



# **Connect Virginia**

## **EXCHANGE**

### **Clinical Content**

# **Implementation Guide**

Version 1

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“Connect Virginia provides a secure, confidential, electronic system to support the exchange of patient medical records among healthcare professionals in Virginia and beyond.”

## 1 Introduction

ConnectVirginia is the Commonwealth of Virginia’s Statewide Health Information Exchange (HIE) which supports the exchange of medical records among healthcare entities through a secure, electronic, and internet-based technology. Our objective is to provide to applicant ConnectVirginia Nodes, clear requirements for the clinical data content and its proper formatting and construction. Testing for adherence to these requirements is a part of the onboarding and certification process required to become a ConnectVirginia EXCHANGE certified Node. This guide will provide guidance, clarity, and standardization in the development of consolidated CDA documents.

### 1.1 ConnectVirginia Specifications and Standards for the HIE

ConnectVirginia EXCHANGE specifications and standards are based on the Nationwide Health Information Network (NwHIN) Exchange recommendations. In addition, ConnectVirginia has created Policies and Procedures specific to ConnectVirginia EXCHANGE. Please review these documents which can be found on the [ConnectVirginia website](#) or via the following link:

- o [ConnectVirginia P&P Documents](#)

The Virginia Information Technologies Agency (VITA) Data Standards

VITA has adopted the HITSP standards which are based on the HL7 Version 3 Standards: Clinical Document Architecture (CDA), Release 2 as the preferred standards. Should an entity not have the preferred code set, then a proprietary code set is permissible for sections 1.2 through 5.5 of this document. For more information on VITA Data standards, please follow the below:

- o <http://www.vita.virginia.gov/oversight/default.aspx?id=10344>

### 1.2 Necessary Content Specifications

The reader of this guide should have general knowledge of Extensible Markup Language (XML) and an understanding of business workflow as it relates to the electronic exchange of clinical documents. The reader should also possess a comprehensive knowledge of the following Health IT content specifications:

- HL7 Clinical Document Architecture (CDA)



- Release 2.0
- HL7 Continuity of Care Document (CCD)
  - Release 1
- HL7 Implementation Guide for History and Physician Notes
  - DSTU Release 1
- HL7 Unstructured Document
  - DSTU Release Rev 1.2
- IHE PCC Medical Documents Specification
  - IHE PCC TF Revision 7.0
- HITSP TN 901 – Technical Note for Clinical Documents
  - Version 1.0
- HITSP/C32 Summary Documents Using HL7 CCD Component
  - Version 2.5
- HITSP/C83 CDA Content Modules Component
  - Version 2.0
- HITSP/C80 Clinical Document and Message Terminology Component
  - Version 2.0
- HITSP/C154 Data Dictionary Component
  - Version 1.0
- HITSP/C62 Unstructured Document
  - Version 1.1

### 1.3 ConnectVirginia EXCHANGE Continuity of Care Document

- ConnectVirginia EXCHANGE requires the HITSP/C32 v2.5 to constrain the HL7 Continuity of Care Document. In the event Data elements and structure are not stated in the C32/C83, then the HL7 CCD specification should be followed. Should both the C32/C83 and the HL7 CCD not define the data elements, then the HL7 Clinical Document Architecture (CDA) should be used unless instructed not to in this guide. **If defined**, healthcare participants should use HITSP/C32 v2.5 to constrain the HL7 CCD.
  - **If not defined**, healthcare participants should follow the HL7 CCD specification.
  - **If not defined** in the HL7 CCD specification, then follow the HL7 CDA **except** when noted in this Guide.
  - **There** should be allowances for date parameters so it is possible to apply to query documents during a specific timeframe.

ConnectVirginia EXCHANGE follows the NwHIN Query for Documents and Retrieve Document specifications regarding date ranges. The creation of the CCD should accommodate the date

range parameters received in the query. The date range should be used to constrain the data to include in the CCD except for items such as active problems, allergies, and current medications which should convey in all Continuity of Care Documents.

ConnectVirginia has provided a sample CCD, [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#) as a reference. This is a complete CCD based on the HITSP/C32 v2.5 with additional information provided by ConnectVirginia.

A correct ConnectVirginia EXCHANGE CCD can be partially validated using the National Institutes of Standards and Technology (NIST) Validation Tool (<http://xreg2.nist.gov/cda-validation/validation.html>). When using this tool, select the HITSP/C32 v2.5--HITSP/C83 v2.0, HITSP/C32 v2.5 Summary Documents Using HL7 CCD validation version. Please note that the NIST and other appropriate organizations are currently evaluating some outstanding errors related to the validation results. ConnectVirginia has made note of these errors in the sections in which they occur throughout this Guide.

### 1.4 Document Guide Conventions

Key words are utilized throughout this Guide “SHALL”, “SHALL NOT”, “SHOULD”, “SHOULD NOT”, “MAY” and “NEED NOT” and should be interpreted as defined in the HL7 Version 3 Publishing Facilitator’s Guide (<http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm>). If not an HL7 member, below is an excerpt from this guide:

#### Use of SHALL, SHOULD and Other Modal Verbs

This section describes the terminology for expressing the stringency of a conformance statement.

