

Row	ONC Proposed 2014 Edition EHR Certification Criteria and Standards/Implementation Specifications	HITSC Recommended Certification Criteria and Standards/Implementation Specifications
1	<u>Computerized provider order entry.</u> <ul style="list-style-type: none"> Identified as an “unchanged” certification criterion. 	No revisions required to support HITPC proposed MU Stage 2 objective and measure.
2A	<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(h). Standards § 170.205(b)((2) (NCPDP SCRIPT version 10.6) and § 170.207(h) (RxNorm February 6, 2012 Release) <ul style="list-style-type: none"> The HITSC recommended that we require as a condition of certification for the inpatient setting that certain HL7 standards be adopted for exchange within a legal entity. As noted in the preamble of the proposed rule, we did not accept this part of the recommendation because it is inconsistent with our approach of adopting standards for the exchange of health information between <u>different</u> legal entities. The preamble also discusses the potential use of NCPDP SCRIPT version 8.1 if CMS does not proceed as anticipated. 	No revision recommended for ambulatory setting except to move to RxNorm as the vocabulary standard. For inpatient setting: <i>Electronic prescribing. Enable a user to electronically generate and transmit discharge prescriptions and prescription-related information in accordance with:</i> (1) The standard specified in §170.205(b)(1) or § 170.205(b)(2); (2) The standard specified in 170.207(d); and (3) One of the standards specified in_____. Standards and Implementation Specifications & Workgroup Statement on Intent The standards that are available under number (3) above are the HL7 versions recommended by the e-Prescribing of Discharge Meds Power Team . NCPDP SCRIPT 8.1 & 10.6 <u>Note:</u> 10.6 is required by CMS under Part D in regulation RxNorm
2B	<u>Drug-formulary checks.</u> <ul style="list-style-type: none"> Identified as an “unchanged” certification criterion. 	No revisions required to support HITPC proposed MU Stage 2 objective and measure.

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3	<p><u>Demographics.</u> (i) Enable a user to electronically record, change, and access patient demographic data including preferred language, gender, race, ethnicity, and date of birth. (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. (B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(j) and whether a patient declines to specify a preferred language. (ii) <u>Inpatient setting only.</u> Enable a user to electronically record, change, and access preliminary cause of death in the event of a mortality in accordance with the standard specified in § 170.207(k).</p> <p>Standards § 170.207(f)(OMB standards); § 170.207(j) (ISO 639-1:2002); and § 170.207(k) (ICD-10-CM)</p> <ul style="list-style-type: none"> Proposes compliance with ICD-10-CM for preliminary cause of death. The standard will permit more specificity for the cause of death data element. 	<p>Revised to include new standard for preferred language. Use ISO 639-1 standard for preferred language Maintain OMB standards for race and ethnicity</p>
4	<p><u>Vital signs, body mass index, and growth charts.</u> (i) <u>Vital signs.</u> Enable a user to electronically record and change, and access recordings of a patient’s vital signs including, at a minimum, height/length, weight, and blood pressure. (ii) <u>Calculate body mass index.</u> Automatically calculate and electronically display body mass index based on a patient’s height and weight. (iii) <u>Optional. Plot and display growth charts.</u> Plot and electronically display, upon request, growth charts for patients.</p> <ul style="list-style-type: none"> Identified as an “unchanged” certification criterion. “Plot and display growth charts” is proposed as an optional capability. 	<p>No revisions required to support HITPC proposed MU Stage 2 objective and measure.</p>
5	<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(l).</p> <p>Standard § 170.207(l) (smoking status types)</p> <ul style="list-style-type: none"> Identified as an “unchanged” certification criterion. Smoking status types are proposed as a standard. 	<p>No revisions required to support HITPC proposed MU Stage 2 objective and measure.</p>

