

# 2015 Edition Certification Companion Guide

## Demographics - 45 CFR 170.315(a)(5)

Links will be updated as available: [Final Rule Preamble](#) – [Correction Notice Preamble](#) – [Test Procedure](#) – [Test Data](#)

Version 1.4 – Last Updated 9/19/2016

New/Revised/Unchanged Compared to 2014 Edition	Gap Certification Eligible	Base EHR Definition	Certified EHR Technology Definition	Associated EHR Incentive Program Objective(s)
Revised	No	Yes	Included	N/A

### Certification Requirements

**Privacy and Security:** This certification criterion was adopted at § 170.315(a)(5). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(a) “paragraph (a)” criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (a) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) “VDT” and (e)(2) “secure messaging,” which are explicitly stated.

**Design and Performance:** The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, the QMS’ need to be identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.

Privacy and Security (§ 170.315(d))	Design and Performance (§ 170.315(g))
<ul style="list-style-type: none"> <li>• If choosing Approach 1: <ul style="list-style-type: none"> <li>○ <a href="#">Authentication, access control, and authorization (§ 170.315(d)(1))</a></li> <li>○ <a href="#">Auditable events and tamper-resistance (§ 170.315(d)(2))</a></li> <li>○ <a href="#">Audit reports (§ 170.315(d)(3))</a></li> <li>○ <a href="#">Amendments (§ 170.315(d)(4))</a></li> <li>○ <a href="#">Automatic access time-out (§ 170.315(d)(5))</a></li> <li>○ <a href="#">Emergency access (§ 170.315(d)(6))</a></li> <li>○ <a href="#">End-user device encryption (§ 170.315(d)(7))</a></li> </ul> </li> <li>• If choosing Approach 2: <ul style="list-style-type: none"> <li>○ For each applicable P&amp;S certification criterion not certified for approach 1, the health IT developer may certify for the criterion using system documentation which provides a clear description of how the external services necessary to meet the P&amp;S criteria would be deployed and used. Please see the 2015 Edition final rule correction notice at <a href="#">80 FR 76870</a> for additional clarification.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">Safety-enhanced design (§ 170.315(g)(3))</a></li> <li>• <a href="#">Quality management system (§ 170.315(g)(4))</a></li> <li>• <a href="#">Accessibility-centered design (§ 170.315(g)(5))</a></li> </ul>

## Regulation Text

### Demographics.

(i) Enable a user to record, change, and access patient demographic data including race, ethnicity, preferred language, sex, sexual orientation, gender identity, and date of birth.

(A) Race and ethnicity.

(1) Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify race.

(2) Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify ethnicity.

(3) Aggregate each one of the patient's races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(1) and (2) of this section to the categories in the standard specified in § 170.207(f)(1).

(B) Preferred language. Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.

(C) Sex. Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1).

(D) Sexual orientation. Enable sexual orientation to be recorded in accordance with the standard specified in § 170.207(o)(1) and whether a patient declines to specify sexual orientation.

(E) Gender identity. Enable gender identity to be recorded in accordance with the standard specified in § 170.207(o)(2) and whether a patient declines to specify gender identity.

(ii) Inpatient setting only. Enable a user to record, change, and access the preliminary cause of death and date of death in the event of mortality.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	<p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• The demographic data can come from other sources (e.g., a registration system or practice management system) so long as testing demonstrates the Health IT Module can perform all required functions included in the demographics certification criterion. [FAQ #10]</li> <li>○ Testing for preferred language using the standard at § 170.207(g)(2) (RFC 5646) will focus on <b>all the languages</b> present in ISO 639-2 [<a href="http://www.loc.gov/standards/iso639-2/php/code_list.php">http://www.loc.gov/standards/iso639-2/php/code_list.php</a>]</li> <li>○ Consistent with the RFC 5646, the <b>shortest alpha</b> code for the language should be used. Testing will <b>only test the primary language tag</b> 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: <ul style="list-style-type: none"> <li>▪ use alpha 2 character code if one exists (ISO 639-1);</li> <li>▪ use alpha 3 character code if an alpha 2 character code does not exist (ISO 639-2); and</li> <li>▪ 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).</li> </ul> </li> </ul>	§ 170.207(g)(2) <a href="#">Request for Comments (RFC) 5646, “Tags for Identifying Languages,” September 2009, copyright 2009 Web Site Disclaimers</a>
(i)	<p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• There is no standard required for recording date of birth (i.e., any format may be used).</li> </ul>	N/A
(i)(A)	<ul style="list-style-type: none"> <li>• Technical outcome – <ul style="list-style-type: none"> <li>○ A user can record a patient’s race(s) and ethnicity(ies) according to concepts in the “Race &amp; Ethnicity – CDC” code system Version 1.0.</li> <li>○ The software must be able to aggregate each one of the patient’s race(s) and ethnicity(ies) and record the race(s) and 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 race and ethnicity selections must be aggregated and recorded include: <ul style="list-style-type: none"> <li>▪ American Indian or Alaska Native;</li> <li>▪ Asian;</li> <li>▪ Black or African American;</li> </ul> </li> </ul> </li> </ul>	§ 170.207(f)(1) <a href="#">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</a>

