Social, psychological, and behavioral data

healthit.gov/test-method/social-psychological-and-behavioral-data

- [Certification Companion Guide (CCG)](#)
- [Conformance Method](#)

Updated on 03-11-2024

Regulation Text

Regulation Text

§ 170.315 (a)(15) *Social, psychological, and behavioral data—*

Enable a user to record, change, and access the following patient social, psychological, and behavioral data:

1. *Financial resource strain.* Enable financial resource strain to be recorded in accordance with the standard specified in §170.207(p)(1) and whether a patient declines to specify financial resource strain.
2. *Education.* Enable education to be recorded in accordance with the standard specified in §170.207(p)(2) and whether a patient declines to specify education.
3. *Stress.* Enable stress to be recorded in accordance with the standard specified in §170.207(p)(3) and whether a patient declines to specify stress.
4. *Depression.* Enable depression to be recorded in accordance with the standard specified in §170.207(p)(4) and whether a patient declines to specify depression.
5. *Physical activity.* Enable physical activity to be recorded in accordance with the standard specified in §170.207(p)(5) and whether a patient declines to specify physical activity.
6. *Alcohol use.* Enable alcohol use to be recorded in accordance with the standard specified in §170.207(p)(6) and whether a patient declines to specify alcohol use.
7. *Social connection and isolation.* Enable social connection and isolation to be recorded in accordance the standard specified in §170.207(p)(7) and whether a patient declines to specify social connection and isolation.
8. *Exposure to violence (intimate partner violence).* Enable exposure to violence (intimate partner violence) to be recorded in accordance with the standard specified in §170.207(p)(8) and whether a patient declines to specify exposure to violence (intimate partner violence).

Standard(s) Referenced

Applies to entire criterion

§ 170.207(c)(3) <u>Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, Released June 2015, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.</u> (Adoption of this standard expires on January 1, 2026.)

170.207(c)(1) <u>Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.72, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc., February 16, 2022</u> (This standard is required by December 31, 2025.)

§ 170.207(m)(1) <u>The Unified Code of Units of Measure, Revision 1.9</u> (Adoption of this standard expires on January 1, 2026.)

§ 170.207(m)(2) <u>The Unified Code of Units of Measure, Revision 2.1, November 21, 2017</u> (This standard is required by December 31, 2025.)

Paragraph (a)(15)(i)

§ 170.207(p)(1) *Financial resource strain*. Financial resource strain must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® code 76513-1 and LOINC® answer list ID LL3266-5. (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(1) *Financial resource strain*. Financial resource strain must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with the LOINC® code 76513-1 and LOINC® answer list ID LL3266-5. (This standard is required by December 31, 2025.)

Paragraph (a)(15)(ii)

§ 170.207(p)(2) *Education*. Education must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® code 63504-5 and LOINC® answer list ID LL1069-5. (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(2) *Education*. Education must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with LOINC® code 63504-5 and LOINC® answer list ID LL1069-5. (This standard is required by December 31, 2025.)

Paragraph (a)(15)(iii)

§ 170.207(p)(3) *Stress*. Stress must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® code 76542-0 and LOINC® answer list LL3267-3. (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(3) *Stress*. Stress must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with the LOINC® code 76542-0 and LOINC® answer list LL3267-3. (This standard is required by December 31, 2025.)

Paragraph (a)(15)(iv)

§ 170.207(p)(4) *Depression*. Depression must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® codes 55757-9, 44250-9 (with LOINC® answer list ID LL358-3), 44255-8 (with LOINC® answer list ID LL358-3), and 55758-7 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(4) *Depression*. Depression must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with LOINC® codes 55757-9, 44250-9 (with LOINC® answer list ID LL358-3), 44255-8 (with LOINC® answer list ID LL358-3), and 55758-7 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(v)

§ 170.207(p)(5) *Physical activity*. Physical activity must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® codes 68515-6 and 68516-4. The answers must be coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(5) *Physical activity*. Physical activity must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with LOINC® codes 68515-6 and 68516-4. The answers must be coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(vi)

§ 170.207(p)(6) *Alcohol use*. Alcohol use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® codes 72109-2, 68518-0 (with LOINC® answer list ID LL2179-1), 68519-8 (with LOINC® answer list ID LL2180-9), 68520-6 (with LOINC® answer list ID LL2181-7), and 75626-2 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(6) *Alcohol use*. Alcohol use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with LOINC® codes 72109-2, 68518-0 (with LOINC® answer list ID LL2179-1), 68519-8 (with LOINC® answer list ID LL2180-9), 68520-6 (with LOINC® answer list ID LL2181-7), and 75626-2 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(vii)

