

2015 Edition Common Clinical Data Set (CCDS) Reference Document

Version 1.0– Last Updated 1/20/16

Please consult the Final Rule entitled: *2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications* for a detailed description of the certification requirements. We also encourage developers to consult the Certification Companion Guide as they provide clarifications that may be useful for product development and testing.

Requirements

The following table is a complete list of the 2015 Edition of the Common Clinical Data Set (CCDS) and their associated standards. The complete list of the 2015 CCDS and the associated standards may be found in [Table 8](#) of the Final Rule.

Standard(s):

- § 170.205(a)(4) [HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1](#) (incorporated by reference in § 170.299).
- § 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
- § 170.207(b)(2) Current Procedural Terminology/Healthcare Common Procedure Coding System [CPT-4/HCPCS](#)
- § 170.207(b)(3) Current Dental Terminology ([CDT](#))
- § 170.207(b)(4) International Classification of Diseases [ICD-10-PCS](#)
- § 170.207(c)(3) [Logical Observation Identifiers Names and Codes \(LOINC®\) Database version 2.52](#)
- § 170.207(d)(3) [RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release](#)
- § 170.207(e)(3) [HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015](#)
- § 170.207(e)(4) [National Drug Code \(NDC\) Directory– Vaccine NDC Linker, updates through August 17, 2015](#)
- § 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 \(March 2000\)](#)
- § 170.207(g)(2) [Request for Comments \(RFC\) 5646](#)
- § 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

§ 170.207(m)(1) [The Unified Code of Units for Measure, Revision 1.9](#)

§ 170.207(n)(1) Birth sex must be coded in accordance with [HL7 Version 3](#) Value Sets for AdministrativeGender and NullFlavor attributed as follows:

(i) Male. M

(ii) Female. F

(iii) Unknown. nullFlavor UNK

| 2015 Edition Reference ¶ | System Under Test | Test Lab Verification |
|-----------------------------------|--|---|
| (1) Patient Name | The Common Clinical Data Set (CCDS) includes the Patient Name. | The tester verifies that the CCDS includes the Patient Name. |
| (2) Sex | The CCDS includes the Sex in accordance with and attributed with the standard specified at § 170.207(n)(1): birth sex coded in accordance with HL7 Version 3 Value Sets for AdministrativeGender and NullFlavor attributed as follows: (i) Male. M (ii) Female. F (iii) Unknown. nullFlavor UNK | The tester verifies that the CCDS includes the Sex in accordance with and attributed with the standard specified at § 170.207(n)(1): birth sex coded in accordance with HL7 Version 3 Value Sets for AdministrativeGender and NullFlavor attributed as follows: (i) Male. M (ii) Female. F (iii) Unknown. nullFlavor UNK |
| (3) Date of Birth | The CCDS includes the Date of Birth. | The tester verifies that the CCDS includes Date of Birth. |
| (4) and (5) Race and Ethnicity | The CCDS includes each one of a patient's Race(s) and Ethnicity(ies) in accordance with the standard specified at § 170.207(f)(2), CDC Race and Ethnicity Code Set Version 1.0 (March 2000), and § 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; for each race and ethnicity identified in accordance with 170.207(f)(2). | The tester verifies that the CCDS includes Race(s) and Ethnicity(ies) in accordance with the standards specified at § 170.207(f)(2) and § 170.207(f)(1). |

| 2015 Edition Reference ¶ | System Under Test | Test Lab Verification |
|------------------------------|---|--|
| (6) Preferred Language | The Common Clinical Data Set includes the Preferred Language in accordance with the standard specified at §170.207(g)(2) Request for Comments (RFC) 5646. | The tester verifies that the CCDS includes the Preferred Language in accordance with the standard specified at §170.207(g)(2). |
| (7) Smoking Status | The CCDS includes the Smoking Status in accordance with the standard specified at § 170.207(h) Smoking Status, coded in one of the following SNOMED CT® codes: <ul style="list-style-type: none"> (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 | The tester verifies that the CCDS includes the Smoking Status in accordance with the standard specified at § 170.207(h) coded in one of the following SNOMED CT® codes: <ul style="list-style-type: none"> (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 | The CCDS includes the Problems in accordance with at a minimum, the standard specified at § 170.207(a)(4) IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release. | The tester verifies that the CCDS includes the Problems in accordance with at a minimum, the standard specified at § 170.207(a)(4). |
| (9) Medications | The CCDS includes the Medications in accordance with at a minimum, the standard specified at § 170.207(d)(3) RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release. | The tester verifies that the CCDS includes the Medications in accordance with at a minimum, the standard specified at § 170.207(d)(3). |

