

Ambulatory Setting

**I. INTRODUCTION**

This document contains sample test data that can be used for the certification towards Cures Update objective 170.315(e)(1). This section of the Code of Federal Regulations Title 45 documents the required Health IT technology to be able to create, send and receive a summary care record formatted according to the Consolidated CDA (C-CDA) Release 2.1 and be able to receive a summary care record formatted according to the C-CDA Release 1.1.

A) Test of 45 CFR 170.315 (e)(1)

The following is the summary of test data presented herein for 170.315(e)(1) criteria.

**Conventions used in the document:**

1. The test data outlined below has both required and optional data that is specified to help the vendors create C-CDA's with the appropriate context and follow the HL7 C-CDA best practices. The optional data is indicated by enclosing them in [ ]. For e.g. [Medical Record Custodian] or [Allergy Substance].
  - a. When a narrative or text block is surrounded by [ ] the entire narrative block is optional.
  - b. When a column heading is surrounded by [ ] the data represented by the column is optional. For e.g. [ Allergy Substance ], the display name is optional.
  - c. When the data within a table cell is surrounded by [ ] the data within the cell is optional. For e.g. The information recipient Dr Albert Davis is optional from a certification standpoint. Vendors can include it in their C-CDA's to comply with HL7 C-CDA IG and best practices.

[ Information Recipient ]	[ Dr Albert Davis ]
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- d. The C-CDA IG allows display names and text elements to be optionally included in the structured entries. Hence the above optional markings designated by [ ] in the test data are with respect to the structured entries in the XML. If a certification criteria requires visual display of the structured data (for e.g View, Download and Transmit - VDT), then the vendors have to display the coded data elements in their English representation. For example Medication Name, Problem Name, Vital Sign Name which are English representations of the coded data have to be displayed for the VDT criteria even though they are marked optional in the test data.

2. Additional clarifications are added with the keyword “**Note**”.
3. Data that needs to be visually inspected by the ATL’s in the generated C-CDA’s are indicated by the key word “**Visual Inspection**”.
4. Guidance for No Information Sections: When the test data instructions specify “No Information” for certain data elements, vendors are expected to use the HL7 recommended best practices to represent the information. However vendors don’t have to include sections and entries not required by the document template to represent “No information”.
5. Guidance to Change Test Data: Vendors can work with their ATLs to change the test data specified below. ATLs have been provided a document on how to use the test tools to verify SUT’s capabilities when the test data is changed. This document has also been posted as part of ETT Google Group thread: [https://groups.google.com/forum/#!topic/edge-test-tool/fDYr\\_kqp9\\_g](https://groups.google.com/forum/#!topic/edge-test-tool/fDYr_kqp9_g)

To exemplify 170.315 (e)(1), the following clinical scenario will be employed.

**Document Narrative:**

[ Ms. Alice Newman is a 45 year old female with a history of Hypertension, Hypothyroidism, Iron deficiency and is a recipient of Renal Allograft visits Neighborhood Physicians Practice on 6/22/2015 at 10am EST. The patient disclosed history of nausea, loose stools and weakness. After initial examination the patient was found to have fever, she was administered necessary medications and after examining the history of the patient and the lab results, the doctor suspected anemia. So the patient was referred to Community Health Hospitals an Inpatient facility to get appropriate treatment and was asked to watch for appropriate changes in body temperature, blood pressure and take nebulizer treatment as needed. ]

**Note:** The test data provided in the document was captured during this encounter including historical data. The contextual data provided is to help the vendors create their C-CDA documents using appropriate data. Vendors can ignore the contextual data if it is not required for C-CDA generation; however the generated C-CDA is expected to contain the data relevant to the criteria as specified in the regulation.

**II. HEADER DATA**

**Note:** The following data is part of the medical record header identifying the contextual information necessary when exchanging data.

- A) USCDI Data Class/Element: Patient Demographics

USCDI Data Elements	Contextual Data Elements required for the Medical Record encoding to C-CDA IG	Details	Additional Information
Patient Name (First Name, Last Name, Previous Name, Middle Name, Suffix)		First Name: Alice Last Name: Newman Middle Name: Jones Previous Name: Alicia Suffix:	The Previous Name specified is the Patient's Birth Name and should be coded accordingly.
Birth Sex		Female (F)	
Date of Birth		5/1/1970	
Race		White (2106-3)	
More Granular Race Code		2108-9(White European)	
Ethnicity		Not Hispanic or Latino (2186-5)	
Preferred Language		English (en)	
Current Address	Home Address	1357, Amber Dr, Beaverton, OR-97006	
Phone Number		Mobile: 555-777-1234 Home: 555-723-1544	

B) Relevant Information regarding the Visit

**Note:** The information in this table is provided for context and to help populate the required elements in the C-CDA Header along with any 2015 Cures Update USCDI data elements.

