In addition, examples of these nullFlavor can also be found in the HL7 C-CDA Implementation Guide R2.1 Volume 1, Section 3.6.

8 C-CDA CONTENT TEST PROCEDURES & TEST DATA

8.1 TEST PROCEDURES

TC: CREATE-0001.0 HL7_C-CDA_RECORD – CREATE

Preconditions

This test method will validate that the system under test (SUT) can create a transition of care/referral summary formatted in accordance with the standards and guidance referenced in the 2017 content testing package documentation. This will include document-template conformance that demonstrates a valid implementation of the HITSP C32/CCD or HL7 C-CDA R1.1 or R2.1 document types

In addition, the document created will be scored for vocabulary conformance to the required vocabulary standards (and value sets). These value sets and vocabulary standards can be found referenced to the 2014 or 2015 ONC requirements here:

- https://www.healthit.gov/policy-researchers-implementers/meaningful-use-stage-2-0/2015-standards-hub

It is recommended that health IT developers and providers follow the guidance provided in the documents referenced in section 1.4 of this document. These Implementation and Companion Guides includes industry best practices guidance for consistent implementation of the HITSP C32/CCD and C- CDA Release 1.1 standard, including mapping Common MU Data Set elements into the C-CDA standard. HL7 is developing a Companion Guide for C-CDA Release 2.1 and the eHealth Exchange Testing Workgroup intends to update this document once it becomes publicly available. In the meantime, we recommend developers follow the guidance provided by the HL7 CDA Example Task Force for implementation of the C- CDA Release 2.1 standard.

Data Load Set – See Appendix D: (2017_eHEX_Content_Test_Data_CREATE.pdf)

Test Tools

To Be Determined -

Test Steps

1. SUT uses the specified Test Data - Set and produces an HL7 C-CDA Document. The naming convention for the file should be “[Applicant Name]_CCDA_[DocumentType]_submission[x]” where ‘Type’ is the document type (e.g. CCD, Discharge Summary, Referral, etc) and ‘x’ is the submission attempt number.
2. Applicant emails the C-CDA Message File to testing@sequoiaproject.org.
3. eHeallth Exchange tester downloads the Applicant’s C-CDA document file from the email to the Applicants Box folder.
4. eHealth Exchange tester uploads and validates the SUT file(s) against the eHealth Exchange chosen testing tool (this will be updated when tooling is chosen):
    a. eHealth Exchange tester determines which validator to use (C32/CDAR2, C-CDA R1.1 or C-CDA R2.1) based on application/survey form answers
        i. File is uploaded to the testing tool and the appropriate version is selected in the validation tools as required.
        ii. eHealth Exchange Tester uploads file received from SUT and clicks validate

iii. A summary of this tooling report is included in the SUT Summary report

i. eHealth Exchange tester saves the results from the validation report to the SUT folder on Box.

6. eHealth Exchange Tester performs visual inspection of XML Document Sample(s) to verify the requirements as outlined.
7. The Summary Report will include all errors, warnings and a summary of overall findings and testing results to the primary point of contact identified on the submission form.

Applicant has the ability to fix the errors and resubmit to testing@sequoiaproject.org.

Participants who wish to include a fully populated C-CDA document SHALL use the guidance below for appropriate information to provide. The document created will be validated for the data included in the Common Clinical Data Set definition below:

1. Participant to create a transition of care/referral summary formatted in accordance with HITSP C32/CCD or HL7 C-CDA template R1.1 or for R2.1 that includes, at a minimum:
    1. The Common Clinical Data Set –means the following data expressed:
        1. Patient name (C-CDA R2.1 allows suffix to be included as an additional qualifier to the last name field
        2. Sex
        3. Date of birth
        4. Race
        5. Ethnicity
        6. Preferred language
        7. Smoking status
        8. Problems
        9. Medications
        10. Medication allergies
        11. Laboratory test(s)
        12. Laboratory value(s)/result(s)
        13. Vital signs
            a. Patient's diastolic blood pressure
            b. Patient's systolic blood pressure
            c. Body height
            d. Body weight
            e. Heart rate
            f. Respiratory rate
            g. Body temperature
            h. Pulse Oximetry
            i. Inhaled oxygen concentration must be exchanged in numerical values only and with the associated applicable unit of measure for vital sign measurement in this documentation.
            j. Optional: The patient's BMI percentile per age and sex must be recorded in numerical values only in accordance with the standard specified in Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, Released June 2015 or newer and with the associated applicable unit of measure for the vital sign measurement in the standard specified in The Unified Code of Units of Measure, Revision 1.9, October 23, 2013.
    2. Encounter diagnosis (included encounter diagnoses using either ICD-10-CM or SNOMED CT codes)
    3. Cognitive status
    4. Functional status