§ 170.207(p)(7) *Social connection and isolation*. Social connection and isolation must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® codes 76506-5, 63503-7 (with LOINC® answer list ID LL1068-7), 76508-1 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76509-9 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76510-7 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76511-5 (with LOINC® answer list ID LL963-0), and 76512-3 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(7) *Social connection and isolation*. Social connection and isolation must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with the LOINC® codes 76506-5, 63503-7 (with LOINC® answer list ID LL1068-7), 76508-1 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76509-9 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76510-7 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76511-5 (with LOINC® answer list ID LL963-0), and 76512-3 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(viii)

§ 170.207(p)(8) *Exposure to violence (intimate partner violence)*. Exposure to violence: intimate partner violence must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® code 76499-3, 76500-8 (with LOINC® answer list ID LL963-0), 76501-6 (with LOINC® answer list ID LL963-0), 76502-4 (with LOINC® answer list ID LL963-0), 76503-2 (with LOINC® answer list ID LL963-0), and 76504-0 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(8) *Exposure to violence (intimate partner violence)*. Exposure to violence: intimate partner violence must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with the LOINC® code 76499-3, 76500-8 (with LOINC® answer list ID LL963-0), 76501-6 (with LOINC® answer list ID LL963-0), 76502-4 (with LOINC® answer list ID LL963-0), 76503-2 (with LOINC® answer list ID LL963-0), and 76504-0 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)). (This standard is required by December 31, 2025.)

Required Update Deadlines

The following outlines deadlines for required updates for this criterion as they relate to changes published in recent ONC final rules. Developers must update their products to the requirements outlined and provide them to their customers by the stated deadlines. These represent one-time deadlines as set by recent regulatory updates and do not encompass ongoing deadlines related to the Conditions and Maintenance of Certification. Please review those requirements for additional compliance activities related to one's certification under Certification Dependencies.

Deadline: December 31, 2025

Action to be taken: Developers certified to this criterion must update their use of minimum standard code sets outlined throughout the criterion to reflect updates to LOINC® and Unified Code of Units of Measure (UCUM) versions.

Certification Dependencies

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 needs 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(a)(15). As a result, an ONC Authorized Certification Body (ONC-ACB) must ensure that a product presented for certification to a § 170.315(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 presented 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 transfer 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 for 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 the Health IT Module to access external services necessary to meet the requirements of the privacy and security certification criterion. Please see the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* 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 (a)(15) *Social, psychological, and behavioral data*—

Enable a user to record, change, and access the following patient social, psychological, and behavioral data:

1. *Financial resource strain.* Enable financial resource strain to be recorded in accordance with the standard specified in §170.207(p)(1) and whether a patient declines to specify financial resource strain.

2. *Education.* Enable education to be recorded in accordance with the standard specified in §170.207(p)(2) and whether a patient declines to specify education.
3. *Stress.* Enable stress to be recorded in accordance with the standard specified in §170.207(p)(3) and whether a patient declines to specify stress.
4. *Depression.* Enable depression to be recorded in accordance with the standard specified in §170.207(p)(4) and whether a patient declines to specify depression.
5. *Physical activity.* Enable physical activity to be recorded in accordance with the standard specified in §170.207(p)(5) and whether a patient declines to specify physical activity.
6. *Alcohol use.* Enable alcohol use to be recorded in accordance with the standard specified in §170.207(p)(6) and whether a patient declines to specify alcohol use.
7. *Social connection and isolation.* Enable social connection and isolation to be recorded in accordance the standard specified in §170.207(p)(7) and whether a patient declines to specify social connection and isolation.
8. *Exposure to violence (intimate partner violence).* Enable exposure to violence (intimate partner violence) to be recorded in accordance with the standard specified in §170.207(p)(8) and whether a patient declines to specify exposure to violence (intimate partner violence).

Standard(s) Referenced

Applies to entire criterion

§ 170.207(c)(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, Released June 2015, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc. (Adoption of this standard expires on January 1, 2026.)

170.207(c)(1) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.72, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc., February 16, 2022 (This standard is required by December 31, 2025.)

§ 170.207(m)(1) The Unified Code of Units of Measure, Revision 1.9 (Adoption of this standard expires on January 1, 2026.)

§ 170.207(m)(2) The Unified Code of Units of Measure, Revision 2.1, November 21, 2017 (This standard is required by December 31, 2025.)

Paragraph (a)(15)(i)

§ 170.207(p)(1) *Financial resource strain*. Financial resource strain must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® code 76513-1 and LOINC® answer list ID LL3266-5.

(Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(1) *Financial resource strain*. Financial resource strain must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with the LOINC® code 76513-1 and LOINC® answer list ID LL3266-5. (This standard is required by December 31, 2025.)

Paragraph (a)(15)(ii)

§ 170.207(p)(2) *Education*. Education must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® code 63504-5 and LOINC® answer list ID LL1069-5. (Adoption of this standard expires on January 1, 2026.)

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Paragraph (a)(15)(iii)

§ 170.207(p)(3) *Stress*. Stress must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® code 76542-0 and LOINC® answer list LL3267-3. (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(3) *Stress*. Stress must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with the LOINC® code 76542-0 and LOINC® answer list LL3267-3. (This standard is required by December 31, 2025.)

Paragraph (a)(15)(iv)

§ 170.207(p)(4) *Depression*. Depression must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® codes 55757-9, 44250-9 (with LOINC® answer list ID LL358-3), 44255-8 (with LOINC® answer list ID LL358-3), and 55758-7 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(4) *Depression*. Depression must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with LOINC® codes 55757-9, 44250-9 (with LOINC® answer list ID LL358-3), 44255-8 (with LOINC® answer list ID LL358-3), and 55758-7 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(v)

§ 170.207(p)(5) *Physical activity*. Physical activity must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® codes 68515-6 and 68516-4. The answers must be coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(5) *Physical activity*. Physical activity must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with LOINC® codes 68515-6 and 68516-4. The answers must be coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(vi)

§ 170.207(p)(6) *Alcohol use*. Alcohol use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® codes 72109-2, 68518-0 (with LOINC® answer list ID LL2179-1), 68519-8 (with LOINC® answer list ID LL2180-9), 68520-6 (with LOINC® answer list ID LL2181-7), and 75626-2 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(6) *Alcohol use*. Alcohol use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with LOINC® codes 72109-2, 68518-0 (with LOINC® answer list ID LL2179-1), 68519-8 (with LOINC® answer list ID LL2180-9), 68520-6 (with LOINC® answer list ID LL2181-7), and 75626-2 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(vii)

§ 170.207(p)(7) *Social connection and isolation*. Social connection and isolation must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® codes 76506-5, 63503-7 (with LOINC® answer list ID LL1068-7), 76508-1 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76509-9 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76510-7 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76511-5 (with LOINC® answer list ID LL963-0), and 76512-3 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(7) *Social connection and isolation*. Social connection and isolation must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with the LOINC® codes 76506-5, 63503-7 (with LOINC® answer list ID LL1068-7), 76508-1 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76509-9 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76510-7 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76511-5 (with LOINC® answer list ID LL963-0), and 76512-3 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(viii)

§ 170.207(p)(8) *Exposure to violence (intimate partner violence)*. Exposure to violence: intimate partner violence must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® code 76499-3, 76500-8 (with LOINC® answer list ID LL963-0), 76501-6 (with LOINC® answer list ID LL963-0), 76502-4 (with LOINC® answer list ID LL963-0), 76503-2 (with LOINC® answer list ID LL963-0), and 76504-0 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

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Required Update Deadlines
The following outlines deadlines for required updates for this criterion as they relate to changes published in recent ONC final rules. Developers must update their products to the requirements outlined and provide them to their customers by the stated deadlines. These represent one-time deadlines as set by recent regulatory updates and do not encompass ongoing deadlines related to the Conditions and Maintenance of Certification. Please review those requirements for additional compliance activities related to one's certification under Certification Dependencies.

Deadline: December 31, 2025

Action to be taken: Developers certified to this criterion must update their use of minimum standard code sets outlined throughout the criterion to reflect updates to LOINC® and Unified Code of Units of Measure (UCUM) versions.

Certification Dependencies

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 needs to be identified for every capability to which it was applied.
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Privacy & Security Requirements

This certification criterion was adopted at § 170.315(a)(15). As a result, an ONC Authorized Certification Body (ONC-ACB) must ensure that a product presented for certification to a § 170.315(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 presented 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 transfer 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))
  - Amendments (§ 170.315(d)(4))
  - Automatic access time-out (§ 170.315(d)(5))
  - Emergency access (§ 170.315(d)(6))
  - 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 for 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 the Health IT Module to access external services necessary to meet the requirements of the privacy and security certification criterion. Please see the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* Final Rule at 85 FR 25710 for additional clarification.

Revision History

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

Testing components

Attestation: As of September 21, 2017, the testing approach for this criterion is satisfied by attestation.

The archived version of the Test Procedure is attached below for reference.

System Under Test	ONC-ACB Verification
The health IT developer will attest directly to the ONC-ACB to conformance with the § 170.315(a)(15) *Social, psychological, and behavioral data* requirements.	The ONC-ACB verifies the health IT developer attests conformance to the § 170.315(a)(15) *Social, psychological, and behavioral data* requirements.