HL7 adheres to ISO/IEC directive, Appendix G, as delineated in the following table:

Stringent Use of SHALL, SHOULD and Other Modal Verbs		
To Convey the Sense of:	Use the Following:	
Required/Mandatory	SHALL	SHALL NOT
Best Practice/Recommendation	SHOULD	SHOULD NOT
Acceptable/Permitted	MAY	NEED NOT

Examples:

- You **SHALL** clean your room before going out.
  - The action is **REQUIRED**. If the specified action is not performed, the following action is **NOT** allowed.
- You **SHOULD** clean your room before going out.
  - The action is **RECOMMENDED** or a **BEST PRACTICE**. This is a practice that is believed to be beneficial.
- You **MAY** clean your room before going out.
  - This action is **ALLOWED**.

## 1.5 Understanding and Following the Guide

By following the instructions in this guide, the applicant for ConnectVirginia EXCHANGE Node Certification will understand how to construct the CDA based documents.

In this Guide each section is organized by:

- a general section which contains section optionality information
- a content section which contains guidance
- when necessary, a table section with updated data element information

Please note that some sections could contain a list of NIST Validation Tool errors that may be encountered, and direction on how to handle them.

### Content

This section is to clarify content within the XML, and to assist in understanding the complex standards of ConnectVirginia's requirements. The location of examples within **Test\_ConnectVirginia\_CCD\_v3\_0.xml** will be provided in this section.

### Table Section

This Table Section shows the XPATH (location) of each data element and the significance of that element as it relates to industry standards and ConnectVirginia constraints. The tables refer to the following items:

- **Field Name**- Unless noted otherwise, Field Names correlate to documented industry standards for consistency purposes.
- **XPATH**- The XPath field displays the location path of each XML element and/or attribute.
- **HIT**- The HIT column illustrates the "**R- Required**", "**R2- Required if Known**", and "**O- Optional**" XML elements and/or attributes as defined by industry standards in section **1.3 Necessary Content Specifications**.



- **ConnectVirginia-** The ConnectVirginia column illustrates the “**R- Required**”, “**R2- Required if Known**”, and “**O- Optional**” XML elements and/or attributes that are based on the ConnectVirginia EXCHANGE data requirements. Although ConnectVirginia prefers to conform to the industry standard (C83/CCD/CDA R2) whenever possible, there are some cases where there may be differences and those would be noted in this column.

<b>R- Required</b>	<b>Required data elements must always be sent.</b>
<b>R2- Required if Known</b>	<b>Required if Known data elements must be sent when the sending application has that data available.</b>
<b>O- Optional</b>	<b>Optional data elements may be sent at the choice of the sending application.</b>

### NIST Validation Tools Errors

The NIST Validation Tool errors are color coded as such:

- **Blue** The NIST Validation Tool identifies an error message.
- **Purple** XPath where the error is located.
- **Red** Schematron test that identifies an error.

## 2 Continuity of Care Header

### 2.1 Header Information

The Header Information is a **Required-R** section. Please refer to HITSP C32/C83, CCD, and CDA specifications for additional guidance on this section.

**Note:** There are important constraints and requirements for the Header Section found in the HL7 Implementation Guide for History and Physical Notes specification. We recommend you review the Header chapter of that document before proceeding.

#### Header Section Content

For an example of a complete Header, please refer to **Test\_ConnectVirginia\_CCD\_v3\_0.xml**. As described in the HITSP/C83, each field is noted with the field’s unique identifier and name (example 1.01 – Document Timestamp). The Header begins with the ClinicalDocument element and ends at the component element.

### 3 Continuity of Care Header Representation

#### 3.1 Personal Information Section

The Personal Information section is a **Required-R** section. The Personal Information section SHALL be implemented in compliance with the HITSP/C83 Section 2.2.2.1 specifications. There are no additional ConnectVirginia data elements, constraints, optionality changes or modifications. Please refer to HITSP C32/C83, CCD, HL7 Implementation Guide for History and Physical Notes (Header only), and CDA specifications for guidance on the Personal Information section.

##### Personal Information Content

For a complete Personal Information section, please refer to [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#). Each field, as described in the HITSP/C83 specification, is commented with the field's unique identifier and name (example 1.02 – Person ID). The section for Personal Information begins in the Header in the recordTarget element.

#### 3.2 Language Spoken Section

The Language Spoken section is a **Required if Known- (R2)** section. The Language Spoken section SHALL be implemented in compliance with the HITSP/C83 Section 2.2.2.2 specifications.

##### Language Spoken Section Content

Each field, as described in the HITSP/C83 is commented with the field's unique identifier and name (example 2.01 – Language). The Language Spoken section begins in the Header, in the ClinicalDocument/participant element; search for 2.16.840.1.113883.3.88.11.83.2 within [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#) for faster navigation.

#### 3.3 Support Section

The Support section is a **Required if Known- (R2)** section. The Support section SHALL be implemented in compliance with the HITSP/C83 Section 2.2.2.3 specifications. Please see the HL7 CCD section 3.3 for constraints applicable to this module.

