

ONC 2014 Edition EHR CERTIFICATION CRITERIA / ONC 2014 Edition Standards

ONC 2014 Edition EHR CERTIFICATION CRITERIA 45 CFR 170.314	ONC 2014 Edition STANDARDS
<p style="text-align: right;">§170.314(a)(1)</p> <p><u>Computerized provider order entry.</u> Enable a user to electronically record, change, and access the following order types, at a minimum:</p> <ul style="list-style-type: none"> <li>(i) Medications;</li> <li>(ii) Laboratory; and</li> <li>(iii) Radiology/imaging.</li> </ul>	
<p style="text-align: right;">§170.314(a)(3)</p> <p><u>Demographics.</u></p> <ul style="list-style-type: none"> <li>(i) (Enable a user to electronically record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth.                             <ul style="list-style-type: none"> <li>(A) Enable race and ethnicity to be recorded in accordance with the standard specified in § 170.207(f) and whether a patient declines to specify race and/or ethnicity.</li> <li>(B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g) and whether a patient declines to specify a preferred language.</li> </ul> </li> <li>(ii) Inpatient setting only. Enable a user to electronically record, change, and access preliminary cause of death in the event of a mortality.</li> </ul>	<ul style="list-style-type: none"> <li>▪ § 170.207(f) – OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997.</li> <li>▪ § 170.207(g) – ISO 639-2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639-1.</li> </ul>
<p style="text-align: right;">§170.314(a)(4)</p> <p><u>Vital signs, body mass index, and growth charts.</u></p> <ul style="list-style-type: none"> <li>(i) <u>Vital signs.</u> Enable a user to electronically record, change, and access, at a minimum, a patient's height/length, weight, and blood pressure. Height/length, weight, and blood pressure must be recorded in numerical values only.</li> <li>(ii) <u>Calculate body mass index.</u> Automatically calculate and electronically display body mass index based on a patient's height and weight.</li> <li>(iii) <u>Optional – Plot and display growth charts.</u> Plot and electronically display, upon request, growth charts for patients.</li> </ul>	

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§170.314(a)(8) / §170.314(a)(2)

### Clinical decision support.

- (i) **Evidence-based decision support interventions.** Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data:
- (A) Problem list;
  - (B) Medication list;
  - (C) Medication allergy list;
  - (D) Demographics;
  - (E) Laboratory tests and values/results; and
  - (F) Vital signs.
- (ii) **Linked referential clinical decision support.**
- (A) EHR technology must be able to:
    - (1) Electronically identify for a user diagnostic and therapeutic reference information; or
    - (2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204 (b)(1) or (2).
  - (B) For paragraph (a)(8)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section.
- (iii) **Clinical decision support configuration.**
- (A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.
  - (B) EHR technology must enable interventions to be electronically triggered:
    - (1) Based on the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section.
    - (2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(iii) of this section.
    - (3) **Ambulatory setting only.** When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(5)(i)(A)(1) of this section.
- (iv) **Automatically and electronically interact.** Interventions triggered in accordance with paragraphs (a)(8)(i)-(iii) of this section must automatically and electronically occur when a user is interacting with EHR technology.
- (v) **Source attributes.** Enable a user to review the attributes as indicated for all clinical decision support resources:
- (A) For evidence-based decision support interventions under paragraph (a)(8)(i) of this section:
    - (1) Bibliographic citation of the intervention (clinical research/guideline);
    - (2) Developer of the intervention (translation from clinical research/guideline);
    - (3) Funding source of the intervention development technical implementation; and
    - (4) Release and, if applicable, revision date(s) of the intervention or reference source.
  - (B) For linked referential clinical decision support in paragraph (a)(8)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph(a)(2) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).
- Drug-drug, drug-allergy interaction checks.**
- (i) **Interventions.** Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.
- (ii) **Adjustments.**
- (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.
  - (B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

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- § 170.204(b) – HL7 V3 Standard: Context-Aware Retrieval Application (Infobutton).
- *Implementation specifications:* § 170.204(b)(1) – HL7 V3 IG: URL-Based Implementations of Context-Aware Information Retrieval (Infobutton) Domain; or § 170.204(b)(2) – HL7 V3 IG: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide.

