Cures Update Test Data for 170.315 (e)(1) - View, Download and Transmit

In-patient 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 | [Dr Albert Davis] | | |
|---------------|---------------------|--|--|
| Recipient] | | | |

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. <u>Guidance for No Information Sections:</u> 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. <u>Guidance to Change Test Data:</u> 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/fDYrkqp9g

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

Document Narrative:

[Ms. Rebecca Larson is a 45 year old female with a history of Hypertension, Hypothyroidism, Iron deficiency and is a recipient of Renal Allograft is admitted on 6/22/2015 at 10 am EST to Community Health and Hospitals with history of intermittent fever for 2 days. The patient disclosed history of nausea, loose stools and weakness. She was found to have Anemia secondary to iron deficiency and CKD. After conducting multiple tests and administering necessary medications, the patient was discharged to Ambulatory facility to follow up with immunosuppression as an out-patient. The condition of the patient at discharge was stable, with controlled blood sugar levels and a pain score below 3. Additional follow up instructions have been provided to the patient.]

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: Rebecca | The Previous Name |
| (First Name, Last | | Last Name: Larson | specified is the |
| Name, Previous | | Middle Name: Jones | Patient's Birth Name |
| Name, Middle | | Previous Name: Robin | and should be coded |
| Name, Suffix) | | Suffix: | accordingly. |
| Birth Sex | | Female (F) | |
| Date of Birth | | 5/1/1970 | |
| Race | | White (2106-3) | |
| More Granular | | 2108-9(White European) | |
| Race Code | | | |
| Ethnicity | | Not Hispanic or Latino | |
| | | (2186-5) | |
| Preferred | | English (en) | |
| Language | | | |
| 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 Cures Update data elements.

| USCDI Data Elements | Contextual Data Elements required for medical record encoding to C-CDA | Details | Additional Information |
|------------------------|---|---|--|
| | Providers Name | Dr Henry Seven First Name: Henry Last Name: Seven | [Dr Seven and his staff work for Community Health and Hospitals 1002, Healthcare Dr, Portland, OR-97266] |
| | Office Contact Information | Mary McDonald First Name: Mary Last Name: McDonald Telephone: 555-555-1002 | |
| | [Author/Legal Authenticator/Authe nticator of Electronic Medical Record] | [Dr Henry Seven Date: 6/22/2015] | |

| USCDI Data Elements | Contextual Data Elements required for medical record encoding to C-CDA | Details | Additional Information |
|------------------------|--|--|---|
| | [System that generated the document] | [Community Health Hospitals EMR] | |
| | [Informants] | [Frank Larson (Spouse) First Name: Frank Last Name: Larson] | |
| | [Medical Record Custodian] [Information | [Community Health and Hospitals] | |
| | Recipient] Admission Date | [Dr Henry Seven] 6/22/2015 | |
| | Discharge Date | 6/24/2015 | |
| Care Team Members | Care Team Members | Dr Henry Seven Mary McDonald | |
| | [Other Participants in event] | [Mr Robert Matthews (Grand Parent) First Name: Robert Last Name: Matthews Mr Frank Larson (Spouse) – Same Address information as Ms Rebecca Larson.] | |
| | [Event Documentation Details or Documentation of Event] | [Dr Henry Seven (PCP) 2 day encounter Event Code = Anemia] | [Code for Anemia Finding: 164139008 , 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 | StartDate: 6/22/2015, End Date 6/30/2015 | Injectable | Two times daily | 1 unit |
| 209459 (SBD) | RxNorm | Tylenol 500mg | StartDate: 6/22/2015, End Date 6/30/2015 | Oral | As needed | 1 unit |
| 731241 (SBD) | RxNorm | Aranesp 0.5 MG/ML | StartDate: 6/22/2015, End Date 6/30/2015 | Injectable | Once a week | 1 unit |
| 284215 (SCD) | RxNorm | Clindamycin 300mg | StartDate: 6/23/2015, End Date 6/30/2015 | Oral | Three times daily | 1 unit |
| 198371 (SCD) | RxNorm | Torsemide 20mg | StartDate: 6/23/2015, End Date 6/30/2015 | Oral | Daily | 1 unit |
| 860886 (SCD) | RxNorm | FenoFibric Acid 35 mg | StartDate: 6/24/2015, End Date: 7/4/2015 | Oral | At the hour of sleep | 1 unit |
| 485023 (SCD) | RxNorm | Mycophenolic Acid 360 mg | StartDate: 6/24/2015, End Date: 6/27/2015 | Oral | Two times daily | 1 unit |
| 977434 (SCD) | RxNorm | Everolimus 0.5 mg | StartDate: 6/24/2015, End Date: 7/20/2015 | Oral | Two times daily | 1 unit |

