



Common Clinical Data Set

Data	2014 Edition Standard	2015 Edition Standard
Patient Name	No associated standard.	No associated standard.
Sex	No associated standard.	The standard specified in § 170.207(n)(1) – Birth sex must be coded in accordance with HL7 Version 3 (V3) Standard, Value Sets for AdministrativeGender and NullFlavor attributed as follows: (1) Male. M (2) Female. F (3) Unknown. nullFlavor UNK
Date of Birth	No associated standard.	No associated standard.
Race	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 (see “Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity”).	The standard specified in § 170.207(f)(2) - CDC Race and Ethnicity Code Set Version 1.0 (March 2000); and The standard specified in § 170.207(f)(1) for each race identified in accordance § 170.207(f)(2).
Ethnicity	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 (see “Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity”).	The standard specified in § 170.207(f)(2) - CDC Race and Ethnicity Code Set Version 1.0 (March 2000); and The standard specified in § 170.207(f)(1) for each ethnicity identified in accordance § 170.207(f)(2).
Preferred Language	The standard specified in § 170.207(g)(1) – As specified by the Library of Congress, ISO 639-2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639-1.	The standard specified in § 170.207(g)(2) – Request for Comments (RFC) 5646.

Data	2014 Edition Standard	2015 Edition Standard
Smoking Status	<p>The standard specified in § 170.207(h) – Smoking status must be coded in one of the following SNOMED CT® codes:</p> <ol 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 standard specified in § 170.207(h) – Smoking status must be coded in one of the following SNOMED CT® codes:</p> <ol 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
Problems	<p>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 Release.</p>	<p>At a minimum, the standard specified in § 170.207(a)(4) - IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release.</p>
Medications	<p>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>At a minimum, the standard specified in § 170.207(d)(3) – RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release.</p>
Medication Allergies	<p>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>At a minimum, the standard specified in § 170.207(d)(3) – RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release.</p>
Laboratory Test(s)	<p>At a minimum, the standard specified in § 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.</p>	<p>At a minimum, the standard specified in § 170.207(c)(3) – Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52.</p>
Laboratory Value(s)/ Result(s)	<p>No associated standard.</p>	<p>No associated standard.</p>



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Vital Signs	Height/length, weight, blood pressure, and BMI (no associated vocabulary standard).	<p>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 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).</p> <p>§ 170.207(c)(3) – Logical Observation Identifiers Names and Codes (LOINC®) version 2.52.</p> <p>§ 170.207(m)(1) – The Unified Code of Units of Measure, Revision 1.9, October 23, 2013.</p> <p><u>Optional.</u> 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.</p>
Care Plan Field(s), including Goals and Instructions	No associated standard.	Not applicable (replaced with Assessment and plan of treatment, goals, and health concerns – see below).



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Procedures	<p>At a minimum, the version of the standard specified in § 170.207(a)(3), or § 170.207(b)(2).</p> <p>§ 170.207(a)(3) - IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release</p> <p>§ 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:</p> <ol style="list-style-type: none"> (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. <p>For technology primarily developed to record dental procedures, the standard specified in § 170.207(b)(3) - The code set specified in 45 CFR 162.1002(a)(4) – <i>Code on Dental Procedures and Nomenclature</i>, as maintained and distributed by the American Dental Association, for dental services.</p>	<p>At a minimum, the version of the standard specified in § 170.207(a)(4), or § 170.207(b)(2).</p> <p>§ 170.207(a)(4) - IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release</p> <p>§ 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:</p> <ol style="list-style-type: none"> (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. <p>For technology primarily developed to record dental procedures, the standard specified in § 170.207(b)(3) - The code set specified in 45 CFR 162.1002(a)(4) – <i>Code on Dental Procedures and Nomenclature</i>, as maintained and distributed by the American Dental Association, for dental services.</p>
Care Team Member(s)	No associated standard.	No associated standard.



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Immunizations	Immunization data not included for 2014 Edition certification.	<p>In accordance with, at a minimum, the standards specified in § 170.207(e)(3) and (4).</p> <p>§ 170.207(e)(3) - HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015</p> <p>§ 170.207(e)(4) - National Drug Code Directory (NDC) – Vaccine NDC Linker, updates through August 17, 2015</p>
Unique Device Identifier(s) (UDIs) for a Patient’s Implantable Device(s)	UDI data not included for 2014 Edition certification.	<p>In accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4).</p> <p>§ 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.</p> <p><u>Unique device identifier</u> is defined as it is in 21 CFR 801.3 - means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of 830.20 of this chapter. A unique device identifier is composed of:</p> <p>(1) A device identifier --a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and</p> <p>(2) A production identifier --a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:</p> <p style="text-align: right;"><i>continued on the next page</i></p>

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<p>Unique Device Identifier(s) (UDIs) for a Patient's Implantable Device(s), continued</p>	<p>UDI data not included for 2014 Edition certification.</p>	<p><i>continued from previous page</i></p> <ul style="list-style-type: none"> (i) The lot or batch within which a device was manufactured; (ii) The serial number of a specific device; (iii) The expiration date of a specific device; (iv) The date a specific device was manufactured; (v) For an HCT/P regulated as a device, the distinct identification code required by 1271.290(c) of this chapter. <p><u>Implantable device</u> is defined as it is in 21 CFR 801.3 – means a device that is intended to be placed in a surgically or naturally formed cavity of the human body. A device is regarded as an implantable device for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner of Food and Drugs determines otherwise in order to protect human health.</p>
<p>Assessment and Plan of Treatment</p>	<p>Not applicable (refer to care plan field(s), including goals and instructions – see above).</p>	<p>§ 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.</p>
<p>Goals</p>	<p>Not applicable (refer to care plan field(s), including goals and instructions – see above).</p>	<p>In accordance with the “Goals Section” of the standard specified in § 170.205(a)(4).</p> <p>§ 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.</p>



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Health Concerns	Not applicable (refer to care plan field(s), including goals and instructions – see above).	<p>In accordance with the “Health Concerns Section” of the standard specified in § 170.205(a)(4).</p> <p>§ 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.</p>