Patient demographics and observations | HealthIT.gov

Updated on 03-11-2024

Regulation Text

Regulation Text

§ 170.315 (a)(5) *Patient demographics and observations—*

1. Enable a user to record, change, and access patient demographic and observations data including race, ethnicity, preferred language, sex, sex parameter for clinical use, sexual orientation, gender identity, name to use, pronouns and date of birth.
     1. *Race and ethnicity.*
          1. Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(3) and whether a patient declines to specify race.
          2. Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(3) and whether a patient declines to specify ethnicity.
          3. Aggregate each one of the patient's races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(*1*) and (*2*) of this section to the categories in the standard specified in § 170.207(f)(1).
     2. *Preferred language.* Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.
     3. *Sex.* Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1) for the period up to and including December 31, 2025; or § 170.207(n)(2).
     4. *Sexual orientation.* Enable sexual orientation to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(1) for the period up to and including December 31, 2025; or § 170.207(o)(3), as well as whether a patient declines to specify sexual orientation.
     5. *Gender identity.* Enable gender identity to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(2) for the period up to and including December 31, 2025; or § 170.207(o)(3), as well as whether a patient declines to specify gender identity.
     6. *Sex Parameter for Clinical Use.* Enable at least one sex parameter for clinical use to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(n)(3). Conformance with this paragraph is required by January 1, 2026.
     7. *Name to Use.* Enable at least one preferred name to use to be recorded. Conformance with this paragraph is required by January 1, 2026.
     8. *Pronouns.* Enable at least one pronoun to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(4). Conformance with this paragraph is required by January 1, 2026.
2. *Inpatient setting only.* Enable a user to record, change, and access the preliminary cause of death and date of death in the event of mortality.

Standard(s) Referenced

Paragraph (a)(5)(i)(A)

§ 170.207(f)(1) <u>The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997</u>

§ 170.207(f)(2) <u>CDC Race and Ethnicity Code Set Version 1.0 (March 2000)</u> (Adoption of this standard expires on January 1, 2026)

§ 170.207(f)(3) <u>CDC Race and Ethnicity Code Set Version 1.2 (July 8, 2021)</u> (This standard is required by December 31, 2025)

Paragraph (a)(5)(i)(B)

§ 170.207(g)(2) <u>Request for Comment (RFC) 5646, "Tags for Identifying Languages", September 2009</u>

Paragraph (a)(5)(i)(C)

Consistent with EO 14168, "Unknown. UNK" is no longer required and only support for SNOMED CT codes 248152002 |Female (finding)| and 248153007 |Male (finding)| must be supported.

§ 170.207(n)(1) Birth sex must be coded in accordance with <u>HL7® Version 3 Standard</u>, Value Sets for <u>AdministrativeGender</u> and <u>NullFlavor</u> attributed as follows:

1. Male. M
2. Female. F
3. Unknown. UNK

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

§ 170.207(n)(2) Sex must be coded in accordance with, at a minimum, the version of SNOMED CT® U.S. Edition codes specified in § 170.207(a)(1) (This standard is required by December 31, 2025.)

Paragraphs (a)(5)(i)(D) and (E)

Consistent with EO 14168, conformance with this paragraph is no longer required.

§ 170.207(o)(1) Sexual orientation must be coded in accordance with, at a minimum, the version of <u>SNOMED CT® codes adopted at paragraph (a)(4) of this section</u> for paragraphs (o)(1)(i) through (iii) of this section and <u>HL7® Version 3</u> for paragraphs (o)(1)(iv) through (vi) of this section, attributed as follows:

1. Lesbian, gay or homosexual. 38628009
2. Straight or heterosexual. 20430005

3. Bisexual. 42035005
4. Something else, please describe. nullFlavor OTH
5. Don't know. nullFlavor UNK
6. Choose not to disclose. nullFlavor ASKU

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

§ 170.207(o)(2) Gender identity must be coded in accordance with, at a minimum, the version of <u>SNOMED CT® codes adopted at paragraph (a)(4) of this section</u> for paragraphs (o)(2)(i) through (v) of this section and <u>HL7® Version 3</u> for paragraphs (o)(2)(vi) and (vii) of this section, attributed as follows:

1. Identifies as Male. 446151000124109
2. Identifies as Female. 446141000124107
3. Female-to-Male (FTM)/Transgender Male/Trans Man. 407377005
4. Male-to-Female (MTF)/Transgender Female/Trans Woman. 407376001
5. Genderqueer, neither exclusively male nor female. 446131000124102
6. Additional gender category or other, please specify. nullFlavor OTH
7. Choose not to disclose. nullFlavor ASKU

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

§ 170.207(o)(3) Sexual Orientation and Gender Identity must be coded in accordance with, at a minimum, the version of SNOMED CT® codes specified in § 170.207(a)(1) (This standard is required by December 31, 2025.)

Paragraph (a)(5)(i)(F)

Consistent with EO 14168, conformance with this paragraph is no longer required.

§ 170.207(n)(3)Sex Parameter for Clinical Use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) (This standard is required by December 31, 2025.)

Paragraph (a)(5)(i)(H)

Consistent with EO 14168, conformance with this paragraph is no longer required.