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6A	<p><u>Clinical decision support.</u></p> <p>(i) <u>Evidence-based decision support interventions.</u> Enable a user to select (or activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in each one or any combination of the following:</p> <ul style="list-style-type: none"> (A) Problem list; (B) Medication list; (C) Medication allergy list; (D) Demographics; (E) Laboratory tests and values/results; and (F) Vital signs. <p>(ii) <u>Linked referential clinical decision support.</u></p> <p>(A) Enable a user to retrieve diagnostic or therapeutic reference information in accordance with the standard specified at § 170.204(b)(1).</p> <p>(B) Enable a user to access the reference information specified in paragraph (ii)(A) relevant to patient context based on the data elements included in each one or any combination of the following:</p> <ul style="list-style-type: none"> (1) Problem list; (2) Medication list; (3) Medication allergy list; (4) Demographics; (5) Laboratory tests and values/results; and (6) Vital signs. <p>(iii) <u>Configure clinical decision support.</u></p> <p>(A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) to be configured by an identified set of users (e.g., system administrator) based on each one of the following:</p> <ul style="list-style-type: none"> (1) A user's role; (2) Clinical setting; and (3) Identified points in the clinical workflow. <p>(B) Enable interventions to be triggered, based on the data elements specified in paragraph (a)(8)(i), when a summary care record is incorporated pursuant to § 170.314(b)(1).</p> <p>(vi) <u>Automatically and electronically interact.</u> Interventions selected and configured in accordance with paragraphs (a)(8)(i)-(iii) must automatically and electronically occur when a user is interacting with EHR technology.</p> <p>(v) <u>Source attributes.</u> Enable a user to review the attributes for each intervention or reference source for all clinical decision support resources including:</p> <ul style="list-style-type: none"> (A) Bibliographic citation (clinical research/guideline) including publication; (B) Developer of the intervention (translation from clinical research/guideline); (C) Funding source of the intervention development technical implementation; and (D) Release and, if applicable, revision date of the intervention. <p>Standard § 170.204(b)(1) (HL7 Context-Aware Knowledge Retrieval (“Infobutton”) Standard, International Normative Edition 2010)</p>	<p><u>Clinical decision support.</u></p> <p>(1) <i>Decision support rules.</i> Enable a user to select (or activate) one or more automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: (i) Problem list;</p> <p>(ii) Medication list;</p> <p>(iii) Medication allergy list;</p> <p>(iv) Demographics;</p> <p>(v) Laboratory test results; and</p> <p>(vi) Vital signs.</p> <p>(2) <i>Configure rules.</i> Enable decision support rules to be configured based on each of the following:</p> <ul style="list-style-type: none"> (i) A user's role; (ii) Specific patient settings; and (iii) Identified points in the clinical workflow. <p>(3) <i>Notifications and care suggestions.</i> Automatically and electronically generate notifications and care suggestions based upon clinical decision support rules selected and configured in accordance with paragraphs (1) and (2) of this section.</p> <p>(4) <i>Display rule source information.</i> Enable a user to review the clinical evidence or source information attributed to each clinical decision support rule when a notification or care suggestion is indicated.</p> <p>Workgroup Statement on Intent</p> <ul style="list-style-type: none"> • CDS rules should be able to be configured based on data elements in any of (1)(i) –(vi) or a combination of data elements in (1)(i)-(vi), but not necessarily based on data elements from all of (1)(i)-(vi) if that is not clinically feasible or acceptable. • CDS rules should be capable of being configured based on any one or combination of the criteria listed in (2)(i)-(iii). • Notifications and care suggestions are different. A notification could be an alert, warning or a piece of information/data that may lead to an action, while a care suggestion provides a suggested action.