Archived Version:

§170.315(a)(15) Test Procedure

Updated on 03-11-2024

Regulation Text

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7. *Social connection and isolation.* Enable social connection and isolation to be recorded in accordance the standard specified in §170.207(p)(7) and whether a patient declines to specify social connection and isolation.
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Standard(s) Referenced

Applies to entire criterion

§ 170.207(c)(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, Released June 2015, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc. (Adoption of this standard expires on January 1, 2026.)

170.207(c)(1) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.72, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc., February 16, 2022 (This standard is required by December 31, 2025.)

§ 170.207(m)(1) The Unified Code of Units of Measure, Revision 1.9 (Adoption of this standard expires on January 1, 2026.)

§ 170.207(m)(2) The Unified Code of Units of Measure, Revision 2.1, November 21, 2017 (This standard is required by December 31, 2025.)

Paragraph (a)(15)(i)

§ 170.207(p)(1) *Financial resource strain*. Financial resource strain must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® code 76513-1 and LOINC® answer list ID LL3266-5. (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(1) *Financial resource strain*. Financial resource strain must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with the LOINC® code 76513-1 and LOINC® answer list ID LL3266-5. (This standard is required by December 31, 2025.)

Paragraph (a)(15)(ii)

§ 170.207(p)(2) *Education*. Education must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® code 63504-5 and LOINC® answer list ID LL1069-5. (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(2) *Education*. Education must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with LOINC® code 63504-5 and LOINC® answer list ID LL1069-5. (This standard is required by December 31, 2025.)

Paragraph (a)(15)(iii)

§ 170.207(p)(3) *Stress*. Stress must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® code 76542-0 and LOINC® answer list LL3267-3. (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(3) *Stress*. Stress must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with the LOINC® code 76542-0 and LOINC® answer list LL3267-3. (This standard is required by December 31, 2025.)

Paragraph (a)(15)(iv)

§ 170.207(p)(4) *Depression*. Depression must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® codes 55757-9, 44250-9 (with LOINC® answer list ID LL358-3), 44255-8 (with LOINC® answer list ID LL358-3), and 55758-7 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(4) *Depression*. Depression must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with LOINC® codes 55757-9, 44250-9 (with LOINC® answer list ID LL358-3), 44255-8 (with LOINC® answer list ID LL358-3), and 55758-7 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(v)

§ 170.207(p)(5) *Physical activity*. Physical activity must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® codes 68515-6 and 68516-4. The answers must be coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(5) *Physical activity*. Physical activity must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with LOINC® codes 68515-6 and 68516-4. The answers must be coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(vi)

§ 170.207(p)(6) *Alcohol use*. Alcohol use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® codes 72109-2, 68518-0 (with LOINC® answer list ID LL2179-1), 68519-8 (with LOINC® answer list ID LL2180-9), 68520-6 (with LOINC® answer list ID LL2181-7), and 75626-2 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(6) *Alcohol use*. Alcohol use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with LOINC® codes 72109-2, 68518-0 (with LOINC® answer list ID LL2179-1), 68519-8 (with LOINC® answer list

ID LL2180-9), 68520-6 (with LOINC® answer list ID LL2181-7), and 75626-2 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(vii)

§ 170.207(p)(7) *Social connection and isolation*. Social connection and isolation must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® codes 76506-5, 63503-7 (with LOINC® answer list ID LL1068-7), 76508-1 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76509-9 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76510-7 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76511-5 (with LOINC® answer list ID LL963-0), and 76512-3 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(7) *Social connection and isolation*. Social connection and isolation must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with the LOINC® codes 76506-5, 63503-7 (with LOINC® answer list ID LL1068-7), 76508-1 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76509-9 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76510-7 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76511-5 (with LOINC® answer list ID LL963-0), and 76512-3 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(viii)

§ 170.207(p)(8) *Exposure to violence (intimate partner violence)*. Exposure to violence: intimate partner violence must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® code 76499-3, 76500-8 (with LOINC® answer list ID LL963-0), 76501-6 (with LOINC® answer list ID LL963-0), 76502-4 (with LOINC® answer list ID LL963-0), 76503-2 (with LOINC® answer list ID LL963-0), and 76504-0 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(8) *Exposure to violence (intimate partner violence)*. Exposure to violence: intimate partner violence must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with the LOINC® code 76499-3, 76500-8 (with LOINC® answer list ID LL963-0), 76501-6 (with LOINC® answer list ID LL963-

0), 76502-4 (with LOINC® answer list ID LL963-0), 76503-2 (with LOINC® answer list ID LL963-0), and 76504-0 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)). (This standard is required by December 31, 2025.)