§ 170.207(o)(4) Pronouns must be coded in accordance with, at a minimum, the version of LOINC® codes specified in 170.207(c)(1). (Adoption of 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 certification under Certification Dependencies.

Deadline: December 31, 2025

Action to be taken: Developers certified to this criterion must update their use of minimum standards code sets for recording race and ethnicity, and sex, as detailed in paragraphs (a)(5)(i)(A) and (C).

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.

- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
- 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(a)(5). 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 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 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)(5) *Patient demographics and observations—*

1. Enable a user to record, change, and access patient demographic and observations data including race, ethnicity, preferred language, sex, sex parameter for clinical use, sexual orientation, gender identity, name to use, pronouns and date of birth.
    1. *Race and ethnicity.*
        1. Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(3) and whether a patient declines to specify race.
        2. Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(3) and whether a patient declines to specify ethnicity.
        3. Aggregate each one of the patient's races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(*1*) and (*2*) of this section to the categories in the standard specified in § 170.207(f)(1).
    2. *Preferred language.* Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.
    3. *Sex.* Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1) for the period up to and including December 31, 2025; or § 170.207(n)(2).
    4. *Sexual orientation.* Enable sexual orientation to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(1) for the period up to and including December 31, 2025; or § 170.207(o)(3), as well as whether a patient declines to specify sexual orientation.
    5. *Gender identity.* Enable gender identity to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(2) for the period up to and including December 31, 2025; or § 170.207(o)(3), as well as whether a patient declines to specify gender identity.
    6. *Sex Parameter for Clinical Use.* Enable at least one sex parameter for clinical use to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(n)(3). Conformance with this paragraph is required by January 1, 2026.
    7. *Name to Use.* Enable at least one preferred name to use to be recorded. Conformance with this paragraph is required by January 1, 2026.
    8. *Pronouns.* Enable at least one pronoun to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(4). Conformance with this paragraph is required by January 1, 2026.
2. *Inpatient setting only.* Enable a user to record, change, and access the preliminary cause of death and date of death in the event of mortality.

Standard(s) Referenced

Paragraph (a)(5)(i)(A)

§ 170.207(f)(1) <u>The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997</u>

§ 170.207(f)(2) <u>CDC Race and Ethnicity Code Set Version 1.0 (March 2000)</u> (Adoption of this standard expires on January 1, 2026)

§ 170.207(f)(3) <u>CDC Race and Ethnicity Code Set Version 1.2 (July 8, 2021)</u> (This standard is required by December 31, 2025)

Paragraph (a)(5)(i)(B)

§ 170.207(g)(2) <u>Request for Comment (RFC) 5646, "Tags for Identifying Languages", September 2009</u>

Paragraph (a)(5)(i)(C)

Consistent with EO 14168, "Unknown. UNK" is no longer required and only support for SNOMED CT codes 248152002 |Female (finding)| and 248153007 |Male (finding)| must be supported.

§ 170.207(n)(1) Birth sex must be coded in accordance with <u>HL7® Version 3 Standard</u>, Value Sets for <u>AdministrativeGender</u> and <u>NullFlavor</u> attributed as follows:

1. Male. M
2. Female. F
3. Unknown. UNK

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

§ 170.207(n)(2) Sex must be coded in accordance with, at a minimum, the version of SNOMED CT® U.S. Edition codes specified in § 170.207(a)(1) (This standard is required by December 31, 2025.)

Paragraphs (a)(5)(i)(D) and (E)

Consistent with EO 14168, conformance with this paragraph is no longer required.

§ 170.207(o)(1) Sexual orientation must be coded in accordance with, at a minimum, the version of <u>SNOMED CT® codes adopted at paragraph (a)(4) of this section</u> for paragraphs (o)(1)(i) through (iii) of this section and <u>HL7® Version 3</u> for paragraphs (o)(1)(iv) through (vi) of this section, attributed as follows:

1. Lesbian, gay or homosexual. 38628009
2. Straight or heterosexual. 20430005

3. Bisexual. 42035005
4. Something else, please describe. nullFlavor OTH
5. Don't know. nullFlavor UNK
6. Choose not to disclose. nullFlavor ASKU

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

§ 170.207(o)(2) Gender identity must be coded in accordance with, at a minimum, the version of <u>SNOMED CT® codes adopted at paragraph (a)(4) of this section</u> for paragraphs (o)(2)(i) through (v) of this section and <u>HL7® Version 3</u> for paragraphs (o)(2)(vi) and (vii) of this section, attributed as follows:

1. Identifies as Male. 446151000124109
2. Identifies as Female. 446141000124107
3. Female-to-Male (FTM)/Transgender Male/Trans Man. 407377005
4. Male-to-Female (MTF)/Transgender Female/Trans Woman. 407376001
5. Genderqueer, neither exclusively male nor female. 446131000124102
6. Additional gender category or other, please specify. nullFlavor OTH
7. Choose not to disclose. nullFlavor ASKU

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

§ 170.207(o)(3) Sexual Orientation and Gender Identity must be coded in accordance with, at a minimum, the version of SNOMED CT® codes specified in § 170.207(a)(1) (This standard is required by December 31, 2025.)

Paragraph (a)(5)(i)(F)

Consistent with EO 14168, conformance with this paragraph is no longer required.