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<p style="text-align: right;">§170.314(a)(11)</p> <p><u>Smoking status</u>. Enable a user to electronically record, change, and access the smoking status of a patient in accordance with the standard specified at § 170.207(h).</p>	<ul style="list-style-type: none"> <li>▪ § 170.207(h) – Coded to one of the following SNOMED CT® codes:               <ol style="list-style-type: none"> <li>(1) <u>Current every day smoker</u>. 449868002</li> <li>(2) <u>Current some day smoker</u>. 428041000124106</li> <li>(3) <u>Former smoker</u>. 8517006</li> <li>(4) <u>Never smoker</u>. 266919005</li> <li>(5) <u>Smoker, current status unknown</u>. 77176002</li> <li>(6) <u>Unknown if ever smoked</u>. 266927001</li> <li>(7) <u>Heavy tobacco smoker</u>. 428071000124103</li> <li>(8) <u>Light tobacco smoker</u>. 428061000124105</li> </ol> </li> </ul>
<p style="text-align: right;">§170.314(a)(14)</p> <p><u>Patient list creation</u>. Enable a user to electronically and dynamically select, sort, access, and create patient lists by: date and time; and based on each one and at least one combination of the following data:</p> <ul style="list-style-type: none"> <li>(i) Problems;</li> <li>(ii) Medications;</li> <li>(iii) Medication allergies;</li> <li>(iv) Demographics;</li> <li>(v) Laboratory tests and values/results; and</li> <li>(vi) <u>Ambulatory setting only</u>. Patient communication preferences.</li> </ul>	
<p style="text-align: right;">§170.314(a)(15)</p> <p><u>Patient-specific education resources</u>. EHR technology must be able to electronically identify for a user patient-specific education resources based on data included in the patient's problem list, medication list, and laboratory tests and values/results:</p> <ul style="list-style-type: none"> <li>(i) In accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204(b)(1) or (2); and</li> <li>(ii) By any means other than the method specified in paragraph (a)(15)(i).</li> </ul>	<ul style="list-style-type: none"> <li>▪ § 170.204(b) – HL7 V3 Standard: Context-Aware Retrieval Application (Infobutton).</li> <li>▪ <i>Implementation specifications: § 170.204(b)(1) – HL7 V3 Implementation Guide: URL-Based Implementations of Context-Aware Information Retrieval (Infobutton) Domain; or § 170.204(b)(2) – HL7 V3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide.</i></li> </ul>
<p style="text-align: right;">§170.314(a)(16)</p> <p><u>Inpatient setting only – electronic medication administration record</u>.</p> <ul style="list-style-type: none"> <li>(i) In combination with an assistive technology that provides automated information on the “rights” specified in paragraphs (a)(16)(i)(A) through (E) of this section, enable a user to electronically verify the following before administering medication(s):           <ul style="list-style-type: none"> <li>(A) <u>Right patient</u>. The patient to whom the medication is to be administered matches the medication to be administered.</li> <li>(B) <u>Right medication</u>. The medication to be administered matches the medication ordered for the patient.</li> <li>(C) <u>Right dose</u>. The dose of the medication to be administered matches the dose of the medication ordered for the patient.</li> <li>(D) <u>Right route</u>. The route of medication delivery matches the route specified in the medication order.</li> <li>(E) <u>Right time</u>. The time that the medication was ordered to be administered compared to the current time.</li> </ul> </li> <li>(ii) <u>Right documentation</u>. Electronically record the time and date in accordance with the standard specified in § 170.210(g), and user identification when a medication is administered.</li> </ul>	<ul style="list-style-type: none"> <li>▪ 170.210(g). The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, or (RFC 5905) Network Time Protocol Version 4.</li> </ul>

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Transitions of care: (b)(1) – receive, display, and incorporate transition of care/referral summaries. §170.314(b)(1) & (b)(2)

- (i) **Receive.** EHR technology must be able to electronically receive transition of care/referral summaries in accordance with:
  - (A) The standard specified in § 170.202(a).
  - (B) **Optional.** The standards specified in § 170.202(a) and (b).
  - (C) **Optional.** The standards specified in § 170.202(b) and (c).
- (ii) **Display.** EHR technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following standards (and applicable implementation specifications) specified in: § 170.205(a)(1), § 170.205(a)(2), and § 170.205(a)(3).
- (iii) **Incorporate.** Upon receipt of a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3), EHR technology must be able to:
  - (A) **Correct patient.** Demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.
  - (B) **Data incorporation.** Electronically incorporate the following data expressed according to the specified standard(s):
    - (1) **Medications.** At a minimum, the version of the standard specified in §170.207(d)(2);
    - (2) **Problems.** At a minimum, the version of the standard specified in §170.207(a)(3);
    - (3) **Medication allergies.** At a minimum, the version of the standard specified in §170.207(d)(2).
  - (C) **Section views.** Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the standard adopted at § 170.205(a)(3).

Transitions of care: (b)(2) – create and transmit transition of care/referral summaries.

- (i) **Create.** Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3) that includes, at a minimum, the Common MU Data Set\*\* and the following data expressed, where applicable, according to the specified standard(s):
  - (A) **Encounter diagnoses.** The standard specified in § 170.207(i) or, at a minimum, the version of the standard specified § 170.207(a)(3);
  - (B) **Immunizations.** The standard specified in § 170.207(e)(2);
  - (C) Cognitive status;
  - (D) Functional status; and
  - (E) **Ambulatory setting only.** The reason for referral; and referring or transitioning provider’s name and office contact information.
  - (F) **Inpatient setting only.** Discharge instructions.
- (ii) **Transmit.** Enable a user to electronically transmit the transition of care/referral summary created in paragraph (b)(2)(i) of this section in accordance with:
  - (A) The standard specified in § 170.202(a).
  - (B) **Optional.** The standards specified in § 170.202(a) and (b).
  - (C) **Optional.** The standards specified in § 170.202(b) and (c).

