

# 2015 Edition Certification Companion Guide

## Family health history - 45 CFR 170.315(a)(12)

### [Final Rule Preamble](#) – [Test Procedure](#)

Version 1.2 – Last Updated 3/18/2016

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	No	Included	N/A

### Certification Requirements

**Privacy and Security:** This certification criterion was adopted at § 170.315(a)(12). 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.

- 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="#">Quality management system (§ 170.315(g)(4))</a></li> <li>• <a href="#">Accessibility-centered design (§ 170.315(g)(5))</a></li> </ul>

**Regulation Text**

Family health history. Enable a user to record, change, and access a patient's family health history in accordance with the familial concepts or expressions included in, at a minimum, the version of the standard in § 170.207(a)(4).

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	<ul style="list-style-type: none"> <li>• Technical Outcome - The health IT permits users to record, change, and access a patient’s family health history (FHH) according to the September 2015 Release of SNOMED CT®, U.S. Edition.</li> </ul> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• 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 <a href="#">80 FR 62612</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>○ The SNOMED CT® OID: 2.16.840.1.113883.6.96. [see also <a href="#">80 FR 62612</a>].</li> </ul> </li> <li>• Developers have the discretion to code associated FHH questions in the manner they choose (e.g., including but not limited to LOINC®). [see also <a href="#">80 FR 62624</a>]</li> <li>• Our intent with “familial concepts and expressions” is to focus on the diagnosis. For testing and certification, at a minimum, a system should be able to demonstrate that it can record, change, and access the diagnosis using a SNOMED CT® code. It is entirely up to the developer how the system will represent the familial relationship. For example, the familial relationship can be represented using the pre-coordinated SNOMED CT® codes that link both a relationship with a diagnosis or the developer may choose another method for coding the familial relationship (e.g., HL7 Pedigree).</li> <li>• At a minimum, the health IT must enable a user to record, change, and access information about a patient’s first degree relative within the said patient’s record. However, health IT does not need be able to access the records of the patient’s first degree relatives for certification. [see also <a href="#">77 FR 54174</a>]</li> </ul>	§170.207(a)(4) September 2015 Release of <a href="#">SNOMED CT®, U.S. Edition</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	Added clarification for the testing and certification of “familial concepts or expressions.”	Dec 18, 2015
1.2	Removed “unstructured/free text recording” clarification	Mar 18, 2016