§ 170.207(n)(3)Sex Parameter for Clinical Use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) (This standard is required by December 31, 2025.)

Paragraph (a)(5)(i)(H)

Consistent with EO 14168, conformance with this paragraph is no longer required.

§ 170.207(o)(4) Pronouns must be coded in accordance with, at a minimum, the version of LOINC® codes specified in 170.207(c)(1). (Adoption of this standard is required by December 31, 2025.)

<u>Required Update Deadlines</u>

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 certification under Certification Dependencies.

Deadline: December 31, 2025

Action to be taken: Developers certified to this criterion must update their use of minimum standards code sets for recording race and ethnicity, and sex, as detailed in paragraphs (a)(5)(i)(A) and (C).

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.

- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
- 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(a)(5). 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 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))
  - 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)(5) *Patient demographics and observations* requirements.	The ONC-ACB verifies the health IT developer attests conformance to the § 170.315(a)(5) *Patient demographics and observations* requirements.

Archived Version:

§170.315(a)(5) Test Procedure
Updated on 03-27-2025

Regulation Text

Regulation Text

§ 170.315 (a)(5) *Patient demographics and observations—*

1. Enable a user to record, change, and access patient demographic and observations data including race, ethnicity, preferred language, sex, sex parameter for clinical use, sexual orientation, gender identity, name to use, pronouns and date of birth.
    1. *Race and ethnicity.*
        1. Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(3) and whether a patient declines to specify race.
        2. Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(3) and whether a patient declines to specify ethnicity.
        3. Aggregate each one of the patient's races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(*1*) and (*2*) of this section to the categories in the standard specified in § 170.207(f)(1).
    2. *Preferred language.* Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.
    3. *Sex.* Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1) for the period up to and including December 31, 2025; or § 170.207(n)(2).
    4. *Sexual orientation.* Enable sexual orientation to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(1) for the period up to and including December 31, 2025; or § 170.207(o)(3), as well as whether a patient declines to specify sexual orientation.
    5. *Gender identity.* Enable gender identity to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(2) for the period up to and including December 31, 2025; or § 170.207(o)(3), as well as whether a patient declines to specify gender identity.
    6. *Sex Parameter for Clinical Use.* Enable at least one sex parameter for clinical use to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(n)(3). Conformance with this paragraph is required by January 1, 2026.
    7. *Name to Use.* Enable at least one preferred name to use to be recorded. Conformance with this paragraph is required by January 1, 2026.
    8. *Pronouns.* Enable at least one pronoun to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(4). Conformance with this paragraph is required by January 1, 2026.
2. *Inpatient setting only.* Enable a user to record, change, and access the preliminary cause of death and date of death in the event of mortality.

Standard(s) Referenced

Paragraph (a)(5)(i)(A)

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§ 170.207(f)(2) CDC Race and Ethnicity Code Set Version 1.0 (March 2000) (Adoption of this standard expires on January 1, 2026)

§ 170.207(f)(3) CDC Race and Ethnicity Code Set Version 1.2 (July 8, 2021) (This standard is required by December 31, 2025)

Paragraph (a)(5)(i)(B)

§ 170.207(g)(2) Request for Comment (RFC) 5646, "Tags for Identifying Languages", September 2009

Paragraph (a)(5)(i)(C)

Consistent with EO 14168, "Unknown. UNK" is no longer required and only support for SNOMED CT codes 248152002 |Female (finding)| and 248153007 |Male (finding)| must be supported.

§ 170.207(n)(1) Birth sex must be coded in accordance with HL7® Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor attributed as follows:

1. Male. M
2. Female. F
3. Unknown. UNK

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

§ 170.207(n)(2) Sex must be coded in accordance with, at a minimum, the version of SNOMED CT® U.S. Edition codes specified in § 170.207(a)(1) (This standard is required by December 31, 2025.)

Paragraphs (a)(5)(i)(D) and (E)

Consistent with EO 14168, conformance with this paragraph is no longer required.

§ 170.207(o)(1) Sexual orientation must be coded in accordance with, at a minimum, the version of SNOMED CT® codes adopted at paragraph (a)(4) of this section for paragraphs (o)(1)(i) through (iii) of this section and HL7® Version 3 for paragraphs (o)(1)(iv) through (vi) of this section, attributed as follows:

1. Lesbian, gay or homosexual. 38628009
2. Straight or heterosexual. 20430005

3. Bisexual. 42035005
4. Something else, please describe. nullFlavor OTH
5. Don't know. nullFlavor UNK
6. Choose not to disclose. nullFlavor ASKU

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

§ 170.207(o)(2) Gender identity must be coded in accordance with, at a minimum, the version of SNOMED CT® codes adopted at paragraph (a)(4) of this section for paragraphs (o)(2)(i) through (v) of this section and HL7® Version 3 for paragraphs (o)(2)(vi) and (vii) of this section, attributed as follows:

1. Identifies as Male. 446151000124109
2. Identifies as Female. 446141000124107
3. Female-to-Male (FTM)/Transgender Male/Trans Man. 407377005
4. Male-to-Female (MTF)/Transgender Female/Trans Woman. 407376001
5. Genderqueer, neither exclusively male nor female. 446131000124102
6. Additional gender category or other, please specify. nullFlavor OTH
7. Choose not to disclose. nullFlavor ASKU

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

§ 170.207(o)(3) Sexual Orientation and Gender Identity must be coded in accordance with, at a minimum, the version of SNOMED CT® codes specified in § 170.207(a)(1) (This standard is required by December 31, 2025.)