| Code | CodeSystem | [Medication Name] | [Timing Information] | Route | Frequency | Dose |
|-----------------|------------|-------------------------|---|-------|-------------------------|--------|
| 197511 (SCD) | RxNorm | Ciprofloxacin 250 mg | StartDate: 6/24/2015 , End Date: 7/24/2015 | Oral | Three times daily | 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] | Health concern status |
|-----------|------------|--|--|-----------------------------|
| 59621000 | SNOMED-CT | Essential hypertension (Disorder,) | 5/10/2015 - Start Date | Active |
| 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 |
| 87522002 | SNOMED-CT | Iron deficiency anemia (disorder) | 6/22/2015 – Start Date | Active |
| 64667001 | SNOMED-CT | Interstitial pneumonia (disorder) | 6/22/2015 – Start Date | Active |
| 238131007 | SNOMED-CT | Overweight (finding) | 12/31/2006 – Start Date 6/1/2007 – End Date | Completed |

D) Encounter Diagnoses

<u>Note:</u> Encounter Diagnoses can be represented by either SNOMED-CT or ICD-10. So SUT can choose either the ICD-10 code or the SNOMED-CT code as appropriate from the table below based on the CodeSystem supported.

| Code | CodeSystem | [Description] | Start Date | [Service Delivery Location] |
|-----------|------------|--|------------|---|
| D63.1 | ICD-10 | Anemia in Chronic Kidney Disease | 6/22/2015 | Community Health and Hospitals 1002, Healthcare Dr, Portland, OR-97266 |
| 234348004 | SNOMED-CT | Anemia of renal disease | 6/22/2015 | Community Health and Hospitals 1002, Healthcare Dr, Portland, OR-97266 |

E) 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 | CodeSyste m | [Procedure Name] | [Target Site] | [Date] | [Service Delivery Location] |
|-----------|----------------|---|--|-----------|---|
| 10847001 | SNOMED-CT | Bronchoscopy | 91724006 (Tracheobr onchial structure (body structure) | 6/22/2015 | Communit y Health and Hospitals 1002, Healthcare Dr, Portland, OR-97266 |
| 168731009 | SNOMED-CT | Chest X-Ray, PA and Lateral Views | 82094008 (Lower Respiratory Tract Structure) | 6/22/2015 | Communit y Health and Hospitals 1002, Healthcare Dr, Portland, OR-97266 |

| Code | CodeSyste m | [Procedure Name] | [Target Site] | [Date] | [Service Delivery Location] |
|-----------|----------------|---|---|-----------|---|
| 175135009 | SNOMED-CT | Introduction of cardiac pacemaker system via vein | 9454009 – Structure of subclavian vein, Code System - SNOMED-CT | 10/5/2011 | Communit y Health and Hospitals 1002, Healthcare Dr, Portland, OR-97266 |

F) 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.)

F.1 Procedure Note:

Dr Seven examined Ms Rebecca Larson and found that the pacemaker is operating properly and the breathlessness is due to high fever and anxiety.

G) 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 | | Immuno Inc. | Immunization was not given - Patient rejected immunization |

H) USCDI Data Class/Element: Vital Signs

| Code | Code System | [Vitals Name] | Timing Information | Value and Units |
|-------------------|-------------|-----------------|-----------------------|-----------------|
| 8302-2 | LOINC | Height | 6/22/2015 [| Value=177 |
| | | | 10:05 EST] | units=cm |
| 29463-7 | LOINC | Weight | 6/22/2015 [| Value=88 |
| | | | 10:05 EST] | units=kg |
| 8462-4 | LOINC | Blood Pressure- | 6/22/2015 | Value=88 |
| (Diastolic) | | Diastolic | [10:08 EST] | units=mm[Hg] |
| 8480-6 (Systolic) | LOINC | Blood Pressure- | 6/22/2015 | Value=145 |
| | | Systolic | [10:08 EST] | units=mm[Hg] |
| 8867-4 | LOINC | Heart Rate | 6/22/2015 | Value=80 |
| | | | [10:10 EST] | Units=/min |
| 59408-5 | LOINC | O2 % BldC | 6/22/2015 | Value=95 |
| | | Oximetry | [10:12 EST] | units=% |
| 3150-0 | LOINC | Inhaled Oxygen | 6/22/2015 | Value=36 |
| | | Concentration | [10:12 EST] | units=% |
| 8310-5 | LOINC | Body | 6/22/2015 | Value=38 |
| | | Temperature | [10:15 EST] | Units=Cel |
| 9279-1 | LOINC | Respiratory | 6/22/2015 | Value=18 |
| | | Rate | [10:15 EST] | units=/min |