Required Update Deadlines

The following outlines deadlines for required updates for this criterion as they relate to changes published in recent ONC final rules. Developers must update their products to the requirements outlined and provide them to their customers by the stated deadlines. These represent one-time deadlines as set by recent regulatory updates and do not encompass ongoing deadlines related to the Conditions and Maintenance of Certification. Please review those requirements for additional compliance activities related to one's certification under Certification Dependencies.

Deadline: December 31, 2025

Action to be taken: Developers certified to this criterion must update their use of minimum standard code sets outlined throughout the criterion to reflect updates to LOINC® and Unified Code of Units of Measure (UCUM) versions.

Certification Dependencies

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 needs 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(a)(15). As a result, an ONC Authorized Certification Body (ONC-ACB) must ensure that a product presented for certification to a § 170.315(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 presented 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 transfer 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))
  - Amendments (§ 170.315(d)(4))
  - Automatic access time-out (§ 170.315(d)(5))
  - Emergency access (§ 170.315(d)(6))
  - 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 for 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 the Health IT Module to access external services necessary to meet the requirements of the privacy and security certification criterion. Please see the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* 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 (a)(15) *Social, psychological, and behavioral data—*

Enable a user to record, change, and access the following patient social, psychological, and behavioral data:

1. *Financial resource strain.* Enable financial resource strain to be recorded in accordance with the standard specified in §170.207(p)(1) and whether a patient declines to specify financial resource strain.
2. *Education.* Enable education to be recorded in accordance with the standard specified in §170.207(p)(2) and whether a patient declines to specify education.
3. *Stress.* Enable stress to be recorded in accordance with the standard specified in §170.207(p)(3) and whether a patient declines to specify stress.
4. *Depression.* Enable depression to be recorded in accordance with the standard specified in §170.207(p)(4) and whether a patient declines to specify depression.
5. *Physical activity.* Enable physical activity to be recorded in accordance with the standard specified in §170.207(p)(5) and whether a patient declines to specify physical activity.
6. *Alcohol use.* Enable alcohol use to be recorded in accordance with the standard specified in §170.207(p)(6) and whether a patient declines to specify alcohol use.
7. *Social connection and isolation.* Enable social connection and isolation to be recorded in accordance the standard specified in §170.207(p)(7) and whether a patient declines to specify social connection and isolation.
8. *Exposure to violence (intimate partner violence).* Enable exposure to violence (intimate partner violence) to be recorded in accordance with the standard specified in §170.207(p)(8) and whether a patient declines to specify exposure to violence (intimate partner violence).

Standard(s) Referenced

Applies to entire criterion

§ 170.207(c)(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, Released June 2015, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc. (Adoption of this standard expires on January 1, 2026.)

170.207(c)(1) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.72, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc., February 16, 2022 (This standard is required by December 31, 2025.)

§ 170.207(m)(1) The Unified Code of Units of Measure, Revision 1.9 (Adoption of this standard expires on January 1, 2026.)

§ 170.207(m)(2) The Unified Code of Units of Measure, Revision 2.1, November 21, 2017 (This standard is required by December 31, 2025.)

Paragraph (a)(15)(i)

§ 170.207(p)(1) *Financial resource strain*. Financial resource strain must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® code 76513-1 and LOINC® answer list ID LL3266-5. (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(1) *Financial resource strain*. Financial resource strain must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with the LOINC® code 76513-1 and LOINC® answer list ID LL3266-5. (This standard is required by December 31, 2025.)

Paragraph (a)(15)(ii)

§ 170.207(p)(2) *Education*. Education must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® code 63504-5 and LOINC® answer list ID LL1069-5. (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(2) *Education*. Education must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with LOINC® code 63504-5 and LOINC® answer list ID LL1069-5. (This standard is required by December 31, 2025.)

Paragraph (a)(15)(iii)

§ 170.207(p)(3) *Stress*. Stress must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® code 76542-0 and LOINC® answer list LL3267-3. (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(3) *Stress*. Stress must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with the LOINC® code 76542-0 and LOINC® answer list LL3267-3. (This standard is required by December 31, 2025.)