##### Support Section Content

Each field, as described in the HITSP/C83 is commented with the field's unique identifier and name (example 3.02 – Contact Type). The Support section begins in the Header, in the ClinicalDocument/participant element; search for 2.16.840.1.113883.3.88.11.83.3 within [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#) for faster navigation.

### 3.4 Information Source Section

The Information Source section is a **Required-R** section. The Information Source section SHALL be implemented in compliance with the HITSP/C83 Section 2.2.2.10 specifications. This section contains information about the original author and reference to the original document to be provided. Please see the HL7 CCD section 5.2 for constraints applicable to this module.

#### Information Source Section Content

The name of the information source SHALL be provided in the <name> element and SHALL appear with an <assignedPerson> or <representativeOrganization> element appearing in an <assignedEntity>, or within a <relatedPerson> element within a <relatedEntity> element beneath the <informant> element. Please refer to HITSP/C83 and CCD for more information.

### 3.5 Healthcare Providers Section

The section on Healthcare Providers is a **Required-R** section. The Healthcare Providers section SHALL be implemented in compliance with the HITSP/C83 Section 2.2.2.4 in the specifications. ConnectVirginia accepts the National Provider ID (NPI) or a Local Provider ID. Please see the HL7 CCD section 3.17 for constraints applicable to this section.

#### Healthcare Providers Section Content

Each field is noted with the field's unique identifier and name as defined in the HITSP/C83 (example 4.02 – Provider Role Coded). Inclusion examples have been provided for Local Provider ID and National Provider ID (NPI). The Healthcare Providers section begins in the ClinicalDocument/documentationOf element; search for 2.16.840.1.113883.3.88.11.83.4 within [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#) for faster navigation. Please see the HITSP/C83 and CCD (C32) for more information.

#### NIST Validation Tool Errors

The following error could occur in HITSP/C32 v2.5 section of the NIST Validation Tool when providing a Local Provider ID in place of an NPI:

Error: HITSP/C83 Healthcare Provider, National Provider Identifier, the extension attribute SHALL contain the National Provider Identifier. The root attribute SHALL contain the value 2.16.840.1.113883.4.6 to indicate that this identifier is the provider's assigned NPI. See HITSP/C83 Section 2.2.2.4.4, rules C83- [DE-4.10-CDA-1] and C83-[DE-4.10-CDA-2].

#### Location:

`/cda:ClinicalDocument/cda:documentationOf/ cda:serviceEvent/cda:rperformer`

`/ClinicalDocument[1]/documentationOf[1]/serviceEvent[1]/performer[2]/assignedEntity[1]`

**Test: (not(cda:id)) or (cda:id[@extension and @root="2.16.840.1.113881.4.6"])**

Please disregard this error. The appropriate entities are aware of this error and are working on resolution. For more information, see HITSP Public Comment Tracking Issues [#11047](#). If encountered, please disregard this error.

When providing only the Local Provider ID, you may omit HITSP OID 2.16.840.1.113883.3.88.11.83.4 as an alternative to passing the NIST Validation Tool. The NPI OID 2.16.840.1.113883.4.6 is an enforced requirement of HITSP.

### 3.6 Insurance Provider (Payers) Section

The Insurance Provider (Payers) section is an **Optional-O** section. This section SHALL be implemented in compliance with the HITSP/C83 Section 2.2.1.1. Please see the HL7 CCD section 3.1.2.1.2 for any constraints applicable to this Section. For additional guidance, please refer to HITSP/C83, CCD, and CDA specifications for this section.

#### Insurance Provider (Payers) Section Content

For a complete Insurance Provider (Payers) section, reference HITSP/C83 and CCD. Please reference template Id 2.16.840.1.113883.3.88.11.83.101 for the Payer section. The HITSP has limited the ACS X12 vocabulary for Insurance Type Code.

## 4 Continuity of Care Document (CCD) Sections

In this Guide under the CCD Sections there is more than one solution or optionality which may differ from that listed in referenced Content specifications.

### 4.1 Condition / Problem Section

The section on Condition / Problem is a **Required if Known-R2** section. The Condition / Problem section SHALL be implemented in compliance with the HITSP/C83 section 2.2.2.7. This section may contain the Chief Complaint. Please see HL7 CCD section 3.5 for constraints applicable to this module. The fields in the Condition section have been constrained to specific vocabulary sets. It is possible to substitute another vocabulary should those vocabularies not exist. Refer to section **5.5.1 HITSP Vocabulary Extension Recommendation** for guidance.

For VITA's document standards please refer to:

<http://www.vita.virginia.gov/oversight/default.aspx?id=10344> for more information.

#### Condition/Problem Content

Please refer to **Test\_ConnectVirginia\_CCD\_v3\_0.xml** for a complete Condition section, including an example of the vocabulary support solution detailed above. Each field, as described in the

HITSP/C83 is commented with the field's unique identifier and name (e.g. 7.02 - Problem Type). Search for 2.16.840.1.113883.3.88.11.83.103 within [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#) for faster navigation.

## 4.2 Encounters Section

The Encounters section is an [Required if Known- R2](#) section. The HITSP/C83 Specification SHALL be utilized for the implementation of the Encounters section. Further instruction has been provided to support ConnectVirginia data elements. For more information please refer to HITSP C32/C83, CCD, and CDA specifications.