USCDI Data Class/Elements	Contextual Data Elements required for medical record encoding to C-CDA	Details	Additional Information
	Referring or Transitioning Providers Name	Full Name: Dr Albert Davis First Name: Albert Last Name: Davis	
	Office Contact Information	Full Name: Tracy Davis First Name: Tracy Last Name: Davis Telephone: 555-555-1002 Address: 2472, Rocky place, Beaverton, OR-97006	

USCDI Data Class/Elements	Contextual Data Elements required for medical record encoding to C-CDA	Details	Additional Information
	[ Author/Legal Authenticator/ Authenticator of Electronic Medical Record ]	[ Dr Albert Davis Date: 6/22/2015 ]	
	[ System that generated the document ]	[ Neighborhood Physicians Practice EMR ]	
	[ Informants ]	[ Matthew Newman (Spouse) First Name: Matthew Last Name: Newman ]	
	[ Medical Record Custodian ]	[ Neighborhood Physicians Practice ]	
	[ Information Recipient ]	[ Dr Albert Davis ]	
	[ Visit Date ]	[ 6/22/2015 ]	
Care Team Members	Care Team Members	Dr Albert Davis Tracy Davis	
	[ Other Participants in event ]	[ Mr Rick Holler (Grand Parent) First Name: Rick Last Name: Holler Mr Matthew Newman (Spouse) First Name: Matthew Last Name: Newman (Mr Rick and Mr Matthew have the same address as Ms Alice) ]	
	[ Event Documentation Details or Documentation of Event ]	[ Dr Albert Davis 30 minute encounter Event Code = Fever ]	[ Code for Fever Finding: 386661006 , Code System: SNOMED-CT ]

### III. BODY DATA

**Note:** The following data is part of the medical record details identifying the relevant clinical data captured as part of the visit.

A) USCDI Data Class/Element: Allergies and Intolerances

**Note:** Allergies and Intolerances are to be represented using the Allergies and Intolerances Section. The Start Date is to be represented using the effectiveTime data element of Allergy Intolerance Observation as biologically relevant time.

Code	CodeSystem	[ Allergy Substance ]	Reaction	Severity	[Timing Information]	Concern Status
7980 (IN)	RxNorm	Penicillin G	Hives (code-247472004, SNOMED-CT)	Moderate	Start Date – 5/10/1980,	Active
733 (IN)	RxNorm	Ampicillin	Hives (code-247472004, SNOMED-CT)	Moderate	Start Date – 5/10/1980,	Active

B) USCDI Data Class/Element: Medications

**Note:** Timing information (Start and End Dates) are to be represented using the effectiveTime data element in the Medication Activity entry.

Code	CodeSystem	[ Medication Name ]	[Timing Information]	Route	Frequency	Dose
309090 (SCD)	RxNorm	Ceftriaxone 100 MG/ML	6/22/2015 – Start Date 6/30/2015 – End Date	Injectable	Two times daily	1 unit
209459 (SBD)	RxNorm	Tylenol 500mg	For 10 days, starting from 6/22/2015	Oral	As needed	1 unit
731241 (SBD)	RxNorm	Aranesp 0.5 MG/ML	6/22/2015 – Start Date (No End Date)	Injectable	Once a week	1 unit

C) USCDI Data Class/Element: Problems

**Note:** Timing information is to be represented using the effectiveTime data element in the Problem Observation. Start Date is to be used as Onset Date and End Date as Resolution Date.

Code	CodeSystem	[ Problem Name ]	[Timing Information]	Concern Status
59621000	SNOMED-CT	Essential hypertension (Disorder, )	10/5/2011 – Start Date	Active

Code	CodeSystem	[ Problem Name ]	[Timing Information]	Concern Status
83986005	SNOMED-CT	Severe Hypothyroidism (Disorder)	12/31/2006 – Start Date	Active
236578006	SNOMED-CT	Chronic rejection of renal transplant (disorder)	12/31/2011 – Start Date	Active
386661006	SNOMED-CT	Fever (finding)	6/22/2015 – Start Date	Active
238131007	SNOMED-CT	Overweight (finding)	12/31/2006 – Start Date, 6/1/2007 – End Date	Completed

D) USCDI Data Class/Element: Immunizations

**Note:** Additional Notes represent why the Immunization was cancelled and there are no specific notes applicable to the completed immunizations.