Paragraph (a)(15)(iv)

§ 170.207(p)(4) *Depression*. Depression must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® codes 55757-9, 44250-9 (with LOINC® answer list ID LL358-3), 44255-8 (with LOINC® answer list ID LL358-3), and 55758-7 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(4) *Depression*. Depression must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with LOINC® codes 55757-9, 44250-9 (with LOINC® answer list ID LL358-3), 44255-8 (with LOINC® answer list ID LL358-3), and 55758-7 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(v)

§ 170.207(p)(5) *Physical activity*. Physical activity must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® codes 68515-6 and 68516-4. The answers must be coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(5) *Physical activity*. Physical activity must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with LOINC® codes 68515-6 and 68516-4. The answers must be coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(vi)

§ 170.207(p)(6) *Alcohol use*. Alcohol use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with LOINC® codes 72109-2, 68518-0 (with LOINC® answer list ID LL2179-1), 68519-8 (with LOINC® answer list ID LL2180-9), 68520-6 (with LOINC® answer list ID LL2181-7), and 75626-2 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(6) *Alcohol use*. Alcohol use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with LOINC® codes 72109-2, 68518-0 (with LOINC® answer list ID LL2179-1), 68519-8 (with LOINC® answer list ID LL2180-9), 68520-6 (with LOINC® answer list ID LL2181-7), and 75626-2 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(vii)

§ 170.207(p)(7) *Social connection and isolation*. Social connection and isolation must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® codes 76506-5, 63503-7 (with LOINC® answer list ID LL1068-7), 76508-1 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76509-9 (with the associated applicable unit of

measure in the standard specified in § 170.207(m)(1)), 76510-7 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76511-5 (with LOINC® answer list ID LL963-0), and 76512-3 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(7) *Social connection and isolation*. Social connection and isolation must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with the LOINC® codes 76506-5, 63503-7 (with LOINC® answer list ID LL1068-7), 76508-1 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76509-9 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76510-7 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)), 76511-5 (with LOINC® answer list ID LL963-0), and 76512-3 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)). (This standard is required by December 31, 2025.)

Paragraph (a)(15)(viii)

§ 170.207(p)(8) *Exposure to violence (intimate partner violence)*. Exposure to violence: intimate partner violence must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(3) and attributed with the LOINC® code 76499-3, 76500-8 (with LOINC® answer list ID LL963-0), 76501-6 (with LOINC® answer list ID LL963-0), 76502-4 (with LOINC® answer list ID LL963-0), 76503-2 (with LOINC® answer list ID LL963-0), and 76504-0 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)). (Adoption of this standard expires on January 1, 2026.)

§ 170.207(p)(8) *Exposure to violence (intimate partner violence)*. Exposure to violence: intimate partner violence must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) and attributed with the LOINC® code 76499-3, 76500-8 (with LOINC® answer list ID LL963-0), 76501-6 (with LOINC® answer list ID LL963-0), 76502-4 (with LOINC® answer list ID LL963-0), 76503-2 (with LOINC® answer list ID LL963-0), and 76504-0 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(2)). (This standard is required by December 31, 2025.)

Required Update Deadlines
The following outlines deadlines for required updates for this criterion as they relate to changes published in recent ONC final rules. Developers must update their products to the requirements outlined and provide them to their customers by the stated deadlines. These represent one-time deadlines as set by recent regulatory updates and do not encompass ongoing deadlines related to the Conditions and Maintenance of Certification. Please review those requirements for additional compliance activities related to one's certification under Certification Dependencies.

Deadline: December 31, 2025

Action to be taken: Developers certified to this criterion must update their use of minimum standard code sets outlined throughout the criterion to reflect updates to LOINC® and Unified Code of Units of Measure (UCUM) versions.

Certification Dependencies

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 needs 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(a)(15). As a result, an ONC Authorized Certification Body (ONC-ACB) must ensure that a product presented for certification to a § 170.315(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 presented 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 transfer 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 for 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 the Health IT Module to access external services necessary to meet the requirements of the privacy and security certification criterion. Please see the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* Final Rule at 85 FR 25710 for additional clarification.