5. **Ambulatory setting only**. The reason for referral; and referring or transitioning provider's name and office contact information
6. **Inpatient setting only**. Discharge instructions
7. Patient matching data. First name, last name, previous name, middle name (including middle initial), suffix, date of birth, address, phone number, and sex. The following constraints apply:
    1. Date of birth constraint
        a. The year, month and day of birth must be present for a date of birth. The technology must include a null value when the date of birth is unknown.
        b. Optional. When the hour, minute and second are associated with a date of birth the technology must demonstrate the correct time zone offset is included.
    2. Phone number constraint. Represent phone number (home, business, cell) in accorded with the associated documentation. All phone numbers must be included when multiple phone numbers are present.
    3. Sex constraint. Represent sex in accordance with the associated documentation.
8. Optional. The SUT can create a C-CDA (formatted to Release 2.1) that includes encounter diagnoses using either ICD-10-CM or SNOMED CT© codes (International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2015 Release). SUT can present a more recent version of SNOMED CT®, U.S. Edition than the September 2015 Release to a more recent version of certain vocabulary standards.
9. Optional. The SUT can create a C-CDA that includes cognitive status. The C-CDA Cognitive Status Observation template has been deprecated in Release 2.1 and has been replaced with the Mental Status Observation template. Developers should use the Mental Status Observation template for cognitive status and be aware that the C-CDA validator will issue an error if the deprecated Cognitive Status Observation is used instead.
10. Optional. The SUT can create a C-CDA (formatted to Release 2.1) that includes functional status.
11. Optional. The SUT can create a C-CDA (formatted to Release 2.1) that includes certain data to assist with patient matching. Unless otherwise specified, the SUT should follow the guidance in C-CDA Release 2.1 for formatting the data. C-CDA Release 2.1 allows suffix to be included as an additional quality to the last name field. We recommend receiving systems follow the guidance in CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 for normalizing last name before sending ToC/referral summary documents. "Previous name" is intended to capture situations where a patient may use an alias (e.g., maiden name, family name, legally changed last name). C-CDA 2.1 cannot distinguish between historical and current address, but can accommodate more than one address. The C-CDA validation tool will test adherence to the use of the HL7 postal format for address.

TC: RECEIVE-0001.0_HL7_C-CDA_RECORD – RECEIVE – PRODUCT VENDORS ONLY

a. **Receive.** The eHealth Exchange tester uses visual inspection to verify that the Health IT Module can successful receive the applicable types of transitions of care/referral summaries for each summary record document received by the Health IT Module either as a
   I. C32 document formatted as a CCD
   II. C-CDA R1.1 document formatted as a C-CDA with document, header, section and entries template(s) in accordance with the standard specified; or
   III. C-CDA R2.1 document formatted as a C-CDA with document, header, section and entries template(s) in accordance with the standard specified
   IV. **Display:** For each summary record document received by the SUT, the tester verifies the HIT technology SHALL be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted.
      a. Display section views. Allow for individual display of each section (and the accompanying document header information) that is included in the transition of care/referral summary received and formatted in accordance with the standards adopted a manner that enables the user to:

         1. Directly display only the data within a particular section;
         2. Set a preference for the display order of specific sections; and
         3. Set the initial quantity of sections to be displayed..

      ii. Test Data
         1. MU_HITSP_C32C83_4Sections_RobustEntries_NoErrors.xml
         2. 170.315_b5_ccds_amb_ccd_r11_sample2_v1.xml
         3. 170.315_b5_ccds_amb_ccd_r21_sample1_v1.xml

The overall goal for above is to ensure the participant organization can share robust clinical data. Therefore, the following will be tested by leveraging the same associated test data to verify the participant has the capabilities properly implemented and configured among all connected stakeholders.

