Transmission to public health agencies — antimicrobial use and resistance reporting

- Certification Companion Guide (CCG)
- Test Procedure

Updated on 03-11-2024

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) Health Level 7 (HL7®) Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection (HAI) Reports, Release 1, U.S. Realm, August 2013

Technology is only required to conform to the following sections of the implementation guide:

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)

Standards Version Advancement Process (SVAP) Version(s) Approved

§ 170.205(r)(1) HL7® CDA® R2 Implementation Guide: Healthcare Associated Infection (HAI) Reports, Release 3 - US Realm, December 2020

For more information, please visit the Standards Version Advancement Process (SVAP) Version(s) page.

Certification Dependencies

Conditions and Maintenance of Certification

Real World Testing: Products certified to this criterion must complete requirements outlined for the Real World Testing Conditions and Maintenance of Certification.

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.

- Quality management system (§ 170.315(g)(4)): 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.
- Accessibility-centered design (§ 170.315(g)(5)): 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 & Security Requirements

This certification criterion was adopted at § 170.315(f)(6). As a result, an ONC Authorized Certification Body (ONC-ACB) must ensure that a product presented for certification to a § 170.315(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) "View, download and transmit to 3rd party (VDT)" and (e)(2) "Secure messaging," which are explicitly stated.
- § 170.315(d)(2)(i)(C) is not required if the scope of the Health IT Module does not have end-user device encryption features.

For more information on the approaches to meet these Privacy and Security requirements, please review the Privacy and Security CCG.

If choosing Approach 2:

For each applicable privacy and security certification criterion not certified using Approach 1, the health IT developer may certify using system documentation which is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces to access external services necessary to meet the requirements of the privacy and security certification criterion. Please see the ONC Cures Act Final Rule at 85 FR 25710 for additional clarification.

Revision History

Version #	Description of Change	Version Date
1.0	Initial publication	03-11-2024

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) Health Level 7 (HL7®) Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection (HAI) Reports, Release 1, U.S. Realm, August 2013

Technology is only required to conform to the following sections of the implementation guide:

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)

Standards Version Advancement Process (SVAP) Version(s) Approved

§ 170.205(r)(1) HL7® CDA® R2 Implementation Guide: Healthcare Associated Infection (HAI) Reports, Release 3 - US Realm, December 2020

For more information, please visit the Standards Version Advancement Process (SVAP) Version(s) page.

Certification Dependencies
Conditions and Maintenance of Certification

Real World Testing: Products certified to this criterion must complete requirements outlined for the Real World Testing Conditions and Maintenance of Certification.

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.

- Quality management system (§ 170.315(g)(4)): 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.
- Accessibility-centered design (§ 170.315(g)(5)): 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 & Security Requirements
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- 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) "View, download and transmit to 3rd party (VDT)" and (e)(2) "Secure messaging," which are explicitly stated.
- § 170.315(d)(2)(i)(C) is not required if the scope of the Health IT Module does not have end-user device encryption features.

For more information on the approaches to meet these Privacy and Security requirements, please review the Privacy and Security CCG.

- 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))
  - Encrypt authentication credentials (§ 170.315(d)(12))
  - Multi-factor authentication (MFA) (§ 170.315(d)(13))
- If choosing Approach 2:

  For each applicable privacy and security certification criterion not certified using Approach 1, the health IT developer may certify using system documentation which is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces to access external services necessary to meet the requirements of the privacy and security certification criterion. Please see the ONC Cures Act Final Rule at 85 FR 25710 for additional clarification.

Testing

Testing Tool

CDA Validator

Criterion Subparagraph	Test Data
(f)(6)	None

Revision History

Version #	Description of Change	Version Date
1.0	Initial publication	03-11-2024

This Test Procedure illustrates the test steps required to certify a Health IT Module to this criterion. Please consult the most recent ONC Final Rule on the Certification Regulations page for a detailed description of the certification criterion with which these testing steps are associated. ONC also encourages developers to consult the Certification Companion Guide in tandem with the test procedure as it provides clarifications that may be useful for product development and testing.

Note: The tests step order does not necessarily prescribe the order in which the tests should take place.

Testing components


ONC
Supplied
Test
Data

Paragraph (f)(6) Transmission to public health agencies – antimicrobial use and resistance reporting

System Under Test

1. The Health IT Module creates Antimicrobial use and resistance reporting information in accordance with the following sections of the standard specified at § 170.205(r)
   (1) HL7® Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection (HAI) Reports, Release 1:
   - HAI Antimicrobial Use and Resistance (AUR) Antimicrobial Resistance Option Report (Numerator), document template in Section 2.1.2.1;
   - Antimicrobial Resistance Option (ARO) Summary Report (Denominator), document template in Section 2.1.1.1; and Antimicrobial Use (AUP) Summary Report (Numerator and Denominator), document template in Section 2.1.1.2.

Approved SVAP Version(s)

HL7® CDA® R2 Implementation Guide: Healthcare Associated Infection (HAI) Reports, Release 3 - US Realm, December 2020

Test Lab Verification

1. The tester reviews the validation report and verifies that the documents generated are correct and without omission, reflecting the data entered into the Health IT Module, using value sets specified by the HL7® HAI Reports implementation guide.
2. The tester imports each antimicrobial use and resistance reporting document into the test tool for validation and uses the Validation Report produced by the test tool to verify the report indicates passing without error to confirm that the Antimicrobial use and resistance reporting document is conformant to the specified templates of the § 170.205(r)(1).