Revision History

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

Certification Companion Guide: Social, psychological, and behavioral data

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	No	No	No	Yes

Certification Requirements

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- In order to certify to this criterion, a Health IT Module must be certified to all eight domains in paragraphs (a)(15)(i)-(viii). These eight domains together provide a comprehensive picture of the patient that can facilitate care management and coordination. [see also 80 FR 62631]
- We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
  LOINC® OID: 2.16.840.1.113883.6.1 [see also 80 FR 62612]
- Health IT Modules can present for certification to a more recent version of LOINC® than outlined in regulation per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]
- In addition to the privacy and security requirements for this criterion, ONC recommends that institutions develop and maintain policies for the collection and dissemination of the social, psychological, and behavioral data consistent with applicable federal and state laws. [see also 80 FR 62631, 89 FR 1224]
- This criterion does not require that users capture social, psychological, and behavioral data beyond the specified types of data listed in the criterion and only in accordance with the specified standards.
- Certified Health IT Modules must allow all actions to be performed at the questionnaire level. Actions include enabling a user to record, change, and access the patient social, psychological, and behavioral data outlined in this certification criterion.
- A Certified Health IT Module is required to enable a user to record whether the patient declined to specify (i.e., respond/provide) the requested information at the third paragraph level. Paragraphs (a)(15)(i) through (viii) are at the third paragraph level. Therefore, as an example, a Health IT Module is required to enable a user to record whether a patient declined to provide information regarding depression (§ 170.315(a)(15)(iv)) for the purposes of testing and certification. Specification of patient actions in terms of compliance with the standard (i.e., whether the patient declined to respond to a question in a questionnaire) is beyond the scope of testing and certification but may also jeopardize the validity of the questionnaire.
- The criterion requires Certified Health IT Modules to be capable of capturing specific LOINC® codes associated with the identified domain questions and answers. Specific questionnaires, tools, or other documents were not adopted as part of this criterion. Accordingly, they are not within the scope of certification.

- ONC acknowledges that the LOINC® codes adopted for the physical activity domain questions are attributed to the Substance Abuse and Mental Health Services Administration (SAMHSA). Several health IT developers wishing to develop the capabilities outlined in this criterion have commented that these questions differ slightly from the questions that comprise the Kaiser Permanente-developed Exercise Vital Sign (EVS) instrument. ONC acknowledges these differences exist. ONC also acknowledges that the EVS has been recommended as a screening tool by the American College of Sports Medicine's Exercise is Medicine initiative and received the highest available rating by the Institute of Medicine (IOM) as an available standard and for its usefulness and feasibility (see also "Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2" report: Records Phase 2 Report, page 212). Further, in the 2015 Edition proposed rule, ONC expressed a desire to align with the IOM "Phase 2" report (80 FR 16826). LOINC® codes are currently in development by the standards developing organization (Regenstrief Institute) for the EVS questions. When they become available, ONC will provide certification to those LOINC® codes in lieu of the current question LOINC® codes for the physical activity domain. In the interim, health IT developers may choose to proceed with the testing and certification of their Health IT Modules that supports the EVS instrument by demonstrating that the health IT can capture the appropriate EVS questions and associate them with the adopted answer LOINC® codes for the physical activity domain. Health IT developers will be responsible for updating their health IT within six months of the publishing of the LOINC® codes for the EVS questions. After expiration of this time period and during surveillance, a health IT product would be found non-conforming if it could not produce the proper LOINC® codes for the EVS questions. Health IT Modules already certified to this criterion will not be required to retest or recertify to the new LOINC® codes aligned with EVS. Health IT developers may also continue to choose to test and certify to the adopted LOINC® codes for "SAMHSA" questions in lieu of the EVS questions.

Clarifications:

- In order to certify to this criterion, a Health IT Module must be certified to all eight domains in paragraphs (a)(15)(i)-(viii). These eight domains together provide a comprehensive picture of the patient that can facilitate care management and coordination. [see also 80 FR 62631]
- We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
  LOINC® OID: 2.16.840.1.113883.6.1 [see also 80 FR 62612]
- Health IT Modules can present for certification to a more recent version of LOINC® than outlined in regulation per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]
- In addition to the privacy and security requirements for this criterion, ONC recommends that institutions develop and maintain policies for the collection and dissemination of the social, psychological, and behavioral data consistent with applicable federal and state laws. [see also 80 FR 62631, 89 FR 1224]