### Including Documents in the Encounter Section

ConnectVirginia requests that any documents associated with a particular encounter entry (example Discharge Summary) SHOULD be included in the Encounters Section. Documents included in the Encounter section SHALL NOT be included in any other section. Each document included in the narrative block of the Encounter Section SHALL be assigned a tag with a unique ID to provide as a reference from a structured entry back to that document in the narrative block.

Please see Continuity of Care Documents Section 3 Body Representation, CONF-29 ([ftp://ftp.ihe.net/TF\\_Implementation\\_Material/PCC/schemas/ccd/CCD-final.pdf](ftp://ftp.ihe.net/TF_Implementation_Material/PCC/schemas/ccd/CCD-final.pdf)) and HITSP/C83 for more information.

### Encounters Section Content

For a complete Encounters section, please refer to [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#). Each field is noted with the field's unique identifier and name as defined in the HITSP/C83 (example 16.02 – Encounter Type). Several examples of different encounter notes are found in the xml payload section of Encounters. The HITSP C32 overrides the CCD Implementation Guide for this value set. CCD Implementation Guide recommends an HL-7 defined value set. Search for 2.16.840.1.113883.3.88.11.83.127 within [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#) for faster navigation.

### Encounter Location Mapping

For further guidance, please refer to HL7 CCD Section 3.15.

#### XPath: <

```
ClinicalDocument/component/structuredBody/component/section/templateId/@root="2.16.840.1.113883.10.20.1.3"/entry/encounter/participant[templateId/@root='2.16.840.1.113883.10.20.1.45'][@typeCode='LOC']/participantRole[@classCode='SDLOC']/playingEntity/name
```

### NIST Validation Tool Errors

When validating against this section, the following errors may appear in the CDA R2 portion of the NIST Validation Tools:

- cvc-complex-type.2.4.a: Invalid content was found starting with element 'sdtc:dischargeDispositionCode'. One of '{"urn:hl7-org:v3":priorityCode, "urn:hl7-org:v3":subject, "urn:hl7-org:v3":specimen, "urn:hl7-org:v3":performer, "urn:hl7-org:v3":author, "urn:hl7-org:v3":informant, "urn:hl7-org:v3":participant, "urn:hl7-org:v3":entryRelationship, "urn:hl7-org:v3":reference, "urn:hl7-org:v3":precondition}' is expected.

This particular error is caused by missing data in the validation XSD files regarding sdtc extension fields. Please note whenever an sdtc extension field (example sdtc:dischargeDispositionCode) is used this error may occur. The appropriate authorities are aware of this issue and are working on a solution. At this time if these errors are encountered, please disregard.

### 4.3 Functional Status Section

The Functional Status section is a [Required if Known- R2](#) section. The Functional Status section SHALL conform to the HITSP/C83 Specification. There are no additional ConnectVirginia data elements, constraints, or optionality changes. For additional guidance, please refer to HITSP/C83, CCD, and CDA specifications for this section.

#### Functional Status Content

The HL7 Continuity of Care Document defines the content of the Functional Status Section as:

“Functional Statuses can be expressed in 3 different forms. They can occur as a Problem (see section on **Problems**), a Result (see section on **Results**) or as text. Text can be employed if and only if the Functional Status is neither a Problem nor a Result. Functional Statuses expressed as Problems include relevant clinical conditions, diagnoses, symptoms and findings. Results are the interpretation or conclusion derived from a clinical assessment or test battery, such as the Instrumental Activities of Daily Living (IADL) scale or the Functional Status Index (FSI).”

Please refer to [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#) for examples of how to express functional statuses as a test battery (Activities of Daily Living Assessment) or as a problem. For faster navigation, please search for 2.16.840.1.113883.3.88.11.83.109 within [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#).

#### 4.4 Medication Section

The Medications section is a **Required-R** section. The Medication section SHALL be implemented in compliance with the HITSP/C83 Specification. For additional instruction on the Medications section please refer to HITSP/C83 section 2.2.1.12, CCD, and CDA specifications.

##### Medication Section Content

Please refer to [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#) for a complete Medication section. Each field is noted with the field's unique identifier and name as defined in the HITSP/C83 (example 8.01 – Free Text Sig). For faster navigation, search for 2.16.840.1.113883.3.88.11.83.112 within [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#).

#### 4.5 Medical Equipment Section

The Medical Equipment section is a **Required if known-R2** section. The Medical Equipment section SHALL be implemented in compliance with the HITSP/C83 Specification. For additional information on the Medical Equipment section 2.2.1.28, please refer to HITSP/C83, CCD, and CDA specifications.

##### Medical Equipment Content

For a complete Medical Equipment section, refer to [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#). For faster navigation, search for 2.16.840.1.113883.3.88.11.83.128 within [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#).

#### 4.6 Physical Exam Section

The Physical Exam section is a **Required if Known-R2** section. The Physical Exam section SHALL conform to the HITSP/C83 specification. For additional information, please refer to HITSP/C83 section 2.2.1.18 and CDA specifications for this section.

