2015 Edition Certification Companion Guide

2015 Edition Common Clinical Data Set - 45 CFR 170.102

Final Rule Preamble – Correction Notice Preamble

Version 1.1 – Last Updated 1/5/2016

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
(1) Patient name	***Clarifications:*** • There is no standard required for patient name.	N/A
(2) Sex	***Clarifications:*** • The codes required are intended to present birth sex. [see also 80 FR 62618]	§ 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

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. [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. [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.	§ 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)

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. [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 ethnicities for a patient. [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" each one of the 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 and be recorded include:
	  ▪ Hispanic or Latino; and
	  ▪ Not Hispanic or Latino.
	• 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.
		§ 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)

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(6) Preferred language	***Clarifications:*** • RFC 5646 is compatible with C-CDA Release 2.1 and ISO 639-1, 639-2, and 639-3 can be mapped to it. [see also 80 FR 62619] • 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 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
(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 Common Clinical Data Set definition. [see also 77 FR 54205]	§ 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

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(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]	§ 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
(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]	§ 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 Common Clinical Data Set: ▪ 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] • 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. *continued on the next page*	§ 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	*continued from previous page* ▪ 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] *Continued on the next page*	§ 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. *Continued on the next page*

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(15) Procedures, *continued*	*Continued from previous page*	*Continued from previous page* § 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 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

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(17) Immunizations	***Clarifications:*** • The requirements for immunizations in the 2015 Edition Common Clinical Data Set 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.[2]	§ 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
(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. • 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]	§ 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

[2] 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
(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] • If using C-CDA, health IT systems can be certified to either: ▪ "Assessment Section (V2)" and "Plan of Treatment Section (V2),"; or ▪ "Assessment and Plan Section (V2)". • While the "Plan of Treatment" in C-CDA can be used across multiple encounters, the intent of ONC's certification is to focus the Plan of Treatment Section (V2) (or the Assessment and Plan Section (V2) if using this option) on a single encounter, and to use the Goals Section and Health Concerns Section for overarching goals and concerns that are not limited to a single encounter. [see also 80 FR 62695]	§ 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. [see also 80 FR 76870]	§ 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. [see also 80 FR 76870]	§ 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

Note: This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 2015 Edition final regulation. It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

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