**Problem list.** Enable a user to electronically record, change, and access a patient’s problem list: §170.314(a)(5)

- (i) **Ambulatory setting.** Over multiple encounters in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3); or
- (ii) **Inpatient setting.** For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3).

**Medication list.** Enable a user to electronically record, change, and access a patient’s active medication list as well as medication history: §170.314(a)(6)

- (i) **Ambulatory setting.** Over multiple encounters; or
- (ii) **Inpatient setting.** For the duration of an entire hospitalization.

**Medication allergy list.** Enable a user to electronically record, change, and access a patient’s active medication allergy list as well as medication allergy history: §170.314(a)(7)

- (i) **Ambulatory setting.** Over multiple encounters; or
- (ii) **Inpatient setting.** For the duration of an entire hospitalization.

- In **Create.** Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted. In **section views.** Extract and allow for individual display REC Primary Care Providers were Enrolled, each additional section or sections (and the accompanying document header § 170.202(a) – Applicability Statement for Secure Health REC Primary Care Providers were Enrolled, Transport.
- § 170.202(b) – XDR and XDM for Direct Messaging Specification.
- § 170.202(c) – Transport and Security Specification.
- § 170.205(a)(1) – HL7 CDA Release 2, CCD. **Implementation specifications:** HITSP Summary Documents Using HL7 CCD Component HITSP/C32.
- § 170.205(a)(2) – ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369.
- § 170.205(a)(3) – HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation. The use of the “unstructured document” document-level template is prohibited.
- § 170.207(d)(2) – RxNorm, August 6, 2012 Release.
- § 170.207(a)(3) – IHTSDO SNOMED CT® International Release, July 2012; and US Extension to SNOMED CT,® March 2012.
- § 170.207(i) – The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions.
- 170.207(e)(2) – HL7 Standard Code Set CVX – Vaccines Administered, updates through July 11, 2012.

\*\* Common MU Data Set – see end of document.

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<p style="text-align: right;">§170.314(b)(3) / §170.314(a)(10)</p> <p><u>Electronic prescribing.</u> Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with:</p> <ul style="list-style-type: none"> <li>(i) The standard specified in § 170.205(b)(2); and</li> <li>(ii) At a minimum, the version of the standard specified in § 170.207(d)(2).</li> </ul> <p><u>Drug-formulary checks.</u> EHR technology must automatically and electronically check whether a drug formulary (or preferred drug list) exists for a given patient and medication.</p>	<ul style="list-style-type: none"> <li>▪ § 170.205(b)(2) – NCPDP SCRIPT version 10.6.</li> <li>▪ § 170.207(d)(2) – RxNorm, August 6, 2012 Release.</li> </ul>
<p style="text-align: right;">§170.314(b)(4)</p> <p><u>Clinical information reconciliation.</u> Enable a user to electronically reconcile the data that represent a patient’s active medication, problem, and medication allergy list as follows. For each list type:</p> <ul style="list-style-type: none"> <li>(i) Electronically and simultaneously display (i.e., in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date.</li> <li>(ii) Enable a user to create a single reconciled list of medications, medication allergies, or problems.</li> <li>(iii) Enable a user to review and validate the accuracy of a final set of data and, upon a user’s confirmation, automatically update the list.</li> </ul>	
<p style="text-align: right;">§170.314(b)(5)</p> <p><u>Incorporate laboratory tests and values/results.</u></p> <ul style="list-style-type: none"> <li>(i) Receive results. <ul style="list-style-type: none"> <li>(A) <u>Ambulatory setting only.</u> <ul style="list-style-type: none"> <li>(1) Electronically receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in § 170.205(j) and, at a minimum, the version of the standard specified in § 170.207(c)(2).</li> <li>(2) Electronically display the tests and values/results received in human readable format.</li> </ul> </li> <li>(B) <u>Inpatient setting only.</u> Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such tests and values/results in human readable format.</li> </ul> </li> <li>(ii) Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).</li> <li>(iii) Electronically attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.</li> </ul>	<ul style="list-style-type: none"> <li>▪ § 170.205(j) – HL7 Version 2.5.1. Implementation Guide: S&amp;I Framework Lab Results Interface.</li> <li>▪ § 170.207(c)(2) – LOINC® version 2.40, June 2012, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.</li> </ul>
<p style="text-align: right;">§170.314(d)(1)</p> <p><u>Authentication, access control, and authorization.</u></p> <ul style="list-style-type: none"> <li>(i) Verify against a unique identifier(s) (e.g., username or number) that a person seeking access to electronic health information is the one claimed; and</li> <li>(ii) Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in paragraph (d)(1)(i) of this section, and the actions the user is permitted to perform with the EHR technology.</li> </ul>	