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6B	<p><u>Drug-drug, drug-allergy interaction checks.</u></p> <p>(i) <u>Interventions.</u> Before a medication order is placed during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user at the point of care of drug-drug and drug-allergy contraindications based on medication list and medication allergy list.</p> <p>(ii) <u>Adjustments.</u></p> <p>(A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.</p> <p>(B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.</p>	<p><u>Drug-drug, drug-allergy interaction checks.</u></p> <p>(1) <u>Notifications.</u> Automatically and electronically generate and indicate, before the order is executed, notifications at the point of care for drug-drug and drug-allergy contraindications based on medication list and medication allergy list during CPOE.</p> <p>(2) <u>Adjustments.</u></p> <p>(a) Enable the ability to adjust severity level of notifications provided for drug-drug interaction checks.</p> <p>(b) Limit the ability to an identified set of users or available as a system administrative function.</p> <p>Workgroup Statement on Intent Chose to interpret “refined DDI rules” as the “ability to adjust severity level of notifications”. Unclear if this was the specific intent of the HITPC. The criterion was also revised to improve clarity, particularly for testing and certification.</p>
7	<p><u>Incorporate laboratory tests and values/results.</u></p> <p>(i) <u>Receive results.</u></p> <p>(A) <u>Ambulatory setting only.</u></p> <p>(1) Electronically receive clinical laboratory tests and values/results formatted in accordance with the standard (and implementation specifications) specified at § 170.205(k) and, at a minimum, the version of the standard specified in § 170.207(g).</p> <p>(2) Electronically display the tests and values/results received in human readable format.</p> <p>(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.</p> <p>(ii) <u>Display test report information.</u> Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).</p> <p>(iii) <u>Incorporate tests and values/results.</u> Electronically incorporate a laboratory test and value/result with a laboratory order or patient record.</p> <p>Standards and Implementation Specifications § 170.205(k) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Lab Results Interface, Release 1 (US Realm); and § 170.207(g) (LOINC version 2.38)</p> <ul style="list-style-type: none"> Identified as an “unchanged” certification criterion for the inpatient setting. 	<p>No revisions required to support HITPC proposed MU Stage 2 objective and measure.</p> <p><u>HITPC Note to HIT Standards Committee:</u> Use LOINC where available</p>

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8	<u>Patient lists.</u> <ul style="list-style-type: none"> Identified as an “unchanged” certification criterion. 	No revisions required to support HITPC proposed MU Stage 2 objective and measure.
9	<u>Ambulatory setting only – patient reminders.</u> <ul style="list-style-type: none"> Identified as an “unchanged” certification criterion. Preamble: “We clarify and emphasize that EHR technology certified to this certification criterion would need to be capable of creating a patient reminder list that includes a patient’s communication preferences, which would be consistent with current testing procedures for this capability as included in the 2011 Edition EHR certification criterion (§ 170.304(d)). We also note that, consistent with patient communication preferences, we would anticipate that EPs, EHs, and CAHs could use communication mediums made available by EHR technology certified to the proposed “secure messaging” certification criterion (§ 170.314(e)(3)) or the “view, download and transmit to 3rd party” certification criterion (§ 170.314(e)(1)) to send patient reminders. We also anticipate that other modes of communication would be available and may be preferred by patients for sending patient reminders, such as regular mail.” 	(ambulatory setting) <u>Patient reminders.</u> Enable a user to electronically generate clinically relevant patient reminders on all active patients for preventive or follow-up care according to patient preferences based on, at a minimum, the data elements included in: <ol style="list-style-type: none"> (1) Problem list; (2) Medication list; (3) Medication allergy list; (4) Demographics; and (5) Laboratory test results. <p>Workgroup Statement on Intent: A clinically relevant reminder is consistent with the specific entries in a patients’ problem list, medication list, medication allergy list, demographics and lab test results.</p> <p>Active Patient Definition Active patients are defined as all unique patients who have had an office visit with the EP within the previous 24 months.</p> <p>Patient Communication Medium Preference See Row 46</p>