Vaccine Code	CodeSystem	[ Vaccine Name ]	Date	Status	[Lot Number]	[Manufacturer Name]	Additional Notes
106	CVX	Tetanus and diphtheria toxoids	1/4/2012	Completed	2	Immuno Inc.	N/A
166	CVX	influenza, intradermal, quadrivalent, preservative free	6/22/2015	Cancelled	No Lot number provided – Vendors need to use NullFlavor	Immuno Inc.	Immunization was not given - Patient rejected immunization

E) USCDI Data Class/Element: Vital Signs

Code	Code System	[ Vitals Name ]	Timing Information	Value and Units
8302-2	LOINC	Height	6/22/2015, [ 10:05 EST ]	Value=177 units=cm
29463-7	LOINC	Weight	6/22/2015, [ 10:05 EST ]	Value=88 units=kg
8462-4 (Diastolic)	LOINC	Blood Pressure-Diastolic	6/22/2015, [ 10:08 EST ]	Value=88 units=mm[Hg]
8480-6 (Systolic)	LOINC	Blood Pressure-Systolic	6/22/2015, [ 10:08 EST ]	Value=145 units=mm[Hg]

Code	Code System	[ Vitals Name ]	Timing Information	Value and Units
8867-4	LOINC	Heart Rate	6/22/2015 [ 10:10 EST ]	Value=80 Units=/min
59408-5	LOINC	O2 % BldC Oximetry	6/22/2015 [ 10:12 EST ]	Value=95 units=%
3150-0	LOINC	Inhaled Oxygen Concentration	6/22/2015 [10:12 EST]	Value=36 units=%
8310-5	LOINC	Body Temperature	6/22/2015 [ 10:15 EST ]	Value=38 units=Cel
9279-1	LOINC	Respiratory Rate	6/22/2015 [ 10:15 EST ]	Value=18 units=/min

F) USCDI Data Class/Element: Smoking Status

**Note:** The C-CDA IG specifies how Smoking Status has to be represented using a combination of Tobacco Use and Smoking Status templates. Vendors are expected to follow the C-CDA IG to encode these data elements appropriately.

Element Description	[ Description ]	Start Date	End Date	Code	Code System
Current Smoking Status	Current every day smoker	6/22/2015	-	449868002	SNOMED-CT

G) USCDI Data Class/Element: Procedures

**Note:** Target Site is provided for context, vendors may or may not choose to include this as part of the C-CDA entries. Date is to be represented using the effectiveTime data element in the Procedure Activity Procedure entry.

Code	[ Procedure Name ]	[Date]	[ Target Site ]	Status	[ Service Delivery Location ]
(56251003) - SNOMED-CT	Nebulizer Therapy	6/22/2015	82094008- Lower Respiratory Tract Structure, Code System – SNOMED- CT	Completed	Neighborhood Physicians Practice Telephone: 555-555- 1002 Address: 2472, Rocky place, Beaverton, OR-97006

Code	[ Procedure Name ]	[Date]	[ Target Site ]	Status	[ Service Delivery Location ]
175135009 (SNOMED-CT)	Introduction of cardiac pacemaker system via vein	10/5/2011	9454009 – Structure of subclavian vein, Code System - SNOMED-CT	Completed	Community Health Hospitals. Telephone: 555-555-1003 Address: 3525, Newberry Avenue, Beaverton, OR-97006.

- H) USCDI Data Class/Element: Clinical Notes (**Visual Inspection** – ATL’s need to visually inspect the System Under Test (SUT) generated C-CDA for the text content, the validator will validate the presence of the notes section and entry. Only the text content needs to be visually inspected.)

**I.1 Procedure Note:**

Dr Albert Davis examined Ms Alice Newman and found that the pacemaker is operating properly and the breathlessness is due to high fever and anxiety.

- I) USCDI Data Class/Element: Laboratory Tests

**Note:** The pending Urinalysis lab test has no results yet and is a future event and has to be coded accordingly. The HL7 best practice to code a pending lab test is to represent it with a planned observation in the Plan of Treatment section.

Test Code	Code System	[ Name ]	Date
24357-6	LOINC	Urinalysis macro (dipstick) panel	6/22/2015
24357-6	LOINC	Urinalysis macro (dipstick) panel	6/29/2015

- J) USCDI Data Class/Element: Laboratory Values/Results

**Note:** The results below correspond to the Urinalysis lab test on 6/22/2015. Reference Ranges such as YELLOW are optional and vendors may or may not choose to include them as part of their C-CDA entries. Additionally when units are not present then the result value does not require any specific unit.