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<p style="text-align: right;">§170.314(d)(2)</p> <p><b>Auditable events and tamper-resistance.</b></p> <p>(i) <b>Record actions.</b> EHR technology must be able to:</p> <p>(A) Record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1);</p> <p>(B) Record the audit log status (enabled or disabled) in accordance with the standard specified in § 170.210(e)(2) unless it cannot be disabled by any user; and</p> <p>(C) Record the encryption status (enabled or disabled) of electronic health information locally stored on end-user devices by EHR technology in accordance with the standard specified in § 170.210(e)(3) unless the EHR technology prevents electronic health information from being locally stored on end-user devices (see 170.314(d)(7) of this section).</p> <p>(ii) <b>Default setting.</b> EHR technology must be set by default to perform the capabilities specified in paragraph (d)(2)(i)(A) of this section and, where applicable, paragraphs (d)(2)(i)(B) or (d)(2)(i)(C), or both paragraphs (d)(2)(i)(B) and (C).</p> <p>(iii) <b>When disabling the audit log is permitted.</b> For each capability specified in paragraphs (d)(2)(i)(A), (B), and (C) of this section that EHR technology permits to be disabled, the ability to do so must be restricted to a limited set of identified users.</p> <p>(iv) <b>Audit log protection.</b> Actions and statuses recorded in accordance with paragraph (d)(2)(i) must not be capable of being changed, overwritten, or deleted by the EHR technology</p> <p>(v) <b>Detection.</b> EHR technology must be able to detect whether the audit log has been altered.</p> <p style="text-align: right;">§170.314(d)(3)</p> <p><b>Audit report(s).</b> Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the data specified in the standards at § 170.210(e).</p> <p style="text-align: right;">§170.314(d)(4)</p> <p><b>Amendments.</b> Enable a user to electronically select the record affected by a patient's request for amendment and perform the capabilities specified in paragraphs (d)(4)(i) or (ii) of this section.</p> <p>(i) <b>Accepted amendment.</b> For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location.</p> <p>(ii) <b>Denied amendment.</b> For a denied amendment, at a minimum, append the request and denial of the request to the affected record or include a link that indicates this information's location.</p>	<ul style="list-style-type: none"> <li>▪ § 170.210(e)(1)(i) – The audit log must record the information specified in sections 7.2 through 7.4, 7.6, and 7.7 of the standard specified at § 170.210(h) when EHR technology is in use.</li> <li>▪ § 170.210(e)(1)(ii) – The date and time must be recorded in accordance with the standard specified at § 170.210(g).</li> <li>▪ § 170.210(e)(2)(i) – The audit log must record the information specified in sections 7.2 and 7.4 of the standard specified at § 170.210(h) when the audit log status is changed.</li> <li>▪ § 170.210(e)(2)(ii) – The date and time each action occurs in accordance with the standard specified at § 170.210(g).</li> <li>▪ § 170.210(e)(3) – The audit log must record the information specified in sections 7.2 and 7.4 of the standard specified at § 170.210(h) when the encryption status of electronic health information locally stored by the EHR technology on end-user devices is changed. The date and time each action occurs in accordance with the standard specified at § 170.210(g).</li> </ul> <ul style="list-style-type: none"> <li>▪ § 170.210(e)(1)(i) – The audit log must record the information specified in sections 7.2 through 7.4, 7.6, and 7.7 of the standard specified at § 170.210(h) when EHR technology is in use.</li> <li>▪ § 170.210(e)(1)(ii) – The date and time must be recorded in accordance with the standard specified at § 170.210(g).</li> <li>▪ § 170.210(e)(2)(i) – The audit log must record the information specified in sections 7.2 and 7.4 of the standard specified at § 170.210(h) when the audit log status is changed.</li> <li>▪ § 170.210(e)(2)(ii) – The date and time each action occurs in accordance with the standard specified at § 170.210(g).</li> <li>▪ § 170.210(e)(3) – The audit log must record the information specified in sections 7.2 and 7.4 of the standard specified at § 170.210(h) when the encryption status of electronic health information locally stored by the EHR technology on end-user devices is changed. The date and time each action occurs in accordance with the standard specified at § 170.210(g).</li> </ul>
<p style="text-align: right;">§170.314(d)(5)</p> <p><b>Automatic log-off.</b> Prevent a user from gaining further access to an electronic session after a predetermined time of inactivity.</p>	
<p style="text-align: right;">§170.314(d)(6)</p> <p><b>Emergency access.</b> Permit an identified set of users to access electronic health information during an emergency.</p>	