Paragraph (a)(5)(i)(F)

Consistent with EO 14168, conformance with this paragraph is no longer required.

§ 170.207(n)(3)Sex Parameter for Clinical Use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) (This standard is required by December 31, 2025.)

Paragraph (a)(5)(i)(H)

Consistent with EO 14168, conformance with this paragraph is no longer required.

§ 170.207(o)(4) Pronouns must be coded in accordance with, at a minimum, the version of LOINC® codes specified in 170.207(c)(1). (Adoption of 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 certification under Certification Dependencies.

Deadline: December 31, 2025

Action to be taken: Developers certified to this criterion must update their use of minimum standards code sets for recording race and ethnicity, and sex, as detailed in paragraphs (a)(5)(i)(A) and (C).

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.

- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
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- 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.

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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:
  - 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)(5) *Patient demographics and observations—*

1. Enable a user to record, change, and access patient demographic and observations data including race, ethnicity, preferred language, sex, sex parameter for clinical use, sexual orientation, gender identity, name to use, pronouns and date of birth.
    1. *Race and ethnicity.*
        1. Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(3) and whether a patient declines to specify race.
        2. Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(3) and whether a patient declines to specify ethnicity.
        3. Aggregate each one of the patient's races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(*1*) and (*2*) of this section to the categories in the standard specified in § 170.207(f)(1).
    2. *Preferred language.* Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.
    3. *Sex.* Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1) for the period up to and including December 31, 2025; or § 170.207(n)(2).
    4. *Sexual orientation.* Enable sexual orientation to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(1) for the period up to and including December 31, 2025; or § 170.207(o)(3), as well as whether a patient declines to specify sexual orientation.
    5. *Gender identity.* Enable gender identity to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(2) for the period up to and including December 31, 2025; or § 170.207(o)(3), as well as whether a patient declines to specify gender identity.
    6. *Sex Parameter for Clinical Use.* Enable at least one sex parameter for clinical use to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(n)(3). Conformance with this paragraph is required by January 1, 2026.
    7. *Name to Use.* Enable at least one preferred name to use to be recorded. Conformance with this paragraph is required by January 1, 2026.
    8. *Pronouns.* Enable at least one pronoun to be recorded in accordance with, at a minimum, the version of the standard specified in § 170.207(o)(4). Conformance with this paragraph is required by January 1, 2026.
2. *Inpatient setting only.* Enable a user to record, change, and access the preliminary cause of death and date of death in the event of mortality.

Standard(s) Referenced

Paragraph (a)(5)(i)(A)

§ 170.207(f)(1) <u>The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997</u>

§ 170.207(f)(2) <u>CDC Race and Ethnicity Code Set Version 1.0 (March 2000)</u> (Adoption of this standard expires on January 1, 2026)

§ 170.207(f)(3) <u>CDC Race and Ethnicity Code Set Version 1.2 (July 8, 2021)</u> (This standard is required by December 31, 2025)

Paragraph (a)(5)(i)(B)

§ 170.207(g)(2) <u>Request for Comment (RFC) 5646, "Tags for Identifying Languages", September 2009</u>

Paragraph (a)(5)(i)(C)

Consistent with EO 14168, "Unknown. UNK" is no longer required and only support for SNOMED CT codes 248152002 |Female (finding)| and 248153007 |Male (finding)| must be supported.

§ 170.207(n)(1) Birth sex must be coded in accordance with <u>HL7$^®$ Version 3 Standard</u>, Value Sets for <u>AdministrativeGender</u> and <u>NullFlavor</u> attributed as follows:

1. Male. M
2. Female. F
3. Unknown. UNK

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

§ 170.207(n)(2) Sex must be coded in accordance with, at a minimum, the version of SNOMED CT$^®$ U.S. Edition codes specified in § 170.207(a)(1) (This standard is required by December 31, 2025.)

Paragraphs (a)(5)(i)(D) and (E)

Consistent with EO 14168, conformance with this paragraph is no longer required.

§ 170.207(o)(1) Sexual orientation must be coded in accordance with, at a minimum, the version of <u>SNOMED CT$^®$ codes adopted at paragraph (a)(4) of this section</u> for paragraphs (o)(1)(i) through (iii) of this section and <u>HL7® Version 3</u> for paragraphs (o)(1)(iv) through (vi) of this section, attributed as follows:

1. Lesbian, gay or homosexual. 38628009
2. Straight or heterosexual. 20430005

3. Bisexual. 42035005
4. Something else, please describe. nullFlavor OTH
5. Don't know. nullFlavor UNK
6. Choose not to disclose. nullFlavor ASKU

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

§ 170.207(o)(2) Gender identity must be coded in accordance with, at a minimum, the version of <u>SNOMED CT® codes adopted at paragraph (a)(4) of this section</u> for paragraphs (o)(2)(i) through (v) of this section and <u>HL7® Version 3</u> for paragraphs (o)(2)(vi) and (vii) of this section, attributed as follows:

1. Identifies as Male. 446151000124109
2. Identifies as Female. 446141000124107
3. Female-to-Male (FTM)/Transgender Male/Trans Man. 407377005
4. Male-to-Female (MTF)/Transgender Female/Trans Woman. 407376001
5. Genderqueer, neither exclusively male nor female. 446131000124102
6. Additional gender category or other, please specify. nullFlavor OTH
7. Choose not to disclose. nullFlavor ASKU

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

§ 170.207(o)(3) Sexual Orientation and Gender Identity must be coded in accordance with, at a minimum, the version of SNOMED CT® codes specified in § 170.207(a)(1) (This standard is required by December 31, 2025.)