| 2015 Edition Reference ¶ | System Under Test | Test Lab Verification |
|--|---|---|
| (10) Medication Allergies | The CCDS includes the Medication Allergies in accordance with at a minimum, the standard specified at § 170.207(d)(3) RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release. | The tester verifies that the CCDS includes the Medication Allergies in accordance with at a minimum, the standard specified at § 170.207(d)(3). |
| (11) Laboratory Tests | The CCDS includes the Laboratory Tests in accordance with at a minimum, the standard specified at § 170.207(c)(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52. | The tester verifies that the CCDS includes the Laboratory Tests in accordance with at a minimum, the standard specified at § 170.207(c)(3). |
| (12) Laboratory Values(s)/Result(s) | The CCDS includes the Laboratory Value(s)/Result(s). | The tester verifies that the CCDS includes the Laboratory Value(s)/Result(s). |

| 2015 Edition Reference ¶ | System Under Test | Test Lab Verification |
|-----------------------------|--|---|
| (13) Vital Signs | <p>The CCDS includes the Vital Signs with the following vital signs exchanged in numerical values only; and in accordance with the standard specified in § 170.207(c)(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52 and the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1) The Unified Code of Units of Measure, Revision 1.9:</p> <ul style="list-style-type: none"> • diastolic blood pressure; • systolic blood pressure; • body height; • body weight; • heart rate; • respiratory rate; • body temperature; • pulse oximetry; and • inhaled oxygen concentration. | <p>The tester verifies that the CCDS includes the Vital Signs diastolic blood pressure, systolic blood pressure, body height, body weight, heart rate, respiratory rate, body temperature, pulse oximetry, and inhaled oxygen concentration in numerical values only; and in accordance with the standard specified in § 170.207(c)(3) and the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1).</p> |

| 2015 Edition Reference ¶ | System Under Test | Test Lab Verification |
|--|---|--|
| (13) Vital Signs (Optional) | <p>The CCDS Vital signs also include:</p> <ul style="list-style-type: none"> • 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, <p>in numerical values only; and in accordance with the standard specified in § 170.207(c)(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52 and the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1) The Unified Code of Units of Measure, Revision 1.9.</p> | <p>The tester verifies that the CCDS vital signs also include:</p> <ul style="list-style-type: none"> • 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, <p>in numerical values only; and in accordance with the standard specified in § 170.207(c)(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52 and the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1) The Unified Code of Units of Measure, Revision 1.9.</p> |
| (15) Procedures | <p>The CCDS includes the Procedures in accordance with at a minimum, the standard specified at § 170.207(a)(4) IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release or § 170.207(b)(2) CPT-4/HCPCS.</p> <p>If the technology is developed primarily to record dental procedures, the CCDS may include Procedures in accordance with the standard specified in § 170.207(b)(3) CDT, but the technology must at a minimum be able to support SNOMED CT® or CPT-4/HCPCS.</p> | <p>The tester verifies that the CCDS includes the Procedures in accordance with the standard specified in § 170.205(a)(4) or one of the following:</p> <ul style="list-style-type: none"> • § 170.207(a)(4); or • § 170.207(b)(2) CPT-4/HCPCS. <p>If the technology is developed primarily to record dental procedures, the tester verifies that the Common Clinical Data Set includes Procedures in accordance with the standard specified in § 170.207(b)(3) CDT, and verifies that the technology is able to support SNOMED CT® or CPT-4/HCPCS.</p> |
| (15) Procedures (Optional) | <p>The CCDS includes the Procedures in accordance with the standard specified in § 170.207(b)(4) ICD-10-PCS.</p> | <p>The tester verifies that the CCDS includes the Procedures in accordance with the standard specified in § 170.207(b)(4).</p> |

| 2015 Edition Reference ¶ | System Under Test | Test Lab Verification |
|--|---|--|
| (16) Care Team Members | The CCDS includes the Care Team Member(s). | The tester verifies that the CCDS includes the Care Team Member(s). |
| (17) Immunizations | The CCDS includes the Immunizations in accordance with at a minimum, the standards specified in § 170.207(e)(3) HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015 and § 170.207(e)(4) National Drug Code (NDC) Directory—Vaccine NDC Linker, updates through August 17 2015. | The tester verifies that the CCDS includes the Immunizations in accordance with at a minimum, the standards specified in § 170.207(e)(3) and in § 170.207(e)(4). |
| (18) Unique Device Identifier(s) | <p>The CCDS includes the Unique Device Identifier(s) for a Patient's Implantable Device(s), specified in accordance with the "Product Instance" in the "Procedure Activity Procedure" of the standard specified in § 170.205(a)(4) for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1.</p> <p>Note that the system does not have to represent the UDI(s) using the C-CDA's syntax for the Product Instance template. The system must consistently and independently represent the UDI(s) as discrete data that are clearly distinguishable.</p> | <p>The tester verifies that the CCDS includes the Unique Device Identifier(s) for a Patient's Implantable Device(s) specified in accordance with the "Product Instance" in the "Procedure Activity Procedure" of the standard specified in § 170.205(a)(4).</p> <p>Note that the system does not have to represent the UDI(s) using the C-CDA's syntax for the Product Instance template. The system must consistently and independently represent the UDI(s) as discrete data that are clearly distinguishable.</p> |

