

2015 Edition Certification Companion Guide

Transmission to Public Health Agencies – Antimicrobial Use And Resistance Reporting - 45 CFR 170.315(f)(6)

Links will be updated as available: [Final Rule Preamble](#) – [Test Procedure](#) – [Test Tool/Data](#) – [Test Tool User Guide](#) – [MU Specification Sheet](#)

Version 1.2 – Last Updated 2/19/2016

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 ¹	Objective 8

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(f)(6). 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.

¹ 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"> • If choosing Approach 1: <ul style="list-style-type: none"> ○ Authentication, access control, and authorization (§ 170.315(d)(1)) ○ Auditable events and tamper-resistance (§ 170.315(d)(2)) ○ Audit reports (§ 170.315(d)(3)) ○ End-user device encryption (§ 170.315(d)(7)) • If choosing Approach 2: <ul style="list-style-type: none"> ○ For each applicable P&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&S criteria would be deployed and used. 	<ul style="list-style-type: none"> • Quality management system (§ 170.315(g)(4)) • Accessibility-centered design (§ 170.315(g)(5))

Regulation Text

Transmission to public health agencies – antimicrobial use and resistance reporting. Create antimicrobial use and resistance reporting information for electronic transmission in accordance with the standard specified in § 170.205(r)(1).

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
<p>Applies to entire criterion</p>	<p>Technical outcome – Health IT can create an electronic antimicrobial use and resistance report for the following three sections of the HL7 Implementation Guide for CDA[®] Release 2 – Level 3: Healthcare Associated Infection (HAI) Reports, Release 1, U.S. Realm, August 2013:</p> <ol style="list-style-type: none"> 1. HAI Antimicrobial Use and Resistance (AUR) Antimicrobial Resistance Option (ARO) Report (Numerator) specific document template in Section 2.1.2.1 (pages 69-72); 2. Antimicrobial Resistance Option (ARO) Summary Report (Denominator) specific document template in Section 2.1.1.1 (pages 54-56); and 3. Antimicrobial Use (AUP) Summary Report (Numerator and Denominator) specific document template in Section 2.1.1.2 (pages 56-58). <p style="text-align: right;"><i>Continued on next page</i></p>	<p>§ 170.205(r)(1) HL7 Implementation Guide for CDA[®] Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm, August 2013</p> <p>Technology is only required to conform to the following sections of the implementation guide:</p> <p>(i) HAI Antimicrobial Use and Resistance (AUR) Antimicrobial Resistance Option (ARO) Report (Numerator) specific document template in Section 2.1.2.1 (pages 69-72);</p> <p>(ii) Antimicrobial Resistance Option (ARO) Summary Report (Denominator) specific document template in Section 2.1.1.1 (pages 54-56); and</p> <p style="text-align: right;"><i>Continued on next page</i></p>

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion, continued	<p><i>Continued from previous page</i></p> <p>Clarifications:</p> <ul style="list-style-type: none"> The antimicrobial use and resistance reporting information for electronic transmission will be collected by <u>CDC only</u> rather than at the jurisdictional level. [see also 80 FR 62668] <p>For support with the testing and/or test tool for this criterion, please contact CDC at <u>NHSNCD@cdc.gov</u>.</p>	<p><i>Continued from previous page</i></p> <p>(iii) Antimicrobial Use (AUP) Summary Report (Numerator and Denominator) specific document template in Section 2.1.1.2 (pages 56-58)</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 29, 2015
1.1	Added contact email for CDC support on the testing and/or test tool for this criterion.	Dec 7, 2015
1.2	Updated link to test tool	Feb 19, 2016