Paragraph (a)(5)(i)(F)

Consistent with EO 14168, conformance with this paragraph is no longer required.

§ 170.207(n)(3)Sex Parameter for Clinical Use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in § 170.207(c)(1) (This standard is required by December 31, 2025.)

Paragraph (a)(5)(i)(H)

Consistent with EO 14168, conformance with this paragraph is no longer required.

§ 170.207(o)(4) Pronouns must be coded in accordance with, at a minimum, the version of LOINC® codes specified in 170.207(c)(1). (Adoption of this standard is required by December 31, 2025.)

<u>Required Update Deadlines</u>

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 certification under Certification Dependencies.

Deadline: December 31, 2025

Action to be taken: Developers certified to this criterion must update their use of minimum standards code sets for recording race and ethnicity, and sex, as detailed in paragraphs (a)(5)(i)(A) and (C).

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.

- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
- 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(a)(5). 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 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 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
1.1	- For the entire criterion, added clarification regarding updates to safety-enhanced design testing to comply with HTI-1 Final Rule requirements. - For Paragraph (a)(5)(i)(F), added clarification regarding requirements for coding Sex Parameter for Clinical Use. - For Paragraphs (a)(5)(i)(D) and (E), removed a clarification and revised a clarification regarding use of expiring standards.	08-12-2024

Version #	Description of Change	Version Date
1.2	• For entire criterion, added clarification regarding compliance with EO 14168 and OPM guidance. • For Paragraph (a)(5)(i)(A): Updated how clarifications refer to referenced standards and their content for consistency and accuracy. Updated clarification to mention the "Not Hispanic or Latino" category must be aggregated and recorded according to § 170.207(f)(1). Updated clarification for how to access CDCREC. Revised for further clarity the clarification regarding the "combined format" available in the standard adopted at § 170.207(f)(1).	03-27-2025

Certification Companion Guide: Patient demographics and observations

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
Included	No	No	No	Yes

Certification Requirements

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- The demographic data can come from other sources (e.g., a registration system or practice management system) so long as testing demonstrates the Health IT Module can perform all required functions included in the Patient demographics and observations certification criterion. [see also Health IT Certification Program Overview]
- Testing for preferred language using the standard at § 170.207(g)(2) Request for Comments (RFC) 5646 will focus on all the languages present in ISO 639-2.
- Consistent with the § 170.207(g)(2) RFC 5646, the shortest alpha code for the language should be used. Testing will only test the primary language tag and not test for extension components specified in § 170.207(g)(2) RFC 5646 such as extended language sub-tags, script tag, or region tag. [see also 80 FR 16817] Specifically:
  - use alpha 2 character code if one exists (ISO 639-1);
  - use alpha 3 character code if an alpha 2 character code does not exist (ISO 639-2); and
  - region extensions (ISO 3166-1) are permitted but not required (however, if a region extension is used, it will be verified for accuracy as part of testing and must be correct).
- ONC's adoption of the "Sex Parameter for Clinical Use", "Name to Use", and "Pronouns" data elements does not establish a requirement for health care providers or patients to record or disclose this information, or use these capabilities. ONC encourages developers of certified health IT to work with providers to develop appropriate workflows. [see also 89 FR 1296]
- Certified Health IT Developers must assess user-facing functionality gaps between Health IT Modules currently certified to the § 170.315(a)(5) criterion and the updated § 170.315(a)(5) criterion requirements as specified in the HTI-1 Final Rule. Certified Health IT Developers must assess if updates to the Health IT Module's user-facing functionalities to resolve these gaps necessitate user-centered design processes applied during development and thus must be included as part of summative testing in accordance with the § 170.315(g)(3) criterion. Accordingly and as necessary, Certified Health IT Developers must update their safety-enhanced design (SED) testing for updated § 170.315(a)(5) criterion requirements.
- Consistent with Executive Order (EO) 14168 and OPM guidance, Health IT Modules certifying and/or currently certified to the demographics certification criteria at 45 CFR 170.315(a)(5) are only required to demonstrate, for conformance with paragraph (a)(5)(i)(C) ("sex"), that it can record sex in accordance with either the standard specified in § 170.207(n)(1) for the period up to and including December 31, 2025, or the following SNOMED CT® codes found in the standard specified in § 170.207(n)(2):
  - 248152002 |Female (finding)|; and
  - 248153007 |Male (finding)|.