| 2015 Edition Reference ¶ | System Under Test | Test Lab Verification |
|--|--|--|
| <p>(19) Assessment and Plan of Treatment</p> | <p>The CCDS includes either the Assessment and Plan or both the Assessment and Plan of Treatment specified in accordance with the standard specified in § 170.205(a)(4) for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1. At a minimum the Assessment and Plan of Treatment data includes the narrative text.</p> <p>Note that the system does not have to represent the assessment and plan of treatment using the C-CDA's syntax. The system must consistently and independently represent the assessment and plan of treatment as discrete data that are clearly distinguishable.</p> | <p>The tester verifies that the CCDS includes either the Assessment and Plan or both the Assessment and Plan of Treatment specified in accordance with the standard specified in § 170.205(a)(4) as narrative text.</p> <p>Note that the system does not have to represent the assessment and plan of treatment using the C-CDA's syntax. The system must consistently and independently represent the assessment and plan of treatment as discrete data that are clearly distinguishable.</p> |
| <p>(20) Goals</p> | <p>The CCDS includes the Goals specified in accordance with the standard specified in § 170.205(a)(4) for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1. At a minimum the Goals data includes narrative text.</p> <p>Note that the system does not have to represent the Goals using the C-CDA's syntax for the Goals Section. The system must consistently and independently represent the Goals as discrete data that are clearly distinguishable.</p> | <p>The tester verifies that the CCDS includes the Goals specified in accordance with the standard specified in § 170.205(a)(4) and includes the Goals as narrative text.</p> <p>Note that the system does not have to represent the Goals using the C-CDA's syntax for the Goals Section. The system must consistently and independently represent the Goals as discrete data that are clearly distinguishable.</p> |

| 2015 Edition Reference ¶ | System Under Test | Test Lab Verification |
|---------------------------------|---|---|
| (21) Health Concerns | <p>The CCDS includes the Health Concerns specified in accordance with the standard specified in § 170.205(a)(4) for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1. At a minimum the Health Concerns data includes narrative text.</p> <p>Note that the system does not have to represent the Health Concerns using the C-CDA's syntax for the Health Concerns Section. The system must consistently and independently represent the Health Concerns as discrete data that are clearly distinguishable.</p> | <p>The tester verifies that the CCDS includes the Health Concerns specified in accordance with the standard specified in § 170.205(a)(4) and includes the Health Concerns as narrative text.</p> <p>Note that the system does not have to represent the Health Concerns using the C-CDA's syntax for the Health Concerns Section. The system must consistently and independently represent the Health Concerns as discrete data that are clearly distinguishable.</p> |

The following table is a complete list of the 2014 Edition of the CCDS (formerly “Common MU Data Set”) and their associated standards. The complete list of the 2014 Edition of the CCDS and the associated standards may be found in [Table 8](#) of the Final Rule. The 2014 Edition of the CCDS is referenced here to support the backwards compatibility for systems receiving C-CDA R2 Release 1.1 documents.

Standard(s):

- § 170.205(a)(3) [HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 \(US Realm\) Draft Standard for Trial Use July 2012](#). The use of the “unstructured document” document-level template is prohibited.
- § 170.207(a)(3) [International Health Terminology Standards Development Organisation \(IHTSDO\) Systematized Nomenclature of Medicine Clinical Terms \(SNOMED CT®\) International Release July 2012](#) and US Extension to SNOMED CT® March 2012
- § 170.207(b)(2) [CPT-4](#)
- § 170.207(b)(3) [CDT](#)
- § 170.207(b)(4) [ICD-10-PCS](#)
- § 170.207(c)(2) [Logical Observation Identifiers Names and Codes \(LOINC®\) Database version 2.40, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.](#)
- § 170.207(d)(2) [RxNorm, August 6, 2012 Full Release](#)
- § 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(g)(1) ISO 639-2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639-1