Result Code	Code System	[ Name ]	Result Value and Units	Date	[ Reference Range ]
5778-6	LOINC	Color of Urine	YELLOW	6/22/2015	YELLOW
5767-9	LOINC	Appearance of Urine	CLEAR	6/22/2015	CLEAR
5811-5	LOINC	Specific gravity of Urine by Test strip	1.015	6/22/2015	1.005 – 1.030
5803-2	LOINC	pH of Urine by Test strip	Value=5.0 units=[pH]	6/22/2015	5.0-8.0
5792-7	LOINC	Glucose [Mass/volume] in urine by test strip	Value=50 units=mg/dL	6/22/2015	Neg
5797-6	LOINC	Ketones [Mass/Volume] in urine by test strip	Negative	6/22/2015	Negative
5804-0	LOINC	Protein[Mass/Volume] in urine by test strip	Value=100 units=mg/dL	6/22/2015	

Laboratory Location Details for the above Laboratory Results: The laboratory location details are specified to meet the 42 CFR 493.1291(c)(1) through (7) requirements identified in the Regulation. This information can be coded using the Narrative Text or the Author Entry.

**(Visual Inspection – ATL’s need to visually inspect the System Under Test (SUT) generated C-CDA for the Laboratory Location Details in the narrative content or the author entry.)**

Location Item	Location Details
Id	2.16.840.1.113883.19.5
Name	Value Labs
Address	Address: 2474, Rocky place, Beaverton, OR-97006
[Telephone]	[555-666-1002]

- K) USCDI Data Class/Element: Clinical Notes **(Visual Inspection – ATL’s need to visually inspect the System Under Test (SUT) generated C-CDA for the text content, the validator will validate the presence of the notes section and entry. Only the text content needs to be visually inspected.)**

**L.1 Laboratory Narrative:**

Ms Alice Newman was tested for the Urinalysis macro panel and the results have been found to be normal.

L) USCDI Data Class/Element: Unique Device Identifiers for a Patient’s Implantable Device(s)

**Note:** Device Code is provided for context, vendors may or may not choose to include this as part of the C-CDA entries. Also the implantable device identified below was introduced as part of the procedure documented in the procedure section namely “Introduction of cardiac pacemaker system via vein”.

UDI	Assigning Authority	[ Device Code ]	[ Scoping Entity ]
(01)00643169007222(17)160128(21)BLC200461H	FDA	704708004 - Cardiac resynchronization therapy implantable pacemaker, CodeSystem – SNOMED-CT	FDA

M) USCDI Data Class/Element: Assessment and Plan of Treatment:

- a. **Assessment (Visual Inspection – ATL’s need to visually inspect the System Under Test (SUT) generated C-CDA for the below narrative content)**
  - i. The patient was found to have fever and Dr Davis is suspecting Anemia based on the patient history. So Dr Davis asked the patient to closely monitor the temperature and blood pressure and get admitted to Community Health Hospitals if the fever does not subside within a day.
- b. **Plan of Treatment (Visual Inspection– ATL’s need to visually inspect the System Under Test (SUT) generated C-CDA for the below narrative content)**
  - i. Get an EKG done on 6/23/2015.
  - ii. Get a Chest X-ray done on 6/23/2015 showing the Lower Respiratory Tract Structure.
  - iii. Take Clindamycin 300mg three times a day as needed if pain does not subside/
  - iv. Schedule follow on visit with Neighborhood Physicians Practice on 7/1/2015.

N) USCDI Data Class/Element: Goals (**Visual Inspection – ATL’s need to visually inspect the System Under Test (SUT) generated C-CDA for the below narrative content)**

- a. Get rid of intermittent fever that is occurring every few weeks.
- b. Need to gain more energy to do regular activities

O) USCDI Data Class/Element: HealthConcerns (**Visual Inspection – ATL’s need to visually inspect the System Under Test (SUT) generated C-CDA for the below narrative content)**

- a. Chronic Sickness exhibited by patient
- b. HealthCare Concerns refer to underlying clinical facts
  - i. Documented HyperTension problem

- ii. Documented HypoThyroidism problem
- iii. Watch Weight of patient

P) USCDI Data Class/Element: Clinical Notes (**Visual Inspection** – ATL’s need to visually inspect the System Under Test (SUT) generated C-CDA for the text content, the validator will validate the presence of the notes section and entry. Only the text content needs to be visually inspected.)

**T.1 Diagnostic Imaging Narrative – Consulting Specialists Interpretation for Chest x-ray:**

Test Code	[Name]	[Code System]	Date
36643-5	Chest x-ray 2 views	LOINC	6/23/2015

Lungs are not clear, cannot rule out Anemia. Other tests are required to determine the presence or absence of Anemia.