- Health IT Modules certified to § 170.315(a)(5), are not required to demonstrate conformance with paragraphs:
    - (a)(5)(i)(D) ("sexual orientation");
    - (a)(5)(i)(E) ("gender identity");
    - (a)(5)(i)(F) ("sex parameters for clinical use");
    - (a)(5)(i)(G) ("name to use"); and
    - (a)(5)(i)(H) ("pronouns").

Clarifications:

- The demographic data can come from other sources (e.g., a registration system or practice management system) so long as testing demonstrates the Health IT Module can perform all required functions included in the Patient demographics and observations certification criterion. [see also Health IT Certification Program Overview]
- Testing for preferred language using the standard at § 170.207(g)(2) Request for Comments (RFC) 5646 will focus on all the languages present in ISO 639-2.
- Consistent with the § 170.207(g)(2) RFC 5646, the shortest alpha code for the language should be used. Testing will only test the primary language tag and not test for extension components specified in § 170.207(g)(2) RFC 5646 such as extended language sub-tags, script tag, or region tag. [see also 80 FR 16817] Specifically:
  - use alpha 2 character code if one exists (ISO 639-1);
  - use alpha 3 character code if an alpha 2 character code does not exist (ISO 639-2); and
  - region extensions (ISO 3166-1) are permitted but not required (however, if a region extension is used, it will be verified for accuracy as part of testing and must be correct).
- ONC's adoption of the "Sex Parameter for Clinical Use", "Name to Use", and "Pronouns" data elements does not establish a requirement for health care providers or patients to record or disclose this information, or use these capabilities. ONC encourages developers of certified health IT to work with providers to develop appropriate workflows. [see also 89 FR 1296]
- Certified Health IT Developers must assess user-facing functionality gaps between Health IT Modules currently certified to the § 170.315(a)(5) criterion and the updated § 170.315(a)(5) criterion requirements as specified in the HTI-1 Final Rule. Certified Health IT Developers must assess if updates to the Health IT Module's user-facing functionalities to resolve these gaps necessitate user-centered design processes applied during development and thus must be included as part of summative testing in accordance with the § 170.315(g)(3) criterion. Accordingly and as necessary, Certified Health IT Developers must update their safety-enhanced design (SED) testing for updated § 170.315(a)(5) criterion requirements.
- Consistent with Executive Order (EO) 14168 and OPM guidance, Health IT Modules certifying and/or currently certified to the demographics certification criteria at 45 CFR 170.315(a)(5) are only required to demonstrate, for conformance with paragraph (a)(5)(i)(C) ("sex"), that it can record sex in accordance with either the standard specified in § 170.207(n)(1) for the period up to and including December 31, 2025, or the following SNOMED CT® codes found in the standard specified in § 170.207(n)(2):
  - 248152002 |Female (finding)|; and
  - 248153007 |Male (finding)|.
- Health IT Modules certified to § 170.315(a)(5), are not required to demonstrate conformance with paragraphs:
  - (a)(5)(i)(D) ("sexual orientation");
  - (a)(5)(i)(E) ("gender identity");
  - (a)(5)(i)(F) ("sex parameters for clinical use");
  - (a)(5)(i)(G) ("name to use"); and
  - (a)(5)(i)(H) ("pronouns").

Paragraph (a)(5)(i) Enable user to record, change, and access data

Clarifications:

There is no standard required for recording date of birth (i.e., any format may be used).

Clarifications:

There is no standard required for recording date of birth (i.e., any format may be used).

Paragraph (a)(5)(i)(A) Race and ethnicity

Technical outcome –

- A user can record each one of a patient's race(s) and each one of a patient's ethnicity(ies) according to concepts in the CDC Race and Ethnicity (CDCREC) code system Version 1.2.
- The software must be able to aggregate each one of a patient's race(s) and each one of a patient's ethnicity(ies) and record the race(s) and ethnicity(ies) according to the § 170.207(f)(1) The Office of Management and Budget (OMB) Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity. The categories to which race and ethnicity selections must be aggregated and recorded include:
  - American Indian or Alaska Native;
  - Asian;
  - Black or African American;
  - Native Hawaiian or Other Pacific Islander
  - White;
  - Hispanic or Latino; and
  - Not Hispanic or Latino
- The user must be able to record whether the patient declined to specify a race, an ethnicity, and both.

Clarifications:

- Note that while this provision focuses on the capture of race and ethnicity, industry standards require race and ethnicity be exchanged as separate fields (e.g., Consolidated Clinical Document Architecture (C-CDA) and Quality Reporting Document Architecture (QRDA)). ONC suggests developers bear this in mind when developing their health IT systems.

