2015 Edition Certification Companion Guide

2015 Edition Common Clinical Data Set - 45 CFR 170.102

Final Rule Preamble – **Correction Notice Preamble**

Version 1.5 – Last Updated 7/7/2017

The 2015 Edition Common Clinical Data Set cannot be certified in of itself, but is a required element of certification for specified 2015 Edition certification criteria (i.e., § 170.315(b)(1), (b)(4), (b)(5), (b)(6), (e)(1), (f)(5), (g)(6), (g)(8), and (g)(9)). The 2015 Edition Common Clinical Data Set focuses on the representation of clinical data during exchange.

Regulation Text (Note that "***" indicates the 2014 Edition Common Clinical Data Set definition regulation text. This document focuses on the 2015 Edition Common Clinical Data Set definition. Please refer to the 2014 Edition final rule for the 2014 Edition Common Clinical Data Set. (formerly referred to as the Common MU Data Set)

Common Clinical Data Set means the following data expressed, where indicated, according to the specified standard(s):

(1) Patient name. For certification to *** the 2015 Edition health IT certification criteria.

(2) Sex. ***

(ii) The standard specified in § 170.207(n)(1) for certification to the 2015 Edition health IT certification criteria.

(3) Date of birth. For certification to *** the 2015 Edition health IT certification criteria.

(4) Race. ***

(ii) For certification to the 2015 Edition health IT certification criteria:

(A) The standard specified in § 170.207(f)(2);

(B) The standard specified in § 170.207(f)(1) for each race identified in accordance § 170.207(f)(2).

(5) Ethnicity. ***

(ii) For certification to the 2015 Edition health IT certification criteria:

(A) The standard specified in § 170.207(f)(2);

(B) The standard specified in § 170.207(f)(1) for each ethnicity identified in accordance § 170.207(f)(2).

(6) Preferred language. ***

(ii) The standard specified in § 170.207(g)(2) for certification to the 2015 Edition Health IT certification criteria.

(7) Smoking status. For certification to *** the 2015 Edition health IT certification criteria: The standard specified in § 170.207(h).

(8) Problems. ***

(ii) At a minimum, the standard specified in § 170.207(a)(4) for certification to the 2015 Edition Health IT certification criteria.

(9) Medications. ***

(ii) At a minimum, the standard specified in § 170.207(d)(3) for certification to the 2015 Edition Health IT certification criteria.

(10) Medication allergies. ***

(ii) At a minimum, the standard specified in § 170.207(d)(3) for certification to the 2015 Edition Health IT certification criteria.

(11) Laboratory test(s). ***

(ii) At a minimum, the standard specified in § 170.207(c)(3) for certification to the 2015 Edition Health IT certification criteria.

(12) Laboratory value(s)/result(s). For certification to *** the 2015 Edition health IT certification criteria.
(13) Vital signs. ***
(ii) For certification to the 2015 Edition Health IT certification criteria:
(A) The patient's diastolic blood pressure, systolic blood pressure, body height, body weight, heart rate, respiratory rate, body temperature, pulse oximetry, and inhaled oxygen concentration must be exchanged in numerical values only; and
(B) In accordance with the standard specified in § 170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1).
(C) Optional. The patient's BMI percentile per age and sex for youth 2-20 years of age, weight for age per length and sex for children less than 3 years of age, and head occipital-frontal circumference for children less than 3 years of age must be recorded in numerical values only in accordance with the standard specified in § 170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1). For BMI percentile per age and sex for youth 2-20 years of age and weight for age per length and sex for children less than 3 years of age, the reference range/scale or growth curve should be included as appropriate.
(14) ***[1]
(15) Procedures— (i)(A) At a minimum, the version of the standard specified in *** § 170.207(a)(4) for certification to the 2015 Edition health IT certification criteria, or § 170.207(b)(2); or
(B) For technology primarily developed to record dental procedures, the standard specified in § 170.207(b)(3) for certification to *** the 2015 Edition health IT certification criteria.
(ii) Optional. The standard specified in § 170.207(b)(4) for certification to *** the 2015 Edition health IT certification criteria.
(16) Care team member(s). For certification to *** the 2015 Edition health IT certification criteria.
(17) Immunizations. In accordance with, at a minimum, the standards specified in § 170.207(e)(3) and (4) for certification to the 2015 Edition health IT certification criteria.
(18) Unique device identifier(s) for a patient's implantable device(s). In accordance with the "Product Instance" in the "Procedure Activity Procedure Section" of the standard specified in § 170.205(a)(4) for certification to the 2015 Edition health IT certification criteria.
(19) Assessment and plan of treatment. For certification to the 2015 Edition health IT certification criteria:
(i) In accordance with the "Assessment and Plan Section (V2)" of the standard specified in § 170.205(a)(4); or
(ii) In accordance with the "Assessment Section (V2)" and "Plan of Treatment Section (V2)" of the standard specified in § 170.205(a)(4).
(20) Goals. In accordance with the "Goals Section" of the standard specified in § 170.205(a)(4) for certification to the 2015 Edition health IT certification criteria.
(21) Health concerns. In accordance with the "Health Concerns Section" of the standard specified in § 170.205(a)(4) for certification to the 2015 Edition health IT certification criteria.