System Under Test	Test Lab Verification

System Under Test

1. The Health IT Module creates Antimicrobial use and resistance reporting information in accordance with the following sections of the standard specified at § 170.205(r)(1) HL7® Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection (HAI) Reports, Release 1:
    - HAI Antimicrobial Use and Resistance (AUR) Antimicrobial Resistance Option Report (Numerator), document template in Section 2.1.2.1;
    - Antimicrobial Resistance Option (ARO) Summary Report (Denominator), document template in Section 2.1.1.1; and Antimicrobial Use (AUP) Summary Report (Numerator and Denominator), document template in Section 2.1.1.2.

Test Lab Verification

1. The tester reviews the validation report and verifies that the documents generated are correct and without omission, reflecting the data entered into the Health IT Module, using value sets specified by the HL7® HAI Reports implementation guide.
2. The tester imports each antimicrobial use and resistance reporting document into the test tool for validation and uses the Validation Report produced by the test tool to verify the report indicates passing without error to confirm that the Antimicrobial use and resistance reporting document is conformant to the specified templates of the § 170.205(r)(1).

Approved SVAP Version(s)

HL7® CDA® R2 Implementation Guide: Healthcare Associated Infection (HAI) Reports, Release 3 - US Realm, December 2020

Updated on 03-11-2024

Regulation Text

Regulation Text

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Standard(s) Referenced

Applies to entire criterion

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Technology is only required to conform to the following sections of the implementation guide:

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);
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Standards Version Advancement Process (SVAP) Version(s) Approved

§ 170.205(r)(1) HL7® CDA® R2 Implementation Guide: Healthcare Associated Infection (HAI) Reports, Release 3 - US Realm, December 2020

For more information, please visit the Standards Version Advancement Process (SVAP) Version(s) page.

Certification Dependencies

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For more information on the approaches to meet these Privacy and Security requirements, please review the Privacy and Security CCG.

- If choosing Approach 1:
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  - Audit reports (§ 170.315(d)(3))
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  - Encrypt authentication credentials (§ 170.315(d)(12))
  - Multi-factor authentication (MFA) (§ 170.315(d)(13))
- If choosing Approach 2:

  For each applicable privacy and security certification criterion not certified using Approach 1, the health IT developer may certify using system documentation which is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces to access external services necessary to meet the requirements of the privacy and security certification criterion. Please see the ONC Cures Act Final Rule at 85 FR 25710 for additional clarification.

Revision History

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1.0	Initial publication	03-11-2024

Regulation Text

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Applies to entire criterion

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Standards Version Advancement Process (SVAP) Version(s) Approved

§ 170.205(r)(1) HL7® CDA® R2 Implementation Guide: Healthcare Associated Infection (HAI) Reports, Release 3 - US Realm, December 2020

For more information, please visit the Standards Version Advancement Process (SVAP) Version(s) page.

Certification Dependencies
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Revision History

Version #	Description of Change	Version Date
1.0	Initial publication	03-11-2024

Testing

Testing Tool

CDA Validator

Criterion Subparagraph	Test Data
(f)(6)	None

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 certification. The CCG is not a substitute for the requirements outlined in regulation and related ONC final rules. It extracts key portions of ONC final rules' preambles and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the Certification Regulations page for links to all ONC final rules or consult other regulatory references as noted. The CCG is for public use and should not be sold or redistributed.

The below table outlines whether this criterion has additional Maintenance of Certification dependencies, update requirements and/or eligibility for standards updates via SVAP. Review the Certification Dependencies and Required Update Deadline drop-downs above if this table indicates "yes" for any field.

Base EHR Definition	Real World Testing	Insights Condition	SVAP	Requires Updates
Not Included	Yes	No	Yes	No

Certification Requirements

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 the Centers for Disease Control and Prevention (CDC) only rather than at the jurisdictional level. [see also 80 FR 62668]
- Health IT developers choosing to exercise the Standards Version Advancement Process (SVAP) for this criterion should use the following guidance for measures described at 170.205(r)(1):
    - For (i) “HAI Antimicrobial Use and Resistance (AUR) Antimicrobial Resistance Option (ARO) Report (Numerator)...”:
        Use the SVAP-approved standard “HL7® CDA® R2 Implementation Guide: Healthcare Associated Infection (HAI) Reports, Release 3 - US Realm, December 2020
    - For (ii) “Antimicrobial Resistance Option (ARO) Summary Report (Denominator)…":
        Use the SVAP-approved standard “HL7® CDA® R2 Implementation Guide: Healthcare Associated Infection (HAI) Reports, Release 3 - US Realm, December 2020”
    - For (iii) “Antimicrobial Use (AUP) Summary Report (Numerator and Denominator)”:
        Continue to use the base standard adopted at 170.205(r)(1) “Health Level 7 (HL7®) Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection (HAI) Reports, Release 1, U.S. Realm, August 2013”
- For support with the testing and/or test tool for this criterion, please contact CDC at NHSNCDA@cdc.gov.

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);
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        Use the SVAP-approved standard “HL7® CDA® R2 Implementation Guide: Healthcare Associated Infection (HAI) Reports, Release 3 - US Realm, December 2020
    - For (ii) “Antimicrobial Resistance Option (ARO) Summary Report (Denominator)…":
        Use the SVAP-approved standard “HL7® CDA® R2 Implementation Guide: Healthcare Associated Infection (HAI) Reports, Release 3 - US Realm, December 2020”
    - For (iii) “Antimicrobial Use (AUP) Summary Report (Numerator and Denominator)”:
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