- The CDCREC code system includes over 900 concepts for race and ethnicity. [see also 80 FR 16816] A health IT developer is free to determine how the user interface is designed, including how many race and ethnicity values are displayed. No default minimum number of visible selections is expected or implied. During testing, however, any of the concepts for race and ethnicity may be tested. [see also 80 FR 62618]
- Health IT must be able to record multiple races or ethnicities reported by a patient and be able to be correctly roll them up to the OMB categories. While the criterion is not prescriptive in that it does not set a "maximum-minimum" number of multiple entries that must be supported, the criterion supports surveillance that could include detailed race data that would cover up to five OMB race categories and two ethnicity categories at once to show multi-race, multi-ethnicity selection, support across the 900+ value set, and ultimately accurate roll-up.
- The Health IT Module must be able to record multiple races and/or ethnicities for a patient. [see also 80 FR 62618]
- ONC provides the following object identifier (OID) to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
    CDCREC OID: 2.16.840.1.113883.6.238 [see also 80 FR 62612]
- Health IT Modules can present for certification to a more recent version of the CDCREC code system than what is presented in regulation. [see also 80 FR 62612]
- The concepts in the CDCREC code system are mapped to the race and ethnicity categories in the § 170.207(f)(1) The Office of Management and Budget (OMB) Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity. Testing will verify that the granular race and ethnicity values are correctly mapped to the OMB categories. The mapping of these codes uses the hierarchical relationships defined in CDCREC.
- The health IT must be able to represent race and ethnicity categories in the § 170.207(f)(1) The OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity standard using CDCREC. The use of more granular values is permitted, so long as they map to the OMB categories.
- The § 170.207(f)(1) The OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity standard provides two formats for the collection of race and ethnicity data. The first format collects data using two separate questions. The second format, the "combined format", collects data using a single question. Implementation using either format is acceptable for the purposes of certification.
- A product does not need to display all the race and ethnicity values to meet the certification criterion. The health IT developer has the discretion to create a default selection set or enable customization choices for providers. However, for the purposes of testing and surveillance, a developer should be prepared to show that the product can represent any of the races and ethnicities in the value set created by the standard.

Technical outcome –

- A user can record each one of a patient's race(s) and each one of a patient's ethnicity(ies) according to concepts in the CDC Race and Ethnicity (CDCREC) code system Version 1.2.
- The software must be able to aggregate each one of a patient's race(s) and each one of a patient's ethnicity(ies) and record the race(s) and ethnicity(ies) according to the § 170.207(f)(1) The Office of Management and Budget (OMB) Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity. The categories to which race and ethnicity selections must be aggregated and recorded include:
    - American Indian or Alaska Native;
    - Asian;
    - Black or African American;
    - Native Hawaiian or Other Pacific Islander
    - White;
    - Hispanic or Latino; and
    - Not Hispanic or Latino
- The user must be able to record whether the patient declined to specify a race, an ethnicity, and both.

Clarifications:

- Note that while this provision focuses on the capture of race and ethnicity, industry standards require race and ethnicity be exchanged as separate fields (e.g., Consolidated Clinical Document Architecture (C-CDA) and Quality Reporting Document Architecture (QRDA)). ONC suggests developers bear this in mind when developing their health IT systems.
- The CDCREC code system includes over 900 concepts for race and ethnicity. [see also 80 FR 16816] A health IT developer is free to determine how the user interface is designed, including how many race and ethnicity values are displayed. No default minimum number of visible selections is expected or implied. During testing, however, any of the concepts for race and ethnicity may be tested. [see also 80 FR 62618]
- Health IT must be able to record multiple races or ethnicities reported by a patient and be able to be correctly roll them up to the OMB categories. While the criterion is not prescriptive in that it does not set a "maximum-minimum" number of multiple entries that must be supported, the criterion supports surveillance that could include detailed race data that would cover up to five OMB race categories and two ethnicity categories at once to show multi-race, multi-ethnicity selection, support across the 900+ value set, and ultimately accurate roll-up.
- The Health IT Module must be able to record multiple races and/or ethnicities for a patient. [see also 80 FR 62618]
- ONC provides the following object identifier (OID) to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
    CDCREC OID: 2.16.840.1.113883.6.238 [see also 80 FR 62612]
- Health IT Modules can present for certification to a more recent version of the CDCREC code system than what is presented in regulation. [see also 80 FR 62612]

- The concepts in the CDCREC code system are mapped to the race and ethnicity categories in the § 170.207(f)(1) The Office of Management and Budget (OMB) Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity. Testing will verify that the granular race and ethnicity values are correctly mapped to the OMB categories. The mapping of these codes uses the hierarchical relationships defined in CDCREC.
- The health IT must be able to represent race and ethnicity categories in the § 170.207(f)(1) The OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity standard using CDCREC. The use of more granular values is permitted, so long as they map to the OMB categories.
- The § 170.207(f)(1) The OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity standard provides two formats for the collection of race and ethnicity data. The first format collects data using two separate questions. The second format, the "combined format", collects data using a single question. Implementation using either format is acceptable for the purposes of certification.
- A product does not need to display all the race and ethnicity values to meet the certification criterion. The health IT developer has the discretion to create a default selection set or enable customization choices for providers. However, for the purposes of testing and surveillance, a developer should be prepared to show that the product can represent any of the races and ethnicities in the value set created by the standard.

Paragraph (a)(5)(i)(B) Preferred language

Technical outcome – A user can record a patient's preferred language according to the § 170.207(g)(2) RFC 5646 standard. The user must be able to record whether the patient declined to specify preferred language.