[1] Paragraph (14) refers to the 2014 Edition requirement for the "care plan field(s), including goals and instructions" which is no longer required for the 2015 Edition Common Clinical Data Set and has been replaced with the "assessment and plan of treatment," "goals," and "health concerns." Please refer to 80 FR 62695 for more details.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Standards Corrections/Clarifications	• Appropriate updates to the C-CDA 2.1 Validator will be made consistent with FAQ 51. Please see FAQ 51 for the compliance requirements with corrections, including surveillance.	N/A
(1) Patient name	***Clarifications:*** • There is no standard required for patient name.	N/A
(2) Sex	***Clarifications:*** • The codes required are intended to represent birth sex. [see also 80 FR 62618] • The only acceptable codes for use are those in the standard's specified value set: "M," "F," "UNK." • The Common Clinical Data Set "sex" data element (intended to represent a patient's "birth sex") may be placed anywhere in a C-CDA document except in the "Administrative Gender" field (administrativeGenderCode) in the C-CDA header. While the "Administrative Gender" field must be populated (per the C-CDA) in the C-CDA header, the testing requirement associated with the Administrative Gender field is one of general standards conformance consistent with our adoption of the C-CDA and cannot be used to meet this specific CCDS certification requirement. The testing tool will continue to offer the HL7[2] best practice for all who follow that approach. This practice provides a mechanism for industry implementation consistency and to have at least one validator-oriented testing approach. This will also enable ONC-ATLs to perform testing as efficiently as possible. If birth sex is not represented following the method built into the C-CDA validator, this will not constitute a "fail" with the testing tool. It will be a warning and ONC-ATLs will need to follow up with a visual inspection of the C-CDA to identify and confirm that "birth sex" is represented appropriately somewhere in the C-CDA and using the ONC-specified value set.	§ 170.207(n)(1) Birth sex must be coded in accordance with HL7 Version 3 attributed as follows: (i) Male. M (ii) Female. F (iii) Unknown. nullFlavor UNK
(3) Date of birth	***Clarifications:*** • There is no standard required for exchanging date of birth.	N/A

[2] HL7 is in the process of updating their samples guidance into an HL7-owned repository. Currently, the HL7 CDA Example Task Force is utilizing Github to house their approved samples. See http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(4) Race	***Clarifications:*** • The CDC Race and Ethnicity Code Set Version 1.0 includes over 900 concepts for representing race and ethnicity, in which 921 reference race and 43 reference ethnicity. [see also 80 FR 16816] • Health IT Modules can present for certification to a more recent version of the "Race & Ethnicity" – CDC code system than Version 1.0. [see also 80 FR 62612] • A Health IT Module needs to be capable of recording multiple races for a patient. For Example: White; Asian [see also 80 FR 62618] • A product does not need to display all of the race codes to meet the certification criterion. The developer has the discretion to create a default selection set or enable customization choices for providers. However, for the purposes of testing, a developer should be prepared to show that the product can represent any of the races in the value set created by the standard. • The health IT must be able to "aggregate" each one of the patient's race(s) and represent the race(s) according to the OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997. The categories to which race selections must roll-up and be represented include: ▪ American Indian or Alaska Native; ▪ Asian; ▪ Black or African American; ▪ Native Hawaiian or Other Pacific Islander; and ▪ White • The concepts in the "Race & Ethnicity" – CDC code system are pre-mapped to the race and ethnicity categories in the OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15. Testing will verify that the more granular race and ethnicity codes are correctly mapped to the OMB standard. • When race is included within a transmission (pursuant to other certification criteria that reference the CCDS) the applicable OMB roll-up categories must be able to be included in addition to the specific race codes in the CDC code set. The order and grouping of such codes is not dictated by 2015 Edition rules and, thus, defers to a standard or implementation guide's requirements for how such codes would be represented as part of a transmission.	§ 170.207(f)(1) The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997 § 170.207(f)(2) CDC Race and Ethnicity Code Set Version 1.0 (March 2000) - Navigate to the CDCREC Roll-up codes tab