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(i)(A), continued	<ul style="list-style-type: none"> <li>▪ Native Hawaiian or Other Pacific Islander</li> <li>▪ White; and</li> <li>▪ Hispanic or Latino.</li> </ul> <ul style="list-style-type: none"> <li>○ The user must be able to record whether the patient declined to specify a race, an ethnicity, and both.</li> </ul> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• Note that while this provision focuses on the capture of race and ethnicity, industry standards require race and ethnicity be exchanged as separate fields (e.g., C-CDA and QRDA). We suggest developers bear this in mind when developing their health IT systems.</li> <li>• The “Race &amp; Ethnicity – CDC” code system includes over 900 concepts for race and ethnicity. [see also <a href="#">80 FR 16816</a>] A health IT developer is free to determine how the user interface is designed, including how many race and ethnicity values are displayed. No default minimum number of visible selections is expected or implied. During testing, however, any of the concepts for race and ethnicity may be tested. [see also <a href="#">80 FR 62618</a>]</li> <li>• The Health IT Module has to be able to record multiple patient races and/or ethnicities. [see also <a href="#">80 FR 62618</a>]</li> <li>• We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. <ul style="list-style-type: none"> <li>○ “Race &amp; Ethnicity” - CDC code system OID: 2.16.840.1.113883.6.238 [see also <a href="#">80 FR 62612</a>]</li> </ul> </li> <li>• Health IT Modules can present for certification to a more recent version of the “Race &amp; Ethnicity” – CDC code system than Version 1.0. [see also <a href="#">80 FR 62612</a>]</li> <li>• The concepts in the “Race &amp; 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.</li> <li>• The <a href="#">OMB standard</a> permits merging the ethnicity and race categories for a “combined format,” which would <u>no longer</u> require “not Hispanic or Latino” to be recorded. This alternative approach is also acceptable.</li> </ul>	<p>§ 170.207(f)(2)  <a href="#">CDC Race and Ethnicity Code Set Version 1.0 (March 2000)</a>  navigate to the CDCREC Roll-up codes tab</p>

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(i)(A), continued	<ul style="list-style-type: none"> <li>A product does not need to display all of the race and 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 races or ethnicities in the value set created by the standard.</li> </ul>	See above
(i)(B)	<ul style="list-style-type: none"> <li>Technical outcome – A user can record a patient’s preferred language according to the Request for Comments (RFC) 5646 standard. The user must be able to record whether the patient declined to specify preferred language.</li> </ul> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>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 <a href="#">80 FR 62619</a>]</li> <li>We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. <ul style="list-style-type: none"> <li>Tags for Identifying Languages – Request for Comment (RFC) 5646 code system OID: 2.16.840.1.113883.6.316 [see also <a href="#">80 FR 62612</a>]</li> </ul> </li> <li>A product does not need to display all of the language 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 record any of languages in the value set created by the standard.</li> </ul>	§ 170.207(g)(2) <a href="#">RFC 5646</a>
(i)(C)	<ul style="list-style-type: none"> <li>Technical outcome – A user can record a patient’s sex according to HL7 Version 3 and a nullFlavor value attributed as male (M), female (F), and unknown (UNK).</li> </ul> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>The codes required are intended to present birth sex (i.e., the sex recorded on the patient’s birth certificate) and not gender identity or reassigned sex. This criterion requires health IT enable a user to capture sexual orientation and gender identity separately (refer to provisions (i)(D) and (i)(E) below). [see also <a href="#">80 FR 62618</a>]</li> </ul>	§ 170.207(n)(1) Birth sex must be coded in accordance with <a href="#">HL7 Version 3</a> attributed as follows: (i) <u>Male</u> . M (ii) <u>Female</u> . F (iii) <u>Unknown</u> . UNK