§ 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

| 2014 Edition Reference ¶ | System Under Test | Test Lab Verification |
|--------------------------------------|--|---|
| (1) Patient Name | The CCDS includes the Patient Name. | The tester verifies that the CCDS includes the Patient Name. |
| (2) Sex | The CCDS includes the Sex. | The tester verifies that the CCDS includes the Sex. |
| (3) Date of Birth | The CCDS includes the Date of Birth. | The tester verifies that the CCDS includes Date of Birth. |
| (4) and (5) Race and Ethnicity | The CCDS includes the Race and Ethnicity in accordance with the standard specified in § 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. | The tester verifies that the CCDS includes Race and Ethnicity in accordance with the standard specified in § 170.207(f)(1). |
| (6) Preferred Language | The CCDS includes the Preferred Language in accordance with the standard specified in § 170.207(g)(1) as specified by the Library of Congress, ISO639-2 alpha codes limited to those that also have a corresponding alpha-2 code in ISO 639-1. | The tester verifies that the CCDS includes the Preferred Language in accordance with the standard specified in § 170.207(g)(1). |

| 2014 Edition Reference ¶ | System Under Test | Test Lab Verification |
|--------------------------------------|---|--|
| (7) Smoking Status | <p>The CCDS includes the Smoking Status in accordance with the standard specified in § 170.207(h). Smoking Status must be coded in one of the following SNOMED CT® codes:</p> <ul style="list-style-type: none"> (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 | <p>The tester verifies that the CCDS includes the Smoking Status in accordance with the standard specified in § 170.207(h) coded in one of the following SNOMED CT® codes:</p> <ul style="list-style-type: none"> (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 | <p>The CCDS includes the Problems in accordance with at a minimum, the standard specified in § 170.207(a)(3) IHTSDO SNOMED CT®, International Release July 2012 and US Extension to SNOMED CT® March 2012.</p> | <p>The tester verifies that the CCDS includes the Problems in accordance with at a minimum, the standard specified in § 170.207(a)(3).</p> |
| (9) Medications | <p>The CCDS includes the Medications in accordance with at a minimum, the standard specified in § 170.207(d)(2) RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release.</p> | <p>The tester verifies that the CCDS includes the Medications in accordance with at a minimum, the standard specified in § 170.207(d)(2).</p> |
| (10) Medication Allergies | <p>The CCDS includes the Medication Allergies in accordance with at a minimum, the standard specified in § 170.207(d)(2) RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release.</p> | <p>The tester verifies that the CCDS includes the Medication Allergies in accordance with at a minimum, the standard specified in § 170.207(d)(2).</p> |

| 2014 Edition Reference ¶ | System Under Test | Test Lab Verification |
|---|--|--|
| (11) Laboratory Tests | The CCDS includes the Laboratory Tests in accordance with at a minimum, the standard specified in § 170.207(c)(2) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40. | The tester verifies that the CCDS includes the Laboratory Tests in accordance with at a minimum, the standard specified in § 170.207(c)(2). |
| (12) Laboratory Value(s)/Result(s) | The CCDS includes the Laboratory Value(s)/Result(s). | The tester verifies that the CCDS includes the Laboratory Value(s)/Result(s). |
| (13) Vital Signs | The CCDS includes the Vital Signs : <ul style="list-style-type: none"> • height/length; • weight; • blood pressure; and • BMI. | The tester verifies that the CCDS includes the Vital Signs for height/length, weight, blood pressure, and BMI. |
| (14) Care Plan Field(s) | The CCDS includes the Care Plan Field(s), including Goals and Instructions. | The tester verifies that the CCDS includes the Care Plan Field(s), including Goals and Instructions. |
| (15) Procedures | <p>The CCDS includes the Procedures in accordance with at a minimum, the standard specified at § 170.207(a)(3) IHTSDO SNOMED CT®, U.S. Edition, July 2012 Release and US SNOMED CT® Extension to March 2012 Release <u>or</u> § 170.207(b)(2) CPT-4/HCPCS .</p> <p>If the technology is developed primarily to record dental procedures, the CCDS may include Procedures in accordance with the standard specified in § 170.207(b)(3) CDT, but the technology must at a minimum be able to support SNOMED CT® <u>or</u> CPT-4/HCPCS.</p> | <p>The tester verifies that the CCDS includes the Procedures in accordance with the standards specified in § 170.205(a)(3) <u>or</u> § 170.207(b)(2) CPT-4/HCPCS.</p> <p>If the technology is developed primarily to record dental procedures, the tester verifies that the CCDS includes Procedures in accordance with the standard specified in § 170.207(b)(3) CDT, and verifies that the technology is able to support SNOMED CT® <u>or</u> CPT-4/HCPCS.</p> |

| 2014 Edition Reference ¶ | System Under Test | Test Lab Verification |
|----------------------------------|---|--|
| (15) Procedures (Optional) | The CCDS includes the Procedures in accordance with the standard specified in § 170.207(b)(4) ICD-10-PCS. | The tester verifies the CCDS includes the Procedures in accordance with the standard specified in § 170.207(b)(4). |
| (16) Care Team Members | The CCDS includes the Care Team Member(s). | The tester verifies that the CCDS includes the Care Team Member(s). |

Document History

| Version Number | Description of Change | Date |
|----------------|-----------------------|------------------|
| 1.0 | Final Version | January 20, 2016 |