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced

(5) Ethnicity	***Clarifications:***
	• The CDC Race and Ethnicity Code Set Version 1.0 includes over 900 concepts for representing race and ethnicity, in which 921 reference race and 43 reference ethnicity. [see also 80 FR 16816]
	• We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
	  • "Race & Ethnicity" - CDC code system OID: 2.16.840.1.113883.6.238 [see also 80 FR 62612]
	• Health IT Modules can present for certification to a more recent version of the "Race & Ethnicity" – CDC code system than Version 1.0. [see also 80 FR 62612]
	• A Health IT Module needs to be capable of recording multiple detailed ethnicities for a patient (For example: "Dominican" and "Mexican"). [see also 80 FR 62618]
	• A product does not need to display all of the ethnicity codes to meet the certification criterion. The developer has the discretion to create a default selection set or enable customization choices for providers. However, for the purposes of testing, a developer should be prepared to show that the product can represent any of the ethnicities in the value set created by the standard.
	• The software must be able to "aggregate" all of a patient's ethnicity(ies) and represent the ethnicity(ies) according to the OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997. The categories to which ethnicity selections must roll-up include:
	  ▪ Hispanic or Latino; and
	  ▪ Not Hispanic or Latino.
		§ 170.207(f)(1) The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997
		
		§ 170.207(f)(2) CDC Race and Ethnicity Code Set Version 1.0 (March 2000)
		- Navigate to the CDCREC Roll-up codes tab

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(5) Ethnicity, continued	• When ethnicity is included within a transmission (pursuant to other certification criteria that reference the CCDS) only one OMB roll-up ethnicity is permitted (in the context of the OMB standard's two question format for race and ethnicity). • When "Hispanic or Latino" is the applicable OMB roll-up category, it must be able to be included in addition to the specific ethnicity codes (if applicable) in the CDC code set. • The concepts in the "Race & Ethnicity" – CDC code system are pre-mapped to the race and ethnicity categories in the OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15. Testing will verify that the more granular race and ethnicity codes are correctly mapped to the OMB standard. • The OMB standard permits merging the ethnicity and race categories for a "combined format," which would no longer require "not Hispanic or Latino" to be recorded. This alternative approach is also acceptable.	See above
(6) Preferred language	***Clarifications:*** • RFC 5646 is compatible with C-CDA Release 2. [see also 80 FR 62619] • Testing for preferred language using the standard at § 170.207(g)(2) (RFC 5646) will focus on **all the languages** present in ISO 639-2 [http://www.loc.gov/standards/iso639-2/php/code_list.php] • Consistent with the RFC 5646 the **shortest alpha** code for the language should be used. Testing will **only test the primary language tag** and not test for extension components specified in RFC 5646 such as extended language sub-tags, script tag, nor region tag. [see also 80 FR 16817] Specifically: ▪ use alpha 2 character code if one exists (ISO 639-1); ▪ use alpha 3 character code if an alpha 2 character code does not exist (ISO 639-2); and ▪ region extensions (ISO 3166-1) are permitted but not required (however, if a region extension is used, it will be verified for accuracy as part of testing and must be correct). • We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. ▪ Tags for Identifying Languages – Request for Comment (RFC) 5646 code system OID: 2.16.840.1.113883.6.316 [see also 80 FR 62612] • A product does not need to display all of the language codes to meet the 2015 Edition Common Clinical Data Set (CCDS) definition. The developer has the discretion to create a default selection set or enable customization choices for providers. However, for the purposes of testing, a developer should be prepared to show that the product can represent any of languages in the value set created by the standard.	§ 170.207(g)(2) RFC 5646