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(i)(D) and (i)(E)	<ul style="list-style-type: none"> <li>• Technical outcome – A user can record a patient’s sexual orientation and gender identity according to HL7 Version 3 and SNOMED CT® codes specified in the “standard(s) referenced” column. The user must be able to record whether the patient declined to specify sexual orientation and/or gender identity.</li> </ul> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• Note that while SO/GI are included in this 2015 Edition “demographics” certification criterion and the 2015 Edition Base EHR definition, it is not included in the Common Clinical Data Set definition. This means that SO/GI are not required to be exchanged using certain standards, only that systems enable a user to record SO/GI. [see also <a href="#">80 FR 62619</a>]</li> <li>• While we are not requiring certification to structured and coded questions for soliciting SO/GI, we suggested that health care providers and institutions decide whether to include these questions in the collection of SO/GI information as “best practices”: <ul style="list-style-type: none"> <li>○ Do you think of yourself as: <ul style="list-style-type: none"> <li>▪ [Straight or heterosexual;</li> <li>▪ Lesbian, gay, or homosexual;</li> <li>▪ Bisexual;</li> <li>▪ Something else, please describe.</li> <li>▪ Don’t know.]</li> </ul> </li> <li>○ What is your current gender identity? (Check all that apply.) <ul style="list-style-type: none"> <li>▪ [Male;</li> <li>▪ Female;</li> <li>▪ Transgender male/Trans man/Female-to-male;</li> <li>▪ Transgender female/Trans woman/Male-to-female;</li> <li>▪ Genderqueer, neither exclusively male nor female;</li> <li>▪ Additional gender category/(or other), please specify.</li> <li>▪ Decline to answer.] [see also <a href="#">80 FR 62620</a>]</li> </ul> </li> </ul> </li> <li>• We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. <ul style="list-style-type: none"> <li>○ SNOMED CT® code system OID: 2.16.840.1.113883.6.96 [see also <a href="#">80 FR 62612</a>]</li> </ul> </li> <li>• Health IT Modules can present for certification to a more recent version of the U.S. Edition of SNOMED CT® than the September 2015 version. [see also <a href="#">80 FR 62612</a>]</li> </ul>	<p>§ 170.207(o)(1) Sexual orientation must be coded in accordance with, at a minimum, the version of <a href="#">SNOMED CT® codes adopted at paragraph (a)(4) of this section</a> for paragraphs (o)(1)(i) through (iii) of this section and <a href="#">HL7 Version 3</a> for paragraphs (o)(1)(iv) through (vi) of this section, attributed as follows:</p> <ul style="list-style-type: none"> <li>(i) <u>Lesbian, gay or homosexual</u>. 38628009</li> <li>(ii) <u>Straight or heterosexual</u>. 20430005</li> <li>(iii) <u>Bisexual</u>. 42035005</li> <li>(iv) <u>Something else, please describe</u>. nullFlavor OTH</li> <li>(v) <u>Don’t know</u>. nullFlavor UNK</li> <li>(vi) <u>Choose not to disclose</u>. nullFlavor ASKU</li> </ul> <p>§ 170.207(o)(2) Gender identity must be coded in accordance with, at a minimum, the version of <a href="#">SNOMED CT® codes adopted at paragraph (a)(4) of this section</a> for paragraphs (o)(2)(i) through (v) of this section and <a href="#">HL7 Version 3</a> for paragraphs (o)(2)(vi) and (vii) of this section, attributed as follows:</p> <ul style="list-style-type: none"> <li>(i) <u>Identifies as Male</u>. 446151000124109</li> </ul>

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(i)(D) and (i)(E), continued	See Above.	(ii) <u>Identifies as Female.</u> 446141000124107 (iii) <u>Female-to-Male (FTM)/Transgender Male/Trans Man.</u> 407377005 (iv) <u>Male-to-Female (MTF)/Transgender Female/Trans Woman.</u> 407376001 (v) <u>Genderqueer, neither exclusively male nor female.</u> 446131000124102 (vi) <u>Additional gender category or other, please specify.</u> nullFlavor OTH (vii) <u>Choose not to disclose.</u> nullFlavor ASKU
(ii)	<ul style="list-style-type: none"> <li>Technical outcome – For inpatient settings only, a user must be able to record, change, and access a patient’s preliminary cause of death and date of death.</li> </ul> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>No standard is required for recording preliminary cause of death and free text is permitted for certification. [see also <a href="#">77 FR 54209</a> and see also <a href="#">80 FR 62619</a>]</li> </ul>	N/A

**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 22, 2015
1.1	Made a technical correction to the SNOMED CT® code for “straight or heterosexual”; provided a 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.	Dec 18, 2015
1.2	Added clarification for scope of testing to RFC 5646.	Mar 24, 2016
1.3	Corrected the gender descriptors for "male" and "female" to "identifies as male" and "identifies as female" in § 170.207(o)(2).	June 20, 2016
1.4	Updated link to the race and ethnicity standard.	September 19, 2016