APPENDIX A: C-CDA IMPLEMENTATION FAQS

Index	Questions	Best Practice Guidance	Category
1	How does a CCDA implementer differentiate in the structured entries between different sub-sections of the Results section, like lab (chemistry/hematology, radiology, pathology, etc.? This is particularly important if the receiver needs to parse out the different sub-sections, and present them to a user in different tabs of their GUI.	One participant reported that in their production HIE: "They prefer to have partners put clinical notes into the results section and for all results provide an identifier, that allows them to differentiate between lab/pathology/cardiology/radiology/clinical notes/vascular. They use those entry sections to help parse the data into clinical result subsections so that the data is easier to traverse, filter and sort. Implementers should review the various HL7 published Implementation and Companion Guides for additional guidance.	C-CDA - Results Sec
2	Where do I include clinical notes in a summary of care document - e.g., encounters, procedures, results sections?	The 2.1 Companion Guide will be published with updated guidance for where to include clinical notes. The current documentation package leverages heavily the work already published by HL7 and ONC. One participant reported they preferred to have the clinical notes in the results section of the C-CDA CCD so that entry sections could be used to identify the data in a discrete way. They stated "This is not available to us in the encounters section as the specifications are defined today.	General - Notes
3	When I issue a query for a date range what sections in a summary of care document should the range be applied against?	A Gateway is expected to pass along date ranges to underlying EHR systems and they are to respond for all sections as appropriate. Per the new guidance from the TOC documentation published by HL7 9/2014, this should be applied to the document header information pertaining to the overall document rather than at a section level. In addition, two organizations gave differing guidance as follows: **Organization #1** - Date range is relevant to all sections as long as historical data is available except for allergies, problems and medications. For allergies, problems and medications-all active data should be pulled regardless. **Organization #2 - Provide two document types as follows:** "Patient Level documents We send back the last 3 months of data for procedures, results, and encounters. That date range is based on feedback from clinical users and our customers. This is used to limit the amount of data stored in the patient-level document because that negatively impacts the usability of the document. If more data is required, it is sent through an encounter-level document. Encounter Level documents We include all procedures, results, and notes for that encounter. Both document types All allergies, active medications, and problems are always included as of the document generation date.	General - Data limits
4	Is a summary of care or continuity of care document based on a single encounter, multiple encounters, episode of care?	There is no correct answer to this question if you consider various document types such as History and Physical, Discharge Summary, Referral, etc. This information will be requested from all product vendors and participants during the testing program.	General - CCD

5	Do I use the summary of care or continuity of care document like a table of contents referring to specific other documents for the detailed clinical notes? other documents might be a discharge summary, operative note, progress lab, labs? Or, can on include clinical notes/reports inside the CCD health summary?	Implementers can choose what document types are supported by their organization and how data is populated as long as it conforms to the document template requirements. Two organizations provided the following feedback: **Organization #1** responded with: We send back the last 3 months of data for procedures, results, and encounters. That date range is based on feedback from clinical users and our customers. This limits the data that is stored in the patient-level document because it negatively impacts the usability of the document. If other organizations need more data, this is provided through an encounter-level document. Organization #2 responded with: We provide all clinical data in the C-CDA/CCD. This includes lab, pathology, clinical documents, radiology, cardiology, etc. All this data is supplied in the results section of the CCD.	General - Notes
6	How do I handle external references that may cross security contexts?	The use case needs further clarification for proper guidance.	General - Links
7	For a query, how do I deem what is the minimal necessary information required to satisfy a request?	If the Purpose of Use is "Treatment" all data that is available should be provided. Organizations should work with their clinical users to ensure that data provided is usable within the workflow provided.	General - data limits
8	How is embedded formatting handled within text elements?	For the clinical notes, it depends on the formatting. eHealth Exchange staff will gather various formatting used during the new content testing program and provide further guidance to address examples received.	General - Notes
9	What consistency should be enforced between the narrative block and the structured entries?	There SHALL be absolute consistency between the narrative block and structured entries. Otherwise there will be either missed or duplicate information based on how the receiving entity is using that clinical document (i.e. parsing, style sheet, importing, etc.) One organization responded with: We will always include all allergies, active medications, and problems as of the document generation date.	General - Narratives
10	What date ranges or max number of occurrences should be applied to each section of the CCD?	At a minimum, it is expected that all allergies, active medications and problems as of the document generation date be included. Although, it depends on use case (i.e. authorization for disability vs. treatment). Some organizations choose to provide multiple years for what is available within the organizational repository.	General - data limits
11	How do we prevent duplicative information within the CCD? How do we deal with the presence of duplicate information within the CCD?	Duplicate data should be removed from a single source. Across multiple sources it may be safest to present all the information for the clinician to allow them to make a determination.	General - CCD dup d
12	What happens when the CCD is simply too large due to "excessive" amounts of data contained therein--for instance, what if everything is simply "stuffed" into the summary of care section? Should the summary of care section, as a matter of best practice, be advised to serve as an index into other sections/areas that contain the relevant data?	Normally, this can be solved for by reducing the date range. However, this is just as much an issue when separate documents are issued within a date range.	General - CCD size