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(7) Smoking status	***Clarifications:*** • We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. ▪ SNOMED CT® OID: 2.16.840.1.113883.6.96 [see also 80 FR 62612] • Health IT Modules can present for certification 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. [see also 80 FR 62612] • "Light smoker" means fewer than 10 cigarettes per day, or an equivalent (but less concretely) defined quantity of cigar or pipe smoke. [see also 77 FR 54205] • "Heavy smoker" is interpreted to mean greater or equal to 10 cigarettes per day or an equivalent (but less concretely defined) quantity of cigar or pipe smoke. [see also 77 FR 54205 and FAQ #37] • Smoking status is limited to any form of tobacco that is smoked. That would not prohibit a health IT system from capturing other forms of tobacco use that is not smoked (e.g., chewing tobacco), but it is not required to meet the 2015 Edition CCDS definition. [see also 77 FR 54205] • Health IT developers are free to include clinically relevant information, such as lifetime pack year exposure in their interface and system. However, the specific SNOMED CT® codes listed are to be used to reflect the patient's smoking status when such data is required to be included as part of the CCDS.	§ 170.207(h) – Smoking status must be coded in one of the following SNOMED CT® codes: (1) Current every day smoker. 449868002 (2) Current some day smoker. 428041000124106 (3) Former smoker. 8517006 (4) Never smoker. 266919005 (5) Smoker, current status unknown. 77176002 (6) Unknown if ever smoked. 266927001 (7) Heavy tobacco smoker. 428071000124103 (8) Light tobacco smoker. 428061000124105
(8) Problems	***Clarifications:*** • We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. ▪ SNOMED CT® OID: 2.16.840.1.113883.6.96 [see also 80 FR 62612] • Health IT Modules can present for certification 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. [see also 80 FR 62612] • We strongly encourage health IT developers to enable users to perform real-time clinical coding using SNOMED CT®, but clarify that real-time clinical coding in SNOMED CT® is not required for the purposes of certification.	§ 170.207(a)(4) International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2015 Release

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(9) Medications and (10) Medication allergies	***Clarifications:*** • We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. ▪ RxNorm OID: 2.16.840.1.113883.6.88. [see also 80 FR 62612] • Health IT Modules can present for certification to a more recent version of RxNorm than the September 8, 2015 Release per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62612] • We intend for the RxNorm concept unique identifiers (RXCUIs) to be used as drug qualifiers. [see also 77 FR 54199] • All medications may not yet have an equivalent RxNorm code. Where no RxNorm code exists, nothing prohibits another code from being used (e.g., local codes). However, where corresponding RxNorm codes exist, health IT must be able to use those codes. [see also 77 FR 54199] • The C-CDA Validator Version 1.0.5 (October 31, 2016) will implement and validate the No Medications best practice. Please follow the HL7 guidance to codify No Medications at https://github.com/HL7/C-CDA-Examples/blob/master/Medications/No%20Medications/No%20Medications(C-CDA2.1).xml.	§ 170.207(d)(3) RxNorm, September 8, 2015 Full Release Update
(11) Laboratory test(s)	***Clarifications:*** • We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. ▪ LOINC® OID: 2.16.840.1.113883.6.1 [see also 80 FR 62612] • Health IT Modules can present for certification to a more recent version LOINC® than version 2.52 per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62612]	§ 170.207(c)(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52
(12) Laboratory value(s)/result(s)	***Clarifications:*** • There is no standard required for laboratory value(s)/result(s).	N/A

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(13) Vital signs	***Clarifications:*** • The following vital signs are required for the 2015 Edition CCDS: ▪ Diastolic blood pressure ▪ Systolic blood pressure ▪ Body height ▪ Body weight ▪ Heart rate ▪ Respiratory rate ▪ Body temperature ▪ Pulse oximetry ▪ Inhaled oxygen concentration. • Health IT Modules may store and display the systolic and diastolic blood pressure in one field as long as they are exchanged as two separate fields. [see also 80 FR 62694] • For pulse oximetry, implementers can choose the LOINC® code with "pulse oximetry" in its name that best represents the method of measurement for exchange for the purposes of testing and certification. [see also 80 FR 62694] • Systems have the flexibility to choose how to display the vital sign measurement. The requirement only specifies that the vital sign measurement must be exchanged using an applicable unit of measurement with a Unified Code of Units for Measure (UCUM) code. Therefore, systems could exchange a height of 5'6" as 66 inches or 5.5 feet or 167.64 centimeters using the appropriate UCUM code to represent the unit of measure for the measurement (example only). [see also 80 FR 62695] • LOINC provides a translation table that enumerates UCUM syntax for a subset of UCUM codes that are commonly used in health IT that may be a useful reference for developers. [see also 80 FR 62695] • We also recommend health IT developers and providers follow the guidance provided in C-CDA Release 2.1 for exchanging vital signs. [see also 80 FR 62695]	§ 170.207(c)(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52 § 170.207(m)(1) The Unified Code of Units for Measure, Revision 1.9

