

## 2015 Edition Certification Companion Guide

### Transmission to Public Health Agencies – Health Care Surveys - 45 CFR 170.315(f)(7)

Links will be updated as available: [FR preamble](#) – [Test Procedure](#) – [Test Tool/Data](#) – [Test Tool Supplemental Guide](#) – [MU Specification Sheet](#)

Version 1.2 – Last Updated 4/25/2016

New/Revised/Unchanged Compared to 2014 Edition	Gap Certification Eligible	Base EHR Definition	In Scope for Certified EHR Technology Definition	Associated EHR Incentive Program Objective(s)
New	No	No	Yes <sup>1</sup>	Objective 8

#### Certification Requirements

**Privacy and Security:** This certification criterion was adopted at § 170.315(f)(7). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(f) “paragraph (f)” 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 (f) 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.

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<sup>1</sup> For the public health certification criteria in § 170.315(f), health IT will only need to be certified to those criteria that are required to meet the measures the provider intends to report on to meet Objective 8: Public Health and Clinical Data Registry Reporting.

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="#">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**

Transmission to public health agencies – health care surveys. Create health care survey information for electronic transmission in accordance with the standard specified in § 170.205(s)(1).

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	<p>Technical outcome – Health IT can create health care survey data for electronic transmission in compliance with all mandatory elements and requirements of the HL7 Implementation Guide (IG) for CDA Release 2: National Health Care Surveys (NHCS), Release 1 – US Realm, Draft Standard for Trial Use, December 2014.</p> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• In response to a comment requesting clarification regarding the surveys that were included in the IG, we incorrectly indicated in the 2015 Edition final rule that the NHCS was included in the adopted version of the IG (version 1.0) [80 FR 62669]. This was due to a conflation of the name of the IG (NHCS IG), confusion with the <u>three</u> setting types of the two surveys (NAMCS and NHAMCS) included in version 1.0 of the IG, and the pending inclusion of the NHCS in <i>version 1.1</i> of the IG. We clarify that the NHCS is not included in the adopted version 1.0 of the IG and is <b>not</b> currently available for certification as part of the 2015 Edition.</li> <li>• We clarified in the 2015 Edition final rule that the entire IG would be covered as <u>part</u> of certification. [80 FR 62669] We further clarify that certification to each survey within the IG would be based on the selection of the health IT developer. We expect that such selection would be based on the health care setting that the Health IT Module presented for certification is intended to support. To illustrate, a Health IT Module designed to support providers practicing in: <ul style="list-style-type: none"> <li>○ An office setting would be presented for certification to NAMCS.</li> <li>○ A hospital-based outpatient setting would be presented for certification to NHAMCS with the appropriate IG-identified outpatient constraints.</li> <li>○ An emergency department would be presented for certification to NHAMCS with the appropriate IG-identified emergency department constraints.</li> </ul> </li> <li>• The health care surveys for electronic transmission will be collected by <u>CDC only</u> rather than at the jurisdictional level. [see also 80 FR 62669]</li> </ul>	<p>§ 170.205(s)(1) <a href="#">HL7 Implementation Guide for CDA Release 2: National Health Care Surveys (NHCS), Release 1 – US Realm, Draft Standard for Trial Use, December 2014</a></p> <p><a href="#">Errata for NCHS V1.0</a></p>

**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 27, 2015
1.1	Clarifications of the surveys included in the adopted IG (version 1.0) and the approach to testing and certification for each survey.	Mar 30, 2016
1.2	Added reference to Errata for NHCS V1.0	April 25, 2016