##### Physical Exam Content

ConnectVirginia will allow C83 Condition Module entries (as constrained in the C83 for the Physical Exam section) as well as C83 Result Module / Vital Signs Module entries in the Physical Exam section. Please refer to [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#) for a complete Physical Exam section. For faster navigation, search for 2.16.840.1.113883.3.88.11.83.118 within [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#).

#### 4.7 Allergy / Drug Sensitivity Section

The Allergy / Drug Sensitivity section is a **Required-R** section. The Allergy / Drug Sensitivity section SHALL be implemented in compliance with the HITSP/C83 section 2.2.1.2. There are no additional ConnectVirginia data elements, constraints, or optionality changes. For additional guidance, please refer to HITSP C32/C83, CCD, and CDA specifications for this section.

#### Allergy / Drug Sensitivity Section Content

For a complete Allergy / Drug Sensitivity section and entries, refer to [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#). For faster navigation, please search for 2.16.840.1.113883.3.88.11.83.102 within [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#). IHE Allergies and Other Adverse Reactions Section template SHALL contain a template element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.13.

#### 4.8 Plan of Care Section

The Plan of Care section is a [Required if known-R2](#) section. All data relating to “Plan of Care” SHOULD appear in the Narrative Block of the Plan of Care section.

##### Plan of Care Content

For a complete Plan of Care section, reference HITSP/C83 and CCD. Please reference template Id 2.16.840.1.113883.3.88.11.83.124 for the Plan of Care Section.

#### 4.9 Family History Section

The Family History Section is an [Optional – \(O\)](#) section. It contains information about the genetic family members should they be known. This section SHALL be implemented in compliance with the HITSP/C83 section 2.2.1.25. There are no additional ConnectVirginia data elements, constraints, or optionality changes. For additional guidance, please refer to HITSP/C83, CCD, and CDA specifications for this section.

##### Family History Content

In the HITSP/C83 specification, the Family History SHALL conform to the IHE Family Medical History Section, and SHALL contain template element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.14. The template ID is 2.16.840.1.113883.3.88.11.83.125 as stated in the Family History Section of the HITSP/C83, and should be referenced if necessary.

#### 4.10 List of Surgeries / Procedures Section

The List of Surgeries/Procedures section is a [R- Required](#) (In-Patient) and [Required if Known-R2](#) (Out-Patient) section. List of Surgeries section for In-Patient SHALL be implemented in compliance with the HITSP/C83 Section 2.2.1.8. The Procedure section for Out-Patient SHOULD be implemented in compliance with the HITSP/C83 Section 2.2.1.8. Guidance in this section has been provided to support ConnectVirginia data elements. For constraints, please refer to HL7 CCD section 3.14- Procedures, because of various vocabularies exist. The CCD 3.14.2 Coded Procedure Module is optional and the gap of standards is recognized.

**Procedure Table**

<u>Field Name</u>	<u>XPATH</u>	<u>HIT</u>	<u>Connect Virginia</u>
Procedure Indication (Reason)	ClinicalDocument/component/structuredBody/component/section/entry/procedure/entryRelationship[@typeCode="RSON"]/observation/code/@code	O	R2

**Including Documents in the Surgeries/Procedures Section**

Any documents associated with a particular procedure entry (example - Operative Report) should be included in the Surgeries/Procedures Section. A tag with a unique ID SHALL accompany each document included in the narrative block of the Procedure section to serve as a reference from a structured entry back to that document in the narrative block. Please refer to the Continuity of Care Document Section 3 CCR Body Representation, CONF-29. ConnectVirginia has provided an example in [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#).

**Surgeries/Procedure Indication**

The Surgeries/Procedure Indication is an **Optional-O** field. ConnectVirginia requests that a healthcare participant include the Surgery/Procedure Indication and hence making this **Required if Known – (R2)** field. When including the Procedure Indication, please see CCD CONF-439 and CONF-440. ConnectVirginia has provided in [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#).

**Surgeries/Procedures Content**

For a complete Procedure section, refer to [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#). Each field is noted with the field’s unique identifier and name as defined in the HITSP/C83 (example 17.02 – Procedure Type). For faster navigation, please search for 2.16.840.1.113883.3.88.11.83.108 within [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#).

**Example of Procedure Location Mapping**

For guidance please refer to HL7 CCD CONF-437 and CCD Section 3.15.2.2 .

**XPath:**

```
ClinicalDocument/component/structuredBody/component/section/templated/@root="2.16.840.1.113883.388.11.83.103"/entry/procedure/participant[templated/@root='2.16.840.1.113883.10.20.1.45'][@typeCode='LOC']/ participantRole[@classCode = 'SDLOC']/ playingEntity/name
```

#### 4.11 Results Section

The Results section is a [Required in Known-R2](#) section. The Results section SHALL be implemented in compliance with the HITSP/C83 section 2.2.2.15. Guidance in this section has been provided to support ConnectVirginia data elements. For more information on the Results section, please refer to HITSP C32/C83, CCD, and CDA specifications.

##### Result Entry Structure

Results may be conveyed as either a single observation entry, as a test battery, or as a test cluster in an organizer. Please reference HITSP/C83 and CCD for further information

##### Result Text Field

ConnectVirginia uses the observation/text element as a “Result Text” field where a sending system can place additional text about a particular result. The Results Text field SHALL be populated as per Continuity of Care Document section 3 CCR Body Representation, CONF-29. Please reference HITSP/C83 and CCD template ID 2.16.840.1.113883.3.88.11.83.122 in this guide which does exist in sample XML.