I) USCDI Data Class/Element: Laboratory Test

Note: The pending Urinanalysis lab test has no results yet and is a planned 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 | Urinanalysis macro (dipstick) panel | 6/22/2015 |
| 58410-2 | LOINC | CBC | 6/22/2015 |
| 24357-6 | LOINC | Urinanalysis macro (dipstick) panel | 6/29/2015 |

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

Note: The results below correspond to the CBC (First 4 rows) and the Urinanlysis (Rest of the rows in the table except the first 4 rows) lab tests on 6/22/2015. Reference Ranges such as YELLOW are optional and vendors may or 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] |
|-------------|-------------|----------|------------------------|-----------|------------------------|
| 30313-1 | LOINC | HGB | Value=10.2 | 6/22/2015 | |
| | | | units= g/dL | | |

| Result Code | Code System | [Name] | Result Value and units | Date | [Reference Range] |
|-------------|-------------|--|-------------------------------|-----------|------------------------|
| 33765-9 | LOINC | WBC | Value = 12.3 units=10*3/uL | 6/22/2015 | N/A - 500,000 |
| 26515-7 | LOINC | PLT | Value=123 units= 10*3/ul | 6/22/2015 | |
| 50544-6 | LOINC | Everolimus Blood | Value=10 units=ng/mL | 6/22/2015 | 2.0-8.0 |
| 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/Volu me] in urine by test strip | Value=100 units=mg/dL | 6/22/2015 | negative |

<u>Laboratory Location Details for the above Laboratory Results:</u> 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.)

K.1 Laboratory Narrative:

Ms Rebecca Larson was tested for the Urinanalysis macro panel and CBC and the results have been found to be normal.

L) 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 | 6/22/2015 | 1 | 449868002 | SNOMED-CT |

M) UDI List

<u>Note</u>: 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 <u>"Introduction of cardiac pacemaker system via vein"</u>.

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

- N) 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 Anemia and Dr Seven and his staff diagnosed the condition and treated Ms Rebecca for Anemia during the 2 day stay at Community Health Hospitals. Ms Rebecca recovered from Anemia during the stay and is being discharged in a stable condition. If there is fever greater than 101.5 F or onset of chest pain/breathlessness the patient is advised to contact emergency.

- 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. Schedule an appointment with Dr Seven after 1 week for Follow up with Outpatient facility for Immunosuppressive therapy.
- O) 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. Need to gain more energy to do regular activities.(Visual Inspection)
 - b. Negotiated Goal to keep Body Temperature at 98-99 degrees Fahrenheit with regular monitoring.
- P) 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
 - iv. Documented Anemia problem
- Q) Discharge Instructions (Visual Inspection ATL's need to visually inspect the System Under Test (SUT) generated C-CDA for the below narrative content)
 - a. Diet: Diabetic low salt diet
 - b. Medications: Take prescribed medications as advised.
 - c. Appointments: Schedule an appointment with Dr Seven after 1 week. Follow up with Outpatient facility for Immunosuppression treatment.
 - d. For Fever of > 101.5 F, or onset of chest pain/breathlessness contact Emergency.
- R) Functional Status (Visual Inspection ATL's need to visually inspect the System Under Test (SUT) generated C-CDA for the below content)

| Functional Condition | [Code] | [Code System] | Start Date |
|-----------------------------|-----------|---------------|------------|
| Dependence on Cane | 105504002 | SNOMED-CT | 5/1/2005 |

S) Cognitive Status (Visual Inspection – ATL's need to visually inspect the System Under Test (SUT) generated C-CDA for the below content)

| Cognitive Status | [Code] | [Code System] | Start Date |
|------------------|----------|---------------|------------|
| Amnesia | 48167000 | SNOMED-CT | 5/1/2005 |

T) 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 Progress Note Narrative:

Ms Rebecca Larson got admitted due to developing high fever and since has shown considerable improvement and can be discharged shortly.

- U) USCDI Data Class/Element: Clinical Notes
 - a. Diagnostic Imaging Narrative Note:

| Test Code | Code System | [Name] | Date |
|-----------|-------------|---------------------|-----------|
| 36643-5 | LOINC | Chest X-ray 2 Views | 6/22/2015 |

<u>Diagnostic Imaging Report – Consulting Specialists Interpretation:</u> (Visual Inspection – ATL's need to visually inspect the System Under Test (SUT) generated C-CDA for the below narrative content)

- Lungs are not clear. Other tests are required to confirm Anemia.
- V) [Reason For Referral: This is an optional section, provided to aid vendors creating a referral note with a Reason for Referral section.

(Visual Inspection – ATL's need to visually inspect the System Under Test (SUT) generated C-CDA for the below narrative content if a vendor specifies that they are including this section in their generated document.)]

[Ms Rebecca Larson is being referred to Long Term Care facility for a month because of the multiple chronic conditions for observations.]