13	What is the minimal set of metadata that a Content Consumer should display from a query response to help providers have sufficient information to choose from the returned list?	The eHealth Exchange Testing Workgroup members strongly advocated to these concepts, as labels, which were mapped to metadata properties as follows: Date of Service - serviceStartTime Title - title Document Type - typeCode Service Location - authorInstitution List of Services - eventCode Practice Type - practiceSettingCode Document Author - authorPerson Additional Guidance is also provided within the 2017 Content Testing Documentation. Vendors don't typically allow for a user to pick and choose specific documents or filters.	General - metadata
14	Some provider comments recently are: It is just a CCD….where is the narrative? Where are the operative and procedure notes?	In the past, some have sent these narratives/notes as separate C62/Unstructured documents. The issue is that few have implemented such capability to exchange/request C62/Unstructured Documents. As a result, the practical outcome is these items are "stuffed" in the most common document type exchanged Continuity of Care Document (CCD). This connects to pain point above related to excessive size. In some organizations, the C62 was prohibited as a matter of policy. Meaningful Use does not allow for this document type so this has been a matter of confusion as this may well be more related to certification type issues. A point of clarification is the distinction between structured entries and narratives in CCD.	General - Notes
15	How do we encourage the industry to move beyond the use of the CCD document type of C-CDA R1.1? What would encourage the use of the other document types? Relates to the question above on where is the narrative?	CCD Summary information (allergy, meds, etc….) is fairly discrete in terms of information. The patient's story is best told when the appropriate document type is used for the encounter or episode of care. Since the notes constitute 80% of the overall content, and most EHR's don't structure those notes "adequately". Some other issues may well be 2.0 backward compatibility issues to 1.1 is prohibitive. 2.1 solves many of those and therefore may be the next "jump" to be implemented. The end of 2016 and the finalization of the rules making may ease this. The ONC no longer supports 2.0 testing (removed 9/2015) and now has tools only for 2.1. However, until the industry has time to digest the various HL7 C-CDA guidance documentation and time be given to implementers to perform robust testing to validate structure and content, then it is going to be hard to move folks forward. Consistency is going to be a motivation for all.	General - other CCDA templates

16	How do we handle versioning?	The use of proper document template OIDs will help with handling multiple version such as HL7 R1.1 vs HL7 R2.1 etc.	General - versioning
17	How do we handle consistency of meta-information for class and type codes?	The guidance in the testing documentation provides a high level of linkage to requirements from the combined C-CDA R1.1, C-CDA R2.1 and associated companion guides.	QD - doc class code
18	Too many documents response to queries. What is the best set of filters (metadata constraints) in order to reduce the size of the query response?	relates to discussions above on serviceStartTime, but extends into createTime and also needs to be related to the presence of On-Demand Document Entries. It is suggested to use serviceStartTime/serviceStopTime, ClassCode, MimeType Allowing the user to query by date range will help constrain the relevant document. Making the data more manageable once it is received (i.e. parsing, rendering, sorting, filtering, etc) will also make it more useful. See the related TWG Wiki: http://exchange-specifications.wikispaces.com/share/view/76356099	QD response
19	How do systems handle query response for content and/or document types that a Content Consumer cannot handle? What is done to prevent errors from happening for content that a Consumer cannot handle? Are content that cannot be handled filtered out of the query responses before display?	Today most participants of the eHealth Exchange can handle C32, and R1.1 /R2.1 of CCDA-CCD. With improved testing tooling, it is expected that content will continue to improve and expand to various document types being supported by eHealth Exchange participants.	QD response
20	Lack of basic understanding and consistent implementation on service start and stop (to/from) for a query?	This typically presents itself more for those participants leveraging technology that assembles on-demand document creation from a wide variety of data aggregated for a patient from HL7 feeds. For Health IT Partners that support dynamic creation of documents, the partner SHALL explicitly look for queries where the $XDSDocumentEntryStatus is set to a value of 'urn:ihe:iti:2010:StatusCode:DeferredCreation'. In this situation, the document data SHALL honor the service start and stop time values, if they are specified in the request. (Please note prior discussion thread by the eHealth Exchange Specification factory with additional information on this topic can be found at (http://exchange-specifications.wikispaces.com/share/view/54214588)	Query for Doc