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10	<p><u>Inpatient setting only – electronic medication administration record.</u></p> <p>(i) In combination with an assistive technology that provides automated information on the “rights” specified in paragraphs (i)(A) through (i)(D), enable a user to electronically verify the following before administering medication(s):</p> <p>(A) <u>Right patient</u>. The patient to whom the medication is to be administered matches the medication to be administered.</p> <p>(B) <u>Right medication</u>. The medication to be administered matches the medication ordered for the patient.</p> <p>(C) <u>Right dose</u>. The dose of the medication to be administered matches the dose of the medication ordered for the patient.</p> <p>(D) <u>Right route</u>. The route of medication delivery matches the route specified in the medication order.</p> <p>(ii) <u>Right time</u>. Electronically record the time and date in accordance with the standard specified at § 170.210(g), and user identification when a medication is administered.</p> <p>Standard § 170.210(g) (synchronized clocks)</p>	<p><u>Electronic Medication Administration</u> (inpatient setting)</p> <p>Utilize an electronic medication administration record which supports the following process:</p> <p>1. <u>Right Patient</u>: Enable a user to electronically identify and select a patient using a validation methodology to ensure the patient’s identification matches the electronic medication administration record displayed.</p> <p>2. <u>Right Medication</u>: Enable a user to electronically validate a match of physical medication product to existing order using barcode reader (or other assisted technology) or visually match existing medication order in electronic medication administration record against physical medication product</p> <p>3. <u>Right Dose</u>: Enable user to electronically validate the dose of physical medication product to existing order using barcode reader (or other assisted technology) or visually match existing medication dose in electronic medication administration record against physical medication product</p> <p>4. <u>Right Route</u>: Using drug form as a proxy for correct route the electronic system validates the dosage form as safe and compatible with the route of administration for the identified order. The route is validated with visual match to electronic medication administration record.</p> <p>5. <u>Record time medication administration</u>: Require that timestamp and user identification records electronically at the time of medications administration.</p> <p>Workgroup Statement on Intent This draft language describes broad capabilities subject to interpretation during certification testing, and thus will need to be further refined.</p>

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11	<p><u>View, download, and transmit to 3rd party.</u></p> <p>(i) Enable a user to provide patients (and their authorized representatives) with online access to do all of the following:</p> <p>(A) <u>View</u>. Electronically view in accordance with the standard adopted at § 170.204(a), at a minimum, the following data elements:</p> <ol style="list-style-type: none"> (1) Patient name; gender; date of birth; race; ethnicity; preferred language; smoking status; problem list; medication list; medication allergy list; procedures; vital signs; laboratory tests and values/results; provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; and care plan, including goals and instructions. (2) <u>Inpatient setting only</u>. Admission and discharge dates and locations; reason(s) for hospitalization; names of providers of care during hospitalization; laboratory tests and values/results (available at time of discharge); and discharge instructions for patient. <p>(B) <u>Download</u>. Electronically download:</p> <ol style="list-style-type: none"> (1) A file in human readable format that includes, at a minimum: <ol style="list-style-type: none"> (i) <u>Ambulatory setting only</u>. All of the data elements specified in paragraph (e)(1)(i)(A)(1). (ii) <u>Inpatient setting only</u>. All of the data elements specified in paragraphs (e)(1)(i)(A)(1) and (e)(1)(i)(A)(2). (2) A summary care record formatted according to the standards adopted at § 170.205(a)(3) and that includes, at a minimum, the following data elements expressed, where applicable, according to the specified standard(s): <ol style="list-style-type: none"> (i) Patient name; gender; date of birth; medication allergies; vital signs; the provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; care plan, including goals and instructions; (ii) <u>Race and ethnicity</u>. The standard specified in § 170.207(f); (iii) <u>Preferred language</u>. The standard specified in § 170.207(j); (iv) <u>Smoking status</u>. The standard specified in § 170.207(l); (v) <u>Problems</u>. At a minimum, the version of the standard specified in § 170.207(a)(3); (vi) <u>Encounter diagnoses</u>. The standard specified in § 170.207(m); (vii) <u>Procedures</u>. The standard specified in § 170.207(b)(2) or § 170.207(b)(3); (viii) <u>Laboratory test(s)</u>. At a minimum, the version of the standard specified in § 170.207(g); (ix) <u>Laboratory value(s)/result(s)</u>. The value(s)/results of the laboratory test(s) performed; (x) <u>Medications</u>. At a minimum, the version of the standard specified in § 170.207(h); and (xi) <u>Inpatient setting only</u>. The data elements specified in paragraph (e)(1)(i)(A)(2). (3) Images formatted according to the standard adopted at § 170.205(j). <p>(C) <u>Transmit to third party</u>. Electronically transmit the summary care record created in paragraph (e)(1)(i)(B)(2) and images available to download in paragraph (e)(1)(i)(B)(3) in accordance with:</p> <ol style="list-style-type: none"> (1) The standard specified in § 170.202(a)(1); and (2) The standard specified in § 170.202(a)(2). <p>(ii) <u>Patient accessible log</u>.</p> <ol style="list-style-type: none"> (A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A)-(C), the following information must be recorded and made accessible to the patient: <ol style="list-style-type: none"> (1) The electronic health information affected by the action(s); (2) The date and time each action occurs in accordance with the standard specified at § 170.210(g); (3) The action(s) that occurred; and (4) User identification. (B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) 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>Standards</p> <p>§ 170.204(a) (Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance); § 170.205(a)(3) (Consolidated CDA); § 170.205(j) (DICOM PS 3—2011); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT® International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release); § 170.202(a)(1) (Applicability Statement for Secure Health Transport) and § 170.202(a)(2) (XDR and XDM for Direct Messaging); and § 170.210(g) (synchronized clocks)</p>	<p>Ambulatory and Inpatient</p> <p><u>View and Download for patients</u>: Enable a user to provide patients with the ability to view and download their longitudinal health information online, and to electronically transmit this information directly to patients. Also, enable users to track transmission events and when information is viewed and downloaded. Information must include, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, procedures, clinical summaries and discharge instructions, and be provided in:</p> <ol style="list-style-type: none"> (i) Human readable format; (ii) The appropriate standard (and applicable implementation specifications) specified in _____ and with data elements using applicable standards; <ol style="list-style-type: none"> (1) [Enumeration of data elements and applicable standards] (iii) Track the number of patient online accesses (view and download) or transmission events. <p>Standards and Implementation Specifications</p> <p>No change to summary record standards discussed. Changes to vocabs would generally be reflective of changes elsewhere. LOINC where available ICD-10 RxNorm SNOMED CT</p> <p>Workgroup Statement on Intent</p> <p>Electronic access via online access is intended to include an online portal and/or PHR directly tied to the EHR or a third party patient portal and or PHR that is connected to the EHR. The third party solution (PHR and/or patient portal) may be directly connected to that EHR or through an HIE connection that offers electronic patient access. Similarly, the intention here is that the EHR needs to demonstrate one of these options for certification (not all of them). In essence, any means for providing patients the ability to view and download consistent with this certification criterion is acceptable.</p>