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<p style="text-align: right;">§170.314(d)(7)</p> <p><u>End-user device encryption.</u> Paragraph (d)(7)(i) or (ii) of this section must be met to satisfy this certification criterion.</p> <p>(i) EHR technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of EHR technology on those devices stops.</p> <p>(A) Electronic health information that is stored must be encrypted in accordance with the standard specified in § 170.210(a)(1).</p> <p>(B) <u>Default setting.</u> EHR technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users.</p> <p>(ii) EHR technology is designed to prevent electronic health information from being locally stored on end-user devices after use of EHR technology on those devices stops.</p>	<ul style="list-style-type: none"> <li>▪ § 170.210(a)(1) – Any encryption algorithm identified by the NIST as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2.</li> </ul>
<p style="text-align: right;">§170.314(d)(8)</p> <p><u>Integrity.</u></p> <p>(i) Create a message digest in accordance with the standard specified in § 170.210(c).</p> <p>(ii) Verify in accordance with the standard specified in § 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.</p>	<ul style="list-style-type: none"> <li>▪ § 170.210(c) – A hashing algorithm with a security strength equal to or greater than SHA-1 (Secure Hash Algorithm) as specified by the NIST in FIPS PUB 180-4 (March, 2012) must be used to verify that electronic health information has not been altered.</li> </ul>
<p style="text-align: right;">§170.314(d)(9)</p> <p><u>Optional– Accounting of disclosures.</u> Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in §170.210(d).</p>	<ul style="list-style-type: none"> <li>▪ § 170.210(d) – The date, time, patient identification, user identification, and a description of the disclosure must be recorded for disclosures for treatment, payment, and health care operations, as these terms are defined at 45 CFR 164.501.</li> </ul>

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<p style="text-align: right;">§170.314(e)(1)</p> <p><u>View, download, and transmit to 3<sup>rd</sup> party.</u></p> <p>(i) EHR technology must provide patients (and their authorized representatives) with an online means to view, download, and transmit to a 3<sup>rd</sup> party the data specified below. Access to these capabilities must be through a secure channel that ensures all content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).</p> <p>(A) <u>View</u>. Electronically view in accordance with the standard adopted at § 170.204(a), at a minimum, the following data:</p> <ol style="list-style-type: none"> <li>(1) The Common MU Data Set** (which should be in their English (i.e., non-coded) representation if they associate with a vocabulary/code set).</li> <li>(2) <u>Ambulatory setting only</u>. Provider's name and office contact information.</li> <li>(3) <u>Inpatient setting only</u>. Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.</li> </ol> <p>(B) <u>Download</u>.</p> <ol style="list-style-type: none"> <li>(1) Electronically download an ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) in human readable format or formatted according to the standard adopted at § 170.205(a)(3) that includes, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):             <ol style="list-style-type: none"> <li>(i) <u>Ambulatory setting only</u>. All of the data specified in paragraph (e)(1)(i)(A)(1) and (e)(1)(i)(A)(2) of this section.</li> <li>(ii) <u>Inpatient setting only</u>. All of the data specified in paragraphs (e)(1)(i)(A)(1) and (e)(1)(i)(A)(3) of this section.</li> </ol> </li> <li>(2) <u>Inpatient setting only</u>. Electronically download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion adopted at paragraph (b)(2) of this section).</li> </ol> <p>(C) <u>Transmit to third party</u>.</p> <ol style="list-style-type: none"> <li>(1) Electronically transmit the ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) created in paragraph (e)(1)(i)(B)(1) of this section in accordance with the standard specified in § 170.202(a).</li> <li>(2) <u>Inpatient setting only</u>. Electronically transmit transition of care/referral summaries (as a result of a transition of care/referral) selected by the patient (or their authorized representative) in accordance with the standard specified in § 170.202(a).</li> </ol> <p>(ii) <u>Activity history log</u>.</p> <p>(A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section, the following information must be recorded and made accessible to the patient:</p> <ol style="list-style-type: none"> <li>(1) The action(s) (i.e., view, download, transmission) that occurred;</li> <li>(2) The date and time each action occurred in accordance with the standard specified at § 170.210(g); and</li> <li>(3) The user who took the action.</li> </ol> <p>(B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at § 170.314(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.</p>	<ul style="list-style-type: none"> <li>▪ § 170.210(f) – Any encryption and hashing algorithm identified by NIST as an approved security function of Annex A of the FIPS Publication 140-2.</li> <li>▪ § 170.204(a) – Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance.</li> <li>▪ § 170.205(a)(3) – HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation. The use of the “unstructured document” document-level template is prohibited.</li> <li>▪ § 170.202(a) – Applicability Statement for Secure Health Transport.</li> <li>▪ § 170.210(g) – The data and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, or (RFC 5905) Network Time Protocol Version 4.</li> </ul> <p>** Common MU Data Set – see end of document.</p>
<p style="text-align: right;">§170.314(e)(2)</p> <p><u>Ambulatory setting only – clinical summary.</u></p> <p>(i) <u>Create</u>. Enable a user to create a clinical summary for a patient in human readable format and formatted according to the standards adopted at § 170.205(a)(3).</p> <p>(ii) <u>Customization</u>. Enable a user to customize the data included in the clinical summary.</p> <p>(iii) <u>Minimum data from which to select</u>. EHR technology must permit a user to select, at a minimum, the following data when creating a clinical summary:</p> <ol style="list-style-type: none"> <li>(A) Common MU Data Set** (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set)</li> <li>(B) The provider's name and office contact information; date and location of visit; reason for visit; immunizations and/ medications administered during the visit; diagnostic tests pending; clinical instructions; future appointments; referrals to other providers; future scheduled tests; and recommended patient decision aids.</li> </ol>	<ul style="list-style-type: none"> <li>▪ § 170.205(a)(3) – HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation. The use of the “unstructured document” document-level template is prohibited.</li> </ul> <p>** Common MU Data Set – see end of document.</p>