Clarifications:

- § 170.207(g)(2) RFC 5646 is compatible with C-CDA Release 2.1 and ISO 639-1, 639-2, and 639-3 can be mapped to it. [see also 80 FR 62619]
- ONC provides the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
    Tags for Identifying Languages – § 170.207(g)(2) RFC 5646 code system OID: 2.16.840.1.113883.6.316 [see also 80 FR 62612]
- A product does not need to display all of the language codes to meet the certification criterion. The health IT developer has the discretion to create a default selection set or enable customization choices for providers. However, for the purposes of testing, a developer should be prepared to show that the product can record any of languages in the value set created by the standard.

Technical outcome – A user can record a patient's preferred language according to the § 170.207(g)(2) RFC 5646 standard. The user must be able to record whether the patient declined to specify preferred language.

Clarifications:

- § 170.207(g)(2) RFC 5646 is compatible with C-CDA Release 2.1 and ISO 639-1, 639-2, and 639-3 can be mapped to it. [see also <u>80 FR 62619</u>]
- ONC provides the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
    Tags for Identifying Languages – § 170.207(g)(2) RFC 5646 code system OID: 2.16.840.1.113883.6.316 [see also <u>80 FR 62612</u>]
- A product does not need to display all of the language codes to meet the certification criterion. The health IT developer has the discretion to create a default selection set or enable customization choices for providers. However, for the purposes of testing, a developer should be prepared to show that the product can record any of languages in the value set created by the standard.

Paragraph (a)(5)(i)(C) Sex

Technical outcome – A user can record a patient's sex according to HL7® Version 3 as male (M), and female (F), up to and including December 31, 2025, or the SNOMED CT® U.S. Edition codes specified at § 170.207(a)(1).

Clarifications:

No additional clarifications

Technical outcome – A user can record a patient's sex according to HL7® Version 3 as male (M), and female (F), up to and including December 31, 2025, or the SNOMED CT® U.S. Edition codes specified at § 170.207(a)(1).

Clarifications:

No additional clarifications

Paragraphs (a)(5)(i)(D) and (E) Sexual orientation and gender identity

Technical outcome – A user can record a patient's sexual orientation and gender identity according to HL7® Version 3 and SNOMED CT® codes specified in the "standard(s) referenced" column up to and including December 31, 2025 or according to the SNOMED CT® U.S. Edition codes specified at § 170.207(a)(1). The user must be able to record whether the patient declined to specify sexual orientation and/or gender identity.

Clarifications:

> Consistent with EO 14168, Health IT Modules certified to § 170.315(a)(5) are not required to demonstrate conformance with this paragraph.

Technical outcome – A user can record a patient's sexual orientation and gender identity according to HL7® Version 3 and SNOMED CT® codes specified in the "standard(s) referenced" column up to and including December 31, 2025 or according to the SNOMED CT® U.S. Edition codes specified at § 170.207(a)(1). The user must be able to record whether the patient declined to specify sexual orientation and/or gender identity.

Clarifications:

> Consistent with EO 14168, Health IT Modules certified to § 170.315(a)(5) are not required to demonstrate conformance with this paragraph.

Paragraph (a)(5)(i)(F) Sex parameter for clinical use

Technical outcome – A user can record a patient's sex parameter for clinical use according to the LOINC® codes specified in the "standard(s) referenced" column.

Clarifications:

> Consistent with EO 14168, Health IT Modules certified to § 170.315(a)(5) are not required to demonstrate conformance with this paragraph.

Technical outcome – A user can record a patient's sex parameter for clinical use according to the LOINC® codes specified in the "standard(s) referenced" column.

Clarifications:

> Consistent with EO 14168, Health IT Modules certified to § 170.315(a)(5) are not required to demonstrate conformance with this paragraph.

Paragraph (a)(5)(i)(G) Name to use

Technical outcome – A user can record at least one preferred name to use.

Clarifications:

> Consistent with EO 14168, Health IT Modules certified to § 170.315(a)(5) are not required to demonstrate conformance with this paragraph.

Technical outcome – A user can record at least one preferred name to use.

Clarifications:

> Consistent with EO 14168, Health IT Modules certified to § 170.315(a)(5) are not required to demonstrate conformance with this paragraph.

Paragraph (a)(5)(i)(H) Pronouns

Technical outcome – A user can record at least one pronoun according to the LOINC® codes specified in the "standard(s) referenced" column.

Clarifications:

> Consistent with EO 14168, Health IT Modules certified to § 170.315(a)(5) are not required to demonstrate conformance with this paragraph.

Technical outcome – A user can record at least one pronoun according to the LOINC® codes specified in the "standard(s) referenced" column.

Clarifications:

> Consistent with EO 14168, Health IT Modules certified to § 170.315(a)(5) are not required to demonstrate conformance with this paragraph.

Paragraph (a)(5)(ii) Inpatient setting only

Technical outcome – For inpatient settings only, a user must be able to record, change, and access a patient's preliminary cause of death and date of death.

Clarifications:

> No standard is required for recording preliminary cause of death and free text is permitted for certification. [see also <u>77 FR 54209</u> and <u>80 FR 62619</u>]

Technical outcome – For inpatient settings only, a user must be able to record, change, and access a patient's preliminary cause of death and date of death.

Clarifications:

> No standard is required for recording preliminary cause of death and free text is permitted for certification. [see also <u>77 FR 54209</u> and <u>80 FR 62619</u>]