21	Is there general recognition that it is not programmatically feasible to determine whether or not the content of an On-Demand Document Entry has previously been retrieved? This is sometimes a surprise to Community implementations where some endpoints wish to determine from query response whether or not to retrieve content.	All participants should expect that repetitive queries for a patient to an end-point could result in the same data being provided in queries.	RD response
22	Has there been any use of metadata (submission sets attribute/folder) to associate, for instance a C62 (unstructured document) with a C32? [This is not the same as the XDS Submission Set attribute provided as part of the QD process]	Not at this time. It is expected that further considerations will be tested for in the future content testing program proposed. Testing for a security boundary issues with external references such as URL/URI/external link will need to be considered? How would the security boundaries be applied/re-applied?	same as #6
23	We are also interested in how to get participant test systems to a place where they are better ready to test with each other after they complete the current eHealth Exchange testing conducted within the Developers Integration Lab (DIL) testing environment. For instance, how much of certification is happening with harnesses or limited systems & does it really test the actual software/systems that would be used	More rigorous production testing will continue to be implemented to help quickly identify any configuration or networking issues that may be specific to the production setup. The current plan is to receive C-CDA documents during the enhanced content testing program. The samples received during the enhanced content testing will have reported errors and issues identified with an imposed timeline for defect correction by participants. In the future, transport and content testing will be improved with the testing tooling.	Testing
24	How do systems support Unstructured Document? Are systems capable of opening the package and displaying the wrapped content?	It is expected that Unstructured Document types will at least be able to be rendered in a human readable form to clinicians and use the metadata with the unstructured information to make it more usable for the clinician.	Unstructured CCDA

APPENDIX B: TESTING TOOLS UNDER CONSIDERATION

During the pilot phase held April – June 2016, multiple tooling offerings were vetted with static documents to determine requirements coverage and gaps for the overall level of testing outlined within this testing document. This section will be updated to include reference to the final tooling chosen by the eHealth Exchange staff upon evaluation of tooling performance for testing program needs and total cost of ownership. The following tools are being considered for use in 2017 by the Sequoia Project:

Art décor/Gazelle Objects Checker

IHE Services in Europe have bundled Art Décor with Gazelle Objects Checker for CDA Conformance Testing as part of the IHE International Scheme Testing. The tooling was piloted in April 2015 with the first vendors receiving certification reports. The tooling is ISO 17025 Compliant for Conformity Assessment, but covers only the HL7 C-CDA CCD R1.1 and R2.0 versions presently. Initial testing of this tool has shown it reports on warnings and errors not found by other testing tooling to be used by this pilot/program. Testing for version HL7 C-CDA CCD 2.1 will be added to this tooling during the pilot for participants to leverage. (http://gazelle.ihe.net/content/gazelle-objectschecker)

Diameter Health

Diameter Health is focused on using C32 CCDs and C-CDA 1.1 documents as the fuel for its application suite and is actively working with both health systems and HIEs on a software application called “CCD Analyzer”. The CCD Analyzer tool has 200+ rules that grade C32/C-CDA for semantic and clinical completeness and syntax, focusing on the primary sections that are required by Meaningful Use. Diameter Health focuses on things that are not simple schema/schematron rules available in in the NIST TTT and NIST ETT tools. This tool is proprietary, but Sequoia staff will provide the pilot participants a report to include feedback from this tooling. (www.diameterhealth.com)

SITE: Standards Implementation & Testing Environment – C-CDA Sandbox

The Standards Implementation & Testing Environment (SITE) is a centralized collection of tools and resources designed to assist the developers and implementers of Health Information Technology standards in their efforts to adopt EHR standards and achieve interoperability. SITE is divided into sandboxes, one for each supported standard. The Consolidated CDA (C-CDA) Sandbox will be evaluated. Please note that this tooling will continue to be updated during the pilot period with improvements from the HL7 work underway currently and from this pilot’s feedback. (http://sitenv.org/c-cda)

APPENDIX C: EHEALTH_EXCHANGE_CONTENT_TESTING_SURVEY_SUBMISSION_FORM_V2.0.PDF

APPENDIX D:
2017_EHEX_CONTENT_TEST_DATA_CREATE.PDF

APPENDIX E: RECEIVE TEST CASE XML FILES