<p style="text-align: center;">ONC 2014 Edition EHR CERTIFICATION CRITERIA 45 CFR 170.314</p>	<p style="text-align: center;">ONC 2014 Edition STANDARDS</p>
<p style="text-align: right;">§170.314(e)(3)</p> <p><u>Ambulatory setting only—secure messaging.</u> Enable a user to electronically send messages to, and receive messages from, a patient in a manner that ensures:</p> <p>(i) Both the patient (or authorized representative) and EHR technology user are authenticated; and</p> <p>(ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).</p>	<ul style="list-style-type: none"> <li>▪ 170.210(f) – Any encryption and hashing algorithm identified by the NIST as an approved security function in Annex A of the FIPS Publication 140-2</li> </ul>
<p style="text-align: right;">§170.314(f)(1) / §170.314(f)(2)</p> <p><u>Immunization information.</u> Enable a user to electronically record, change, and access immunization information.</p> <p><u>Transmission to immunization registries.</u> EHR technology must be able to electronically create immunization information for electronic transmission in accordance with:</p> <p>(i) The standard and applicable implementation specifications specified in § 170.205(e)(3); and</p> <p>(ii) At a minimum, the version of the standard specified in § 170.207(e)(2).</p>	<ul style="list-style-type: none"> <li>▪ § 170.205(e)(3) – HL7 2.5.1. <i>Implementation specifications:</i> HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4</li> <li>▪ § 170.207(e)(2) – HL7 Standard Code Set CVX – Vaccines Administered, updates through July 11, 2012.</li> </ul>
<p style="text-align: right;">§170.314(f)(3)</p> <p><u>Transmission to public health agencies – syndromic surveillance.</u> EHR technology must be able to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:</p> <p>(i) <u>Ambulatory setting only.</u></p> <p>(A) The standard specified in § 170.205(d)(2).</p> <p>(B) <u>Optional.</u> The standard (and applicable implementation specifications) specified in § 170.205(d)(3).</p> <p>(ii) <u>Inpatient setting only.</u> The standard (and applicable implantation specifications) specified in § 170.205(d)(3).</p>	<ul style="list-style-type: none"> <li>▪ § 170.205(d)(2) – HL7 2.5.1.</li> <li>▪ § 170.205(d)(3) – HL7 2.5.1. <i>Implementation specifications:</i> PHIN Messaging Guide for Syndromic Surveillance and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance.</li> </ul>
<p style="text-align: right;">§170.314(f)(4)</p> <p><u>Inpatient setting only—transmission of reportable laboratory tests and values/results.</u> EHR technology must be able to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with:</p> <p>(i) The standard (and applicable implementation specifications) specified in § 170.205(g); and</p> <p>(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).</p>	<ul style="list-style-type: none"> <li>▪ § 170.205(g) – HL7 2.5.1. <i>Implementation specifications:</i> HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with Errata and Clarifications, and ELR 2.5.1 Clarification Document for EHR Technology Certification.</li> <li>▪ § 170.207(a)(3) – IHTSDO SNOMED CT® International Release, July 2012 and US Extension to SNOMED CT,® March 2012 Release.</li> <li>▪ § 170.207(c)(2) – LOINC® version 2.40, June 2012, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.</li> </ul>
<p style="text-align: right;">§170.314(a)(9)</p> <p><u>Electronic notes.</u> Enable a user to electronically record, change, access, and search electronic notes.</p>	
<p style="text-align: right;">§170.314(a)(12)</p> <p><u>Image results.</u> Electronically indicate to a user the availability of a patient’s images and narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable electronic access to such images and narrative interpretations.</p>	