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(13) Vital signs, continued	• Developers can optionally choose to certify to BMI percentile per age and sex for youth 2-20 years of age, weight for age per length and sex for children less than 3 years of age, and head occipital-frontal circumference for children less than 3 years of age. ▪ BMI percentile per age and sex for youth 2-20 years of age and weight for age per length and sex for children less than 3 years of age should include the reference range/scale or growth curve as appropriate. ▪ The availability of a reference range/scale or growth curve can help with proper interpretation of the measurements for the BMI percentile per age and sex and weight for age per length and sex. [see also 80 FR 62695] • We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. ▪ LOINC® system OID: 2.16.840.1.113883.6.1 [see also 80 FR 62612] • Health IT Modules can present for certification to a more recent version LOINC® than version 2.52 per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62612]	See above.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(15) Procedures	***Clarifications:*** • Health IT must be certified to SNOMED CT® or CPT-4/HCPCS for procedures. • Developers may additionally choose to certify to ICD-10-PCS as an "optional" vocabulary standard for procedures. [see also 77 FR 54178] • Developers may additionally choose to certify to the Code on Dental Procedures and Nomenclature for technology designed to capture dental procedures, but the technology must at a minimum support SNOMED CT® or CPT-4/HCPCS. [see also 77 FR 54178] • We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. ▪ SNOMED CT® system OID: 2.16.840.1.113883.6.96 [see also 80 FR 62612] • If choosing to certify SNOMED CT®, Health IT Modules can present for certification 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. [see also 80 FR 62612]	§ 170.207(b)(2) – The code set specified in 45 CFR 162.1002(a)(5) – The combination of Health Care Financing Administration Common Procedure Coding System (HCPCS), as maintained and distributed by HHS, and Current Procedural Terminology, Fourth Edition (CPT-4), as maintained and distributed by the American Medical Association, for physician services and other health care services. These services include, but are not limited to, the following: (1) Physician services. (2) Physical and occupational therapy services. (3) Radiologic procedures. (4) Clinical laboratory tests. (5) Other medical diagnostic procedures. (6) Hearing and vision services. (7) Transportation services including ambulance. § 170.207(a)(4) International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2015 Release

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(15) Procedures, continued	***See above***	Optional: § 170.207(b)(4) ICD-10-PCS Optional for technology primarily developed to record dental procedures: § 170.207(b)(3) - The code set specified in 45 CFR 162.1002(a)(4) – Code on Dental Procedures and Nomenclature, as maintained and distributed by the American Dental Association, for dental services.
(16) Care team member(s)	***Clarifications:*** • There is no standard required for care team member(s).	N/A
(17) Immunizations	***Clarifications:*** • The requirements for immunizations in the 2015 Edition CCDS are intended to address the use cases to support transitions of care, data export, API access, and a patient's ability to view, download, and transmit their health information. [see also 80 FR 62694] • C–CDA Release 2.1 supports NDC codes as a translational data element, but the CVX code is required to accompany it. • CDC provides a publicly available mapping of NDC codes for vaccines to CVX codes, which we encourage developers to utilize.[3]	§ 170.207(e)(3) HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015 § 170.207(e)(4) National Drug Code Directory (NDC) – Vaccine NDC Linker, updates through August 17, 2015

[3] http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=ndc. See also: http://www2a.cdc.gov/vaccines/iis/iisstandards/ndc_tableaccess.asp.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(18) Unique device identifier(s) for a patient's implantable device(s)	***Clarifications:*** • Exchanging unique device identifier(s) using the "Product Instance" which is embedded in the "Procedure Activity Procedure" in the C-CDA Release 2.1 is intended to make this information more easily retrievable. [see also 80 FR 62695] Note that the 2015 Edition final rule refers to the "Procedure Activity Procedure Section" and we clarify that this is not a Section. • Please follow the following HL7 guidance to include UDI's when Procedures are Not Known[4] https://github.com/benjaminflessner/HL7-C-CDA-Task-Force-Examples/blob/master/Implant%20Without%20Procedure.xml • The reference to the C-CDA is not meant to be strictly interpreted to mean that a developer must use the C-CDA's syntax for the Product Instance template. Reference to the C-CDA was intended to emphasize that the data must be consistently and independently represented as discrete data that are clearly distinguishable. [see also 80 FR 76870] • If a device is still implanted in the patient, it is considered "active." Thus, for the purposes of the CCDS's reference to UDI, all of a patient's current/"active" implanted devices must be included.	§ 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015

