§170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting

2015 Edition CCGs

Version 1.2 Updated on 02-19-2016

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	10-29-2015
1.1	Added contact email for CDC support on the testing and/or test tool for this criterion.	12-07-2015
1.2	Updated link to test tool.	02-19-2016

Regulation Text

Regulation Text

§170.315 (f)(6) *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).

Standard(s) Referenced

Applies to entire criterion

§ 170.205(r)(1) HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm, August 2013

Technology is only required to conform to the following sections of the implementation guide:
(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);
(ii) Antimicrobial Resistance Option (ARO) Summary Report (Denominator) specific document template in Section 2.1.1.1 (pages 54-56); and

(iii) Antimicrobial Use (AUP) Summary Report (Numerator and Denominator) specific document template in Section 2.1.1.2 (pages 56-58)

Certification Companion Guide: Transmission to public health agencies — antimicrobial use and resistance reporting

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is <u>not</u> 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.

Link to Final Rule Preamble

Link to Correction Notice Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
New	No	Not Included	Yes

Certification Requirements

<u>Privacy and Security</u>: 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.

Table for Privacy and Security

- If choosing Approach 1:
  - 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:

- 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. Please see the 2015 Edition final rule correction notice at 80 FR 76870 for additional clarification.

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.

Table for Design and Performance

- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))

Technical Explanations and Clarifications

Applies to entire criterion

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:

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).

Clarifications:

- 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.
- The antimicrobial use and resistance reporting information for electronic transmission will be collected by *CDC only* rather than at the jurisdictional level. [see also 80 FR 62668]
- *For support with the testing and/or test tool for this criterion, please contact CDC at NHSNCD@cdc.gov.*

Content last reviewed on September 21, 2018