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<p style="text-align: right;">§170.314(a)(13)</p> <p>Family health history. Enable a user to electronically record, change, and access a patient's family health history according to: (i) At a minimum, the version of the standard specified in § 170.207(a)(3); or (ii) The standard specified in § 170.207(j)</p>	<ul style="list-style-type: none"> <li>▪ § 170.207(a)(3) – IHTSDO SNOMED CT® International Release, July 2012 and US Extension to SNOMED CT,® March 2012 Release.</li> <li>▪ § 170.207(j) – HL7 Version 3 Standard: Clinical Genomics; Pedigree.</li> </ul>
<p style="text-align: right;">§170.314(a)(17)</p> <p><u>Inpatient setting only – advance directives.</u> Enable a user to electronically record whether a patient has an advance directive.</p>	
<p style="text-align: right;">§170.314(b)(3) / §170.314(a)(10)</p> <p><u>Electronic prescribing.</u> Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with: (i) The standard specified in § 170.205(b)(2); and (ii) At a minimum, the version of the standard specified in § 170.207(d)(2).</p> <p><u>Drug-formulary checks.</u> EHR technology must automatically and electronically check whether a drug formulary (or preferred drug list) exists for a given patient and medication.</p>	<ul style="list-style-type: none"> <li>▪ § 170.205(b)(2) – NCPDP SCRIPT version 10.6.</li> <li>▪ § 170.207(d)(2) – RxNorm, August 6, 2012 Release.</li> </ul>
<p style="text-align: right;">§170.314(b)(6)</p> <p><u>Inpatient setting only – transmission of electronic laboratory tests and values/results to ambulatory providers.</u> EHR technology must be able to electronically create laboratory test reports for electronic transmission in accordance with the standard specified in § 170.205(j) and with laboratory tests expressed in accordance with, at a minimum, the version of the standard specified in § 170.207(c)(2)</p>	<ul style="list-style-type: none"> <li>▪ § 170.205(j) – HL7 Version 2.5.1. Implementation Guide: S&amp;I Framework Lab Results Interface.</li> <li>▪ § 170.207(c)(2) – LOINC® version 2.40, June 2012, a universal code system for indentifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.</li> </ul>
<p style="text-align: right;">§170.314(f)(3)</p> <p><u>Transmission to public health agencies – syndromic surveillance.</u> EHR technology must be able to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with: (i) <u>Ambulatory setting only.</u> (A) The standard specified in § 170.205(d)(2). (B) <u>Optional.</u> The standard (and applicable implementation specifications) specified in § 170.205(d)(3). (ii) <u>Inpatient setting only.</u> The standard (and applicable implantation specifications) specified in § 170.205(d)(3).</p>	<ul style="list-style-type: none"> <li>▪ § 170.205(d)(2) – HL7 2.5.1.</li> <li>▪ § 170.205(d)(3) – HL7 2.5.1. <i>Implementation specifications:</i> PHIN Messaging Guide for Syndromic Surveillance and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance.</li> </ul>
<p style="text-align: right;">§170.314(f)(5) / §170.314(f)(6)</p> <p><u>Optional—ambulatory setting only—cancer case information.</u> Enable a user to electronically record, change, and access cancer case information.</p> <p><u>Optional—ambulatory setting only—transmission to cancer registries.</u> EHR technology must be able to electronically create cancer case information for electronic transmission in accordance with: (i) The standard (and applicable implementation specifications) specified in § 170.205(i); and (ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).</p>	<ul style="list-style-type: none"> <li>▪ § 170.205(i) – HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition <i>Implementation specifications:</i> Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA).</li> <li>▪ § 170.207(a)(3) – IHTSDO SNOMED CT® International Release, July 2012 and US Extension to SNOMED CT,® March 2012 Release.</li> <li>▪ § 170.207(c)(2) – LOINC® version 2.40, June 2012, a universal code system for indentifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.</li> </ul>

# ONC 2014 Edition EHR CERTIFICATION CRITERIA

45 CFR 170.314

# ONC 2014 Edition STANDARDS

<p style="text-align: right;">§170.314(c)(1)-(3)</p> <p>(1) <u>Clinical Quality Measures – capture and export.</u></p> <p>(i) <u>Capture.</u> For each and every CQM for which the EHR technology is presented for certification, EHR technology must be able to electronically record all of the data identified in the standard specified at § 170.204(c) that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of “patient reason,” “system reason,” or “medical reason.”</p> <p>(ii) <u>Export.</u> EHR technology must be able to electronically export a data file formatted in accordance with the standards specified at § 170.205(h) that includes all of the data captured for each and every CQM to which EHR technology was certified under paragraph (c)(1)(i) of this section.</p> <p>(2) <u>Clinical quality measures – import and calculate.</u></p> <p>(i) <u>Import.</u> EHR technology must be able to electronically import a data file formatted in accordance with the standard specified at § 170.205(h) and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. EHR technology presented for certification to all three of the certification criteria adopted in paragraphs (c)(1) through (3) of this section is not required to meet paragraph (c)(2)(i).</p> <p>(ii) <u>Calculate.</u> EHR technology must be able to electronically calculate each and every clinical quality measure for which it is presented for certification.</p> <p>(3) <u>Clinical quality measures – electronic submission.</u> Enable a user to electronically create a data file for transmission of clinical quality measurement data:</p> <p>(i) In accordance with the standards specified at § 170.205(h) and (k); and</p> <p>(ii) That can be electronically accepted by CMS.</p>	<ul style="list-style-type: none"> <li>▪ § 170.204(c) – Data Element Catalog.</li> <li>▪ § 170.205(h) – HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture</li> <li>▪ § 170.205(k) –Quality Reporting Document Architecture—Category III, DSTU Release 1</li> </ul>
<p style="text-align: right;">§170.314(b)(7)</p> <p><u>Data portability.</u> Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the standard adopted at § 170.205(a)(3) that represents the most current clinical information about each patient and includes, at a minimum, the Common MU Data Set** and the following data expressed, where applicable, according to the specified standard(s):</p> <p>(i) <u>Encounter diagnoses.</u> The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(3);</p> <p>(ii) <u>Immunizations.</u> The standard specified in § 170.207(e)(2);</p> <p>(iii) <u>Cognitive status;</u></p> <p>(iv) <u>Functional status; and</u></p> <p>(v) <u>Ambulatory setting only.</u> The reason for referral; and referring or transitioning provider’s name and office contact information.</p> <p>(vi) <u>Inpatient setting only.</u> Discharge instructions.</p>	<ul style="list-style-type: none"> <li>▪ § 170.205(a)(3) – HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation. The use of the “unstructured document” document-level template is prohibited.</li> <li>▪ § 170.207(i) – The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions.</li> <li>▪ § 170.207(a)(3) – IHTSDO SNOMED CT® International Release, July 2012; and US Extension to SNOMED CT,® March 2012.</li> <li>▪ 170.207(e)(2) – HL7 Standard Code Set CVX – Vaccines Administered, updates through July 11, 2012.</li> </ul> <p>** MU Data Set – see end of document.</p>
<p style="text-align: right;">§170.314(g)(1)</p> <p><u>Automated numerator recording.</u> For each meaningful use objective with a percentage-based measure, EHR technology must be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure’s numerator. The information in the report or file created must be of sufficient detail such that it enables a user to match those patients or actions to meet the measure’s denominator limitations when necessary to generate an accurate percentage.</p>	
<p style="text-align: right;">§170.314(g)(2)</p> <p><u>Automated measure calculation.</u> For each meaningful use objective with a percentage-based measure that is supported by a capability included in an EHR technology, electronically record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.</p>	