##### Results Section Content

For a complete Results section, refer to Test\_ConnectVirginia\_CCD\_v3\_0.xml for examples of both individual observation entries and organizer entries. For faster navigation, please search for 2.16.840.1.113883.3.88.11.83.122 within [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#).

##### NIST Validation Tool Errors

When validating against this section, the following error may appear in HITSP/C32 v2.5 section of the NIST Validation Tool:

**Error:** In IHE PCC Simple Observation (1.3.6.1.4.1.19376.1.5.3.1.4.13), the <effectiveTime> element shall be present in Simple Observations, and shall record the date and time when the measurement was taken. This element should be precise to the day. If the date and time is unknown, this element should record that using the nullFlavor attribute.

##### Location:

`/ClinicalDocument[1]/component[1]/structuredBody[1]/component[13]/section[1]/entry[2]/observation[1]`

**Test:** `cda:effectiveTime[@value or @nullFlavor]`

A conflict exists between Schematron files from IHE and HITSP which results in an error. The appropriate entities are aware of the issue and are working on a resolution. See HITSP Public Comment Tracking Issues [#7938](#) for more information. Please disregard these errors if encountered at this time.

A Results section SHALL have a Procedure entry **and** a Results entry to conform to the HITSP/C83. The following NIST errors are received when a healthcare participant is unable to provide a Procedure entry in the Results section:

**Error:** HITSP/C83 Clinical Document, the Diagnostic Results section SHALL include entries from the Procedure module to indicate the diagnostic procedure, and the Result module to provide the results of that procedure. See HITSP/C83 Section 2.2.1.22, rule C83-[CT-122-2].

**Location:** /ClinicalDocument[1]/component[1]/structuredBody[1]/component[13]/section[1]

**Test:** `./cda:templateId/@root="2.16.840.1.113883.3.88.11.83.17"`  
and `./cda:templateId/@root="2.16.840.1.113883.3.88.11.83.15.1"`

**Error:** In IHE PCC Coded Results Section (1.3.6.1.4.1.19376.1.5.3.1.3.28), the Coded Results Section must contain a(n) Procedure Entry Entry.

Please see <http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.3.28>

**Location:** /ClinicalDocument[1]/component[1]/structuredBody[1]/component[13]/section[1]

**Test:** `./cda:templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.4.19"]`

There is an example of an “empty” Procedure entry in [Test\\_ConnectVirginia\\_CCD\\_v3.0.xml](#) that passes the NIST validation tool and may be utilized as a workaround. This example of an “empty” Procedure entry contains the minimum data required to pass the NIST validation tool as defined by HL7 CCD, HITSP/C83, and IHE. Please search for 2.16.840.1.113883.10.20.1.29 within [Test\\_ConnectVirginia\\_CCD\\_v3.0.xml](#) for faster navigation.

## 4.12 Advance Directives Section

The Advance Directive Section is an **Optional – (O)** section. The Advance directive Section SHALL be implemented in compliance with HITSP/C83 Section 2.2.2.12. Please refer to the HL7 CCD Section 3.2- Advance Directives for more information.

### Advance Directive Section Content

For a complete Advance Directive section, reference HITSP/C83 and CCD. Please reference template Id 2.16.840.1.113883.3.88.11.83.116 for the Advance Directive section.

## 4.13 Social History Section

The Social History section is an **Optional – (O)** section. This section SHALL be implemented in compliance with the HITSP/C83 Section 2.1.2.18. There are no additional ConnectVirginia data elements, constraints, or optionality changes. For additional guidance, please refer to HITSP/C83, CCD, and CDA specifications for this section.

### Social History Free Text

In the HITSP/C83 specification, the Social History Text [19.03] maps to observation.text in the Social History section. The Social History Free Text field SHALL be populated as per Continuity of Care Document section 3 CCR Body Representation, CONF-29. [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#) has provided an example.

### Social History Content

For a complete Social History section, refer to [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#). Each field is noted with the field's unique identifier and name as defined in the HITSP/C83 (example 19.03 – Social History). For faster navigation, please search for 2.16.840.1.113883.3.88.11.83.126 within [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#).

## 4.14 Vital Signs

The Vital Signs section is a **Required if known-R2** section. The Vital Signs section SHALL be implemented in compliance with the HITSP/C83 section 2.2.1.19. Please refer to the HL7 CCD section 3.12- Vital Signs. LOINC corresponding codes to this measurement would typically be considered 'Vital Signs' (9279-1- RESPIRATION RATE; 8867-4- HEART BEAT; 2710-2 Oxygen).

### Vital Signs Content

For a complete Vital Signs section and entries, refer to [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#). For faster navigation, please search for 2.16.840.1.113883.3.88.11.83.119 within [Test\\_ConnectVirginia\\_CCD\\_v3\\_0.xml](#).