- This criterion does not require that users capture social, psychological, and behavioral data beyond the specified types of data listed in the criterion and only in accordance with the specified standards.
- Certified Health IT Modules must allow all actions to be performed at the questionnaire level. Actions include enabling a user to record, change, and access the patient social, psychological, and behavioral data outlined in this certification criterion.
- A Certified Health IT Module is required to enable a user to record whether the patient declined to specify (i.e., respond/provide) the requested information at the third paragraph level. Paragraphs (a)(15)(i) through (viii) are at the third paragraph level. Therefore, as an example, a Health IT Module is required to enable a user to record whether a patient declined to provide information regarding depression (§ 170.315(a)(15)(iv)) for the purposes of testing and certification. Specification of patient actions in terms of compliance with the standard (i.e., whether the patient declined to respond to a question in a questionnaire) is beyond the scope of testing and certification but may also jeopardize the validity of the questionnaire.
- The criterion requires Certified Health IT Modules to be capable of capturing specific LOINC® codes associated with the identified domain questions and answers. Specific questionnaires, tools, or other documents were not adopted as part of this criterion. Accordingly, they are not within the scope of certification.
- ONC acknowledges that the LOINC® codes adopted for the physical activity domain questions are attributed to the Substance Abuse and Mental Health Services Administration (SAMHSA). Several health IT developers wishing to develop the capabilities outlined in this criterion have commented that these questions differ slightly from the questions that comprise the Kaiser Permanente-developed Exercise Vital Sign (EVS) instrument. ONC acknowledges these differences exist. ONC also acknowledges that the EVS has been recommended as a screening tool by the American College of Sports Medicine's Exercise is Medicine initiative and received the highest available rating by the Institute of Medicine (IOM) as an available standard and for its usefulness and feasibility (see also "Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2" report: Records Phase 2 Report, page 212). Further, in the 2015 Edition proposed rule, ONC expressed a desire to align with the IOM "Phase 2" report (80 FR 16826). LOINC® codes are currently in development by the standards developing organization (Regenstrief Institute) for the EVS questions. When they become available, ONC will provide certification to those LOINC® codes in lieu of the current question LOINC® codes for the physical activity domain. In the interim, health IT developers may choose to proceed with the testing and certification of their Health IT Modules that supports the EVS instrument by demonstrating that the health IT can capture the appropriate EVS questions and associate them with the adopted answer LOINC® codes for the physical activity domain. Health IT developers will be responsible for updating their health IT within six months of the publishing of the LOINC® codes for the EVS questions. After expiration of this time period and during surveillance, a health IT product would be found non-conforming if it could not produce the proper LOINC® codes for the EVS questions. Health IT Modules already certified to this criterion will not be required to retest or recertify to the new LOINC® codes aligned with EVS. Health IT developers may also continue to choose to test and certify to the adopted LOINC® codes for "SAMHSA" questions in lieu of the EVS questions.

Paragraph (a)(15)(i) Financial resource strain

Technical outcome – A user can record, change, and access financial resource strain using the specified LOINC® codes and whether the patient declines to specify financial resource strain.

> No additional clarifications.

Technical outcome – A user can record, change, and access financial resource strain using the specified LOINC® codes and whether the patient declines to specify financial resource strain.

> No additional clarifications.

Paragraph (a)(15)(ii) Education

Technical outcome – A user can record, change, and access education using the specified LOINC® codes and whether the patient declines to specify education.

> No additional clarifications.

Technical outcome – A user can record, change, and access education using the specified LOINC® codes and whether the patient declines to specify education.

> No additional clarifications.

Paragraph (a)(15)(iii) Stress

Technical outcome – A user can record, change, and access stress using the specified LOINC® codes and whether the patient declines to specify stress.

> No additional clarifications.

Technical outcome – A user can record, change, and access stress using the specified LOINC® codes and whether the patient declines to specify stress.

No additional clarifications.

Paragraph (a)(15)(iv) Depression

Technical outcome – A user can record, change, and access depression using the specified LOINC® codes and whether the patient declines to specify depression.

No additional clarifications.

Technical outcome – A user can record, change, and access depression using the specified LOINC® codes and whether the patient declines to specify depression.

No additional clarifications.

Paragraph (a)(15)(v) Physical activity

Technical outcome – A user can record, change, and access physical activity using the specified LOINC® codes and whether the patient declines to specify physical activity.

No additional clarifications.

Technical outcome – A user can record, change, and access physical activity using the specified LOINC® codes and whether the patient declines to specify physical activity.

No additional clarifications.

Paragraph (a)(15)(vi) Alcohol use

Technical outcome – A user can record, change, and access alcohol use using the specified LOINC® codes and whether the patient declines to specify alcohol use.

No additional clarifications.

Technical outcome – A user can record, change, and access alcohol use using the specified LOINC® codes and whether the patient declines to specify alcohol use.

No additional clarifications.

Paragraph (a)(15)(vii) Social connection and isolation

Technical outcome – A user can record, change, and access social connection and isolation using the specified LOINC® codes and whether the patient declines to specify social connection and isolation.

No additional clarifications.

Technical outcome – A user can record, change, and access social connection and isolation using the specified LOINC® codes and whether the patient declines to specify social connection and isolation.

No additional clarifications.

Paragraph (a)(15)(viii) Exposure to violence (intimate partner violence)

Technical outcome – A user can record, change, and access exposure to violence (intimate partner violence) using the specified LOINC® codes and whether the patient declines to specify exposure to violence (intimate partner violence).

No additional clarifications.

Technical outcome – A user can record, change, and access exposure to violence (intimate partner violence) using the specified LOINC® codes and whether the patient declines to specify exposure to violence (intimate partner violence).

No additional clarifications.