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<p style="text-align: right;">§170.314(g)(3)</p> <p><u>Safety-enhanced design</u>. User-centered design processes must be applied to each capability an EHR technology includes that is specified in the following certification criteria: § 170.314(a)(1), (2), (6) through (8), and (16) and (b)(3) and (4).</p>	
<p style="text-align: right;">§170.314(g)(4)</p> <p><u>Quality management system</u>. For each capability that an EHR technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation and maintenance of that capability must be identified.</p> <ul style="list-style-type: none"> <li>(i) If a single QMS was used for applicable capabilities, it would only need to be identified once.</li> <li>(ii) If different QMS were applied to specific capabilities, each QMS applied would need to be identified. This would include the application of a QMS to some capabilities and none to others.</li> <li>(iii) If no QMS was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.</li> </ul>	

COMMON MU DATA SET**	
Data	Standards
<p>Common MU Data Set means the following data expressed, where indicated, according to the specified standard(s):</p> <ol style="list-style-type: none"> <li>(1) Patient name.</li> <li>(2) Sex.</li> <li>(3) Date of birth.</li> <li>(4) Race – the standard specified in § 170.207(f).</li> <li>(5) Ethnicity – the standard specified in § 170.207(f).</li> <li>(6) Preferred language – the standard specified in § 170.207(g).</li> <li>(7) Smoking status – the standard specified in § 170.207(h).</li> <li>(8) Problems – at a minimum, the version of the standard specified in § 170.207(a)(3)</li> <li>(9) Medications – at a minimum, the version of the standard specified in § 170.207(d)(2).</li> <li>(10) Medication allergies – at a minimum, the version of the standard specified in § 170.207(d)(2).</li> <li>(11) Laboratory test(s) – at a minimum, the version of the standard specified in § 170.207(c)(2).</li> <li>(12) Laboratory value(s)/result(s).</li> <li>(13) Vital signs – height, weight, blood pressure, BMI.</li> <li>(14) Care plan field(s), including goals and instructions.</li> <li>(15) Procedures –               <ol style="list-style-type: none"> <li>(i) (A) At a minimum, the version of the standard specified in §170.207(a)(3) or §170.207(b)(2); or</li> <li>(B) For EHR technology primarily developed to record dental procedures, the standard specified in §170.207(b)(3).</li> <li>(ii) Optional. The standard specified at §170.207(b)(4).</li> </ol> </li> <li>(16) Care team member(s).</li> </ol>	<ul style="list-style-type: none"> <li>▪ § 170.207(f) – OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997.</li> <li>▪ § 170.207(g) – ISO 639-2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639-1.</li> <li>▪ § 170.207(h) – Coded to one of the following SNOMED CT® codes:               <ol style="list-style-type: none"> <li>(1) <u>Current every day smoker</u>. 449868002</li> <li>(2) <u>Current some day smoker</u>. 428041000124106</li> <li>(3) <u>Former smoker</u>. 8517006</li> <li>(4) <u>Never smoker</u>. 266919005</li> <li>(5) <u>Smoker, current status unknown</u>. 77176002</li> <li>(6) <u>Unknown if ever smoked</u>. 266927001</li> <li>(7) <u>Heavy tobacco smoker</u>. 428071000124103</li> <li>(8) <u>Light tobacco smoker</u>. 428061000124105</li> </ol> </li> <li>▪ § 170.207(a)(3) – IHTSDO SNOMED CT® International Release, July 2012; and US Extension to SNOMED CT,® March 2012.</li> <li>▪ § 170.207(d)(2) – RxNorm, August 6, 2012 Release.</li> <li>▪ § 170.207(c)(2) – LOINC® version 2.40, June 2012, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.</li> </ul>