## 4.15 Pregnancy Section

The Pregnancy section is an **Optional-O** section. The Pregnancy Section SHALL be implemented in compliance with HITSP/C83 section 2.2.2.9. Data elements are 9.01 – Pregnancy. There are no additional ConnectVirginia data elements, constraints, or optionality changes. For additional guidance, please refer to HITSP C32/C83, CCD, and CDA specifications for this section.

### Pregnancy Section Content

For a complete Pregnancy section, please reference HITSP/C83 and CCD. Please reference template Id 1.3.6.1.4.1.19376.1.5.3.1.4.13.5 for the Pregnancy section for more information.

## 4.16 Immunization Section

The Immunization section is an **Optional – (O)** section. The Immunization Section SHOULD be implemented in compliance with HITSP/C83 Section 2.2.2.17. Please refer to the NWHIN CR420 for more information.

### Immunization Section Content

For a complete Immunization section, reference HITSP/C83 and CCD. Please reference template Id 2.16.840.1.113883.3.88.11.83.117 for the Immunization section.

#### 4.17 Comment Section

The Comment section is an **Optional – (O)** section. This section contains a comment for any of the sections. This section SHALL be implemented in compliance with the HITSP/C83 section 2.2.2.11 section. For additional guidance, please refer to the HL7 CCD Section 4.3 for constraints in regard to this section.

#### Comment Section Content

For a complete Comment section, please refer to HITSP/C83 and CCD. Please reference template ID 2.16.840.1.113883.3.88.11.83.11 for the Comment section. Each field, as described in the HITSP/C83 is noted with the field's unique identifier and name (example 11.01- Free Text Comment). See HL7 CCD section 4.3 for constraints applicable to this section.

## 5 Production Data Lessons and Additional Guidance Section

Based on ConnectVirginia's production experiences, the following section is meant to provide guidance on the creation of the CCD.

### 5.1 Valid XML

The healthcare participant SHALL confirm that the data placed into the CCD does not cause the XML to be invalid when creating the CDA document. Please note that in XML there are characters that require special encoding. In addition, Byte Order Marker SHALL NOT be present in the XML.

Please note the following example:

The less-than character '<' must be encoded as &lt; when it is part of the document context and has clinical significance, such as a lab whereby the intent is to indicate 'less-than'. Special encoding SHALL not be used as part of an XML element or attribute value.

The healthcare participant SHOULD refer to the latest edition of the World Wide Web Consortium (W3C) Extensible Markup Language (XML) specification for additional information.

## 5.2 HL7 2.X Message Delimiters

The healthcare participant SHALL convert HL7 2.x message delimiters into the appropriate CCD data elements during the creation of a CCD.

Example:

Should an HL7 2.x message be the healthcare entities source of information and the tilde denotes a line feed, then the healthcare entity SHALL encode the tilde as a <br/> element.

## 5.3 ID Generation

When creating a CCD, the clinical statement ids SHOULD be produced in a way that identifies the clinical statement if it was included on a separate Continuity of Care Document.

Example:

The id of the same procedure would be the same, if acknowledged in various or different Continuity of Care Documents.

## 5.4 Restricted CDA Elements

At this time, ConnectVirginia does not accept external references such as the usage of CDA <linkHtml> element. The healthcare entity SHALL include all data and content in preparation for electronic transmittal.

## 5.5 Use of Proprietary Code Sets

The use of proprietary code sets are permissible if the required code set is not available. Please note this must be discussed and agreed upon with ConnectVirginia before implementation.

### 5.5.1 HITSP Vocabulary Extension Recommendation

Please be aware that some content specifications MAY constrain which vocabulary set is utilized in a specific field. Also, not all healthcare entities' systems may have an integrated required vocabulary set. In an effort to be in compliance with the HITSP/C83 specifications, HITSP has offered the following solution:

HITSP solution:

...it is permissible to include a <code> element using a **nullFlavor** of UNK indicating that the information is unknown, and include <translation> elements which indicate codes from other code systems. The following example shows a case where the <value> element in a condition entry includes the optional coded value for the Problem Code data element.

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->  
<observation classCode='OBS' moodCode='EVN'>  
<templateId root='2.16.840.1.113883.10.20.1.28' />
```

```
...  
<value xsi:type='CD' code='37796009' displayName='Migraine'  
codeSystem='2.16.840.1.113883.96' codeSystemName='SNOMED CT'/>  
</observation>
```

For more information, consult the HITSP/C83 specification, “USE OF VOCABULARY RECOMMENDED TO SUPPORT ARRA HITECH”.

The appropriate entities are aware of this problem and are working on a resolution. This error has been documented in the HITSP Public Comment Tracking system as issue #11050.

### 5.5.2 CodeSystem OIDs for Proprietary Systems

This guide suggests sub-arcing an OID assigned to the participant and placing that value in the codeSystem attribute. For example, Test HIE’s OID is 2.16.840.1.113883.3.1839. Test HIE could sub-arc the OID to look like:

```
2.16.840.1.113883.3.1839.5 = Test HIE Lab Systems  
2.16.840.1.113883.3.1839.5.1 = Proprietary code set 1  
2.16.840.1.113883.3.1839.5.2 = Proprietary code set 2
```

ConnectVirginia also requests the name of the proprietary code set in the codeSystemName attribute.

### 5.6 Data/Reference Usage with Text and Original Text Elements

Data and reference elements may be present within the text and originalText elements that point to the narrative block. Often structured data is obtained from the narrative block. For this reason, ConnectVirginia requests that references to the narrative block be used instead of entering data directly into text/originalText elements unless explicitly stated in a HL7, HITSP, or IHE specification for a particular field. For more information, please see the Continuity of Care Document section 3 CCR Body Representation, CONF-29 on how references work. In addition, data should have reference into the narrative block and SHALL NOT be placed directly into a text/originalText element. This could potentially result in an ambiguous situation if the data did not correspond exactly.

### 5.7 Narrative Block Ordering Preference

The reverse of chronological order (most recent to oldest) is preferred method that data be organized and applied to the narrative block. This method assists with readability of the narrative block, and considered significant within the Encounters and Procedures sections, however it can be generally applied.

## 6 HITSP C62 Unstructured Document Section

ConnectVirginia uses HITSP/C62 v1.1 to exchange unstructured document content, such as text, PDF/A, and images rendered in PDF/A. Please note that there are additional requirements per Integrating the Healthcare Enterprise (IHE) standards. ConnectVirginia has provided a sample CCD, [Test\\_ConnectVirginia\\_C62\\_v1\\_0.xml](#) as reference.

### 6.1 Header Information

The Header section is a **R-Required** section. For additional guidance on this section, please refer to HITSP C62 and CDA specifications.

### 6.2 HITSP C62 NonXMLBody

ClinicalDocument/component/nonXMLBody/text @mediaType shall be “application/pdf” for PDF/A, or “text/plain” for plaintext.

ClinicalDocument/component/nonXMLBody/text @representation SHALL be present. The @representation for both PDF/A and plaintext scanned content will be “B64”.

## 7 HL7 Unstructured Document Section

ConnectVirginia uses HL7 Unstructured Document DSTU Release Rev 1.2 to exchange unstructured document content, such as text, GIF, HTML, PDF, RTF, TIF, JPEG, and PNG.

### 7.1 Header Information

The Header section is a **R-Required** section. For additional guidance on this section, please refer to HL7 Unstructured Document and CDA specifications.

### 7.2 HL7 NonXMLBody

The ClinicalDocument element SHALL contain component/nonXMLBody/text element. The text element SHALL have a representation attribute with the value of B64, a mediaType attribute, and contain the media content.

The value of @mediaType SHALL be taken from the value set 2.16.840.1.113883.11.20.7.1 SupportedFileFormats STATIC 20100512

**Value Set: SupportedFileFormats 2.16.840.1.113883.11.20.7.1**

Please Note: ConnectVirginia restricts the usage of file referencing in our exchange process  
Healthcare entities SHALL NOT provide a HL7 unstructured document with a  
ClinicalDocument/component/nonXMLBody/text/reference/@value

### 7.3 Clinical Content Preference

In the case of dynamically generated documents, ConnectVirginia requests the content provided as test when possible, as opposed to images sent in PDF, MSWORD, HTML, etc.

## 8 Document Properties Section

ConnectVirginia is capable of accepting the following file types as part of document exchange: GIF, MSWORD, PDF, Plain Text, RTF Text, TIFF, TIFF, JPEG, PNG, and HTML.

### 8.1 Document Properties

All Document preferences apply to **C62, HL7 Unstructured, and Native Document Types** when applicable.

In the exchange process, healthcare entities SHALL NOT password protect or encrypt files.

For file types that are applicable:

- Dots per Inch (DPI) of 200x200 is preferred
- Color schema- bitonal
- Compression CCHIT Group 4

<b>Word Processing/Narrative Formats</b>	<b>Code</b>
MSWORD	application/msword
PDF	application/pdf
Plain Text	text/plain
RTF Text	text/rtf
HTML	text/html
<b>Graphic Formats</b>	<b>Code</b>
GIF Image	Image/gif
TIF Image	Image/tif
JPEG	Image/jpeg
PNG Image	Image/jpeg

Portrait layout and dimensions of 8.5" x 11" (letter size) is preferred.

ConnectVirginia prefers that text in the case of dynamically generated documents, as opposed to images found in PDF, MSWORD, HTML, etc.

## **8.2 Hyperlinks and Embedded Media**

Documents SHOULD be self-contained. ConnectVirginia prefers that healthcare entities omit hyperlinks and embedded media (example- audio, video) from exchanged documents.

## **8.3 DICOM**

ConnectVirginia does NOT support Digital Imaging and Communications in Medicine (DICOM) at this time. This limitation extends to DICOM usage in C62 and HL7 Unstructured Documents.

## **9 Modifications and Updates to ConnectVirginia Guide**

ConnectVirginia will update this Guide once the consolidated CDA is approved and supported by the NWHIN Coordinating Committee. Please be aware that there may be future modifications to this Guide to address changes in standards as a result of Meaningful Use Stage II and future stages.

## **Attachment A: Content Checklist**

The EHR Content Checklist is intended to help ConnectVirginia evaluate the potential accessibility of health information and the content value of your EHR for each facility within your organization. This document is required to be submitted during the content evaluation process.

Attachment A Checklist.xlsx