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12	<p><u>Ambulatory setting only – clinical summaries.</u> Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, the following data elements: provider’s name and office contact information; date and location of visit; reason for visit; patient’s name; gender; race; ethnicity; date of birth; preferred language; smoking status; vital signs and any updates; problem list and any updates; medication list and any updates; medication allergy list and any updates; immunizations and/or medications administered during the visit; procedures performed during the visit; laboratory tests and values/results, including any tests and values/results pending; clinical instructions; care plan, including goals and instructions; recommended patient decision aids (if applicable to the visit); future scheduled tests; future appointments; and referrals to other providers. If the clinical summary is provided electronically, it must be:</p> <ul style="list-style-type: none"> (i) Provided in human readable format; and (ii) Provided in a summary care record formatted according to the standard adopted at § 170.205(a)(3) with the following data elements expressed, where applicable, according to the specified standard(s): <ul style="list-style-type: none"> (A) <u>Race and ethnicity.</u> The standard specified in § 170.207(f); (B) <u>Preferred language.</u> The standard specified in § 170.207(j); (C) <u>Smoking status.</u> The standard specified in § 170.207(l); (D) <u>Problems.</u> At a minimum, the version of the standard specified in § 170.207(a)(3); (E) <u>Encounter diagnoses.</u> The standard specified in § 170.207(m); (F) <u>Procedures.</u> The standard specified in § 170.207(b)(2) or § 170.207(b)(3); (G) <u>Laboratory test(s).</u> At a minimum, the version of the standard specified in § 170.207(g); (H) <u>Laboratory value(s)/result(s).</u> The value(s)/results of the laboratory test(s) performed; and (I) <u>Medications.</u> At a minimum, the version of the standard specified in § 170.207(h). <p>Standards § 170.205(a)(3) (Consolidated CDA); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT® International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release)</p>	<p>Revise to reflect new standards for problem lists and other vocabulary standards. No change to summary record standards discussed. LOINC where available ICD-10 RxNorm SNOMED CT</p>

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13	<p><u>Patient-specific education resources</u>. Enable a user to electronically identify and provide patient-specific education resources according to:</p> <p>(i) At a minimum, each one of the data elements included in the patient's: problem list; medication list; and laboratory tests and values/results; and</p> <p>(ii) The standard specified at § 170.204(b)(1).</p> <p>Standard § 170.204(b)(1) (HL7 Context-Aware Knowledge Retrieval (Infobutton) Standard, International Normative Edition 2010)</p>	<p>No revisions required to support HITPC proposed MU Stage 2 objective and measure.</p> <p>Workgroup Note ONC should consider removing the redundancy at the end of the sentence (i.e., “as well as provide such resources to the patient”).</p>
14	<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 and EHR technology 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> <p>Standard § 170.210(f) Any encryption and hashing algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2.</p> <ul style="list-style-type: none"> Preamble: “Additionally, we are proposing, consistent with the HITSC’s recommendations, that methods for meeting this certification criterion could include, but would not be limited to, designing EHR technology to meet the following standards: IETF RFC 2246 (TLS 1.0) and SMTP/SMIME as well as implementation specifications such as NIST Special Publication 800-52 (“Guidelines for the Selection and Use of TLS Implementations”) and specifications developed as part of nationwide health information network initiatives.” 	<p>(ambulatory setting) <u>Secure messaging</u>. Enable a user to electronically:</p> <p>(1) Send a secure message to a patient; and</p> <p>(2) Receive a secure message from a patient.</p> <p>Workgroup Note Need secure definition included in here from security requirements.</p> <p><u>Privacy and Security Workgroup</u></p> <p>EHR must provide the capability to send messages to, and receive messages from, patients using a mechanism that assures that (1) the identity of the patient is authenticated; (2) the identity of the EHR is authenticated; and (3) message content is encrypted and integrity protected.</p> <p>EXAMPLE STANDARDS: FIPS Pub 140-2, Annex A; IETF RFC 2246 (TLS 1.0); SMTP/SMIME</p> <p>IS: NIST SP 800-52 (TLS); NwHIN Transport Specifications</p>

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15	<p><u>Clinical information reconciliation</u>. Enable a user to electronically reconcile the data elements 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"> (i) Electronically display the data elements from two or more sources in a manner that allows a user to view the data elements and their attributes, which must include, at a minimum, the source and last modification date. (ii) Enable a user to merge and remove individual data elements. (iii) Enable a user to review and validate the accuracy of a final set of data elements and, upon a user’s confirmation, automatically update the list. 	No revisions required to support HITPC proposed MU Stage 2 objective and measure.

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16	<p>(b)(1) <u>Transitions of care – incorporate summary care record.</u> Upon receipt of a summary care record formatted according to the standard adopted at § 170.205(a)(3), electronically incorporate, at a minimum, the following data elements: Patient name; gender; race; ethnicity; preferred language; date of birth; smoking status; vital signs; medications; medication allergies; problems; procedures; laboratory tests and values/results; the referring or transitioning provider’s name and contact information; hospital admission and discharge dates and locations; discharge instructions; reason(s) for hospitalization; care plan, including goals and instructions; names of providers of care during hospitalization; and names and contact information of any additional known care team members beyond the referring or transitioning provider and the receiving provider.</p> <p>(b)(2) <u>Transitions of care – create and transmit summary care record.</u></p> <p>(i) Enable a user to electronically create a summary care record formatted according to the standard adopted at § 170.205(a)(3) and that includes, at a minimum, the following data elements expressed, where applicable, according to the specified standard(s):</p> <p>(A) Patient name; gender; date of birth; medication allergies; vital signs; laboratory tests and values/results; the referring or transitioning provider’s name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; care plan, including goals and instructions;</p> <p>(B) <u>Race and ethnicity.</u> The standard specified in § 170.207(f);</p> <p>(C) <u>Preferred language.</u> The standard specified in § 170.207(j);</p> <p>(D) <u>Smoking status.</u> The standard specified in § 170.207(1);</