[4] HL7 is in the process of updating their samples guidance into an HL7-owned repository. Currently, the HL7 CDA Example Task Force is utilizing Github to house their approved samples. See http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(19) Assessment and plan of treatment	***Clarifications:*** • The reference to the C-CDA is not meant to be strictly interpreted to mean that a developer must use the C-CDA's syntax for the Assessment and Plan Section (V2), Assessment Section (V2), or Plan of Treatment Section (V2). Reference to the C-CDA was intended to emphasize that the data must be consistently and independently represented as discrete data that are clearly distinguishable. Only the narrative part of the Assessment and Plan Section (V2), Assessment Section (V2), or Plan of Treatment Section (V2) are necessary and required to satisfy the CCDS definition. Testing and certification will focus on the presence of data represented with just the narrative part of the referenced section templates. [see also 80 FR 76870] • For certification criteria that reference the CCDS to be included within C-CDA document templates, health IT systems can be certified to either: ▪ "Assessment Section (V2)" and "Plan of Treatment Section (V2),"; or ▪ "Assessment and Plan Section (V2)." [see also 80 FR 62696] • For certification criteria that reference the CCDS to be included within C-CDA document templates, it is permissible to include "goals" in the Plan of Treatment Section that relate to specific actions documented in the plan of treatment. (see also paragraph "(20) Goals" for additional clarification)."	§ 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015
(20) Goals	***Clarifications:*** • The reference to the C-CDA is not meant to be strictly interpreted to mean that a developer must use the C-CDA's syntax for the Goals Section. Reference to the C-CDA was intended to emphasize that the data must be consistently and independently represented as discrete data that are clearly distinguishable. Only the narrative part of the Goals Section is necessary and required to satisfy the CCDS definition. Testing and certification will focus on the presence of data represented with just the narrative part of the Goals Section document template. [80 FR 76870] • For certification criteria that reference the CCDS to be included within C-CDA document templates, "patient goals," those of the care team, and those that are longitudinal in nature **must** be recorded in the Goals Section.	§ 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(21) Health concerns	***Clarifications:*** • The reference to the C-CDA is not meant to be strictly interpreted to mean that a developer must use the C-CDA's syntax for the Health Concerns Section. Reference to the C-CDA was intended to emphasize that the data must be consistently and independently represented as discrete data that are clearly distinguishable. Only the narrative part of the Health Concerns Section is necessary and required to satisfy the CCDS definition. Testing and certification will focus on the presence of data represented with just the narrative part of the Health Concerns Section document template. [80 FR 76870] • The Problem Section within C-CDA based document templates contains the problem list of the "priority concerns" that the author deemed significant enough to be on the problem list related to the current encounter. Any additional health concerns should not be contained in the Problem Section.	§ 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015

Version History

Version #	Change(s) Summary	Date Made
1.0	Initial Publication	Oct 30, 2015
1.1	Provided clarification regarding the mapping of the concepts in the "Race & Ethnicity" – CDC code system to the race and ethnicity categories in the OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15. Added clarifications from the 2015 Edition final rule correction notice about the intent and testing expectations for unique device identifier(s) for a patient's implantable device(s), assessment and plan of treatment, goals, and health concerns.	Jan 5, 2016
1.2	• Paragraphs (4) and (5) were revised to add the number of codes relevant to Race and Ethnicity in the value set. • Paragraph (6) was revised to add clarification for scope of testing to RFC 5646. • Paragraph (7) was revised to add a clarification. • Paragraph (8) was revised to add a clarification. • Paragraphs (18) through (21) were revised to include added clarifications.	Mar 25, 2016
1.3	• Paragraph (2) was revised to add a clarification. • Paragraph (18) was revised to add a clarification. • CDC Race and Ethnicity Code Set Version 1.0 (March 2000) link was updated.	Sep 16, 2016
1.4	• Race and ethnicity were updated to add a clarity that the order and grouping of OMB and detailed race/ethnicity codes is not dictated by 2015 Edition rules	Oct 21, 2016
1.5	• Added clarifications related to birth sex and compliance with C-CDA 2.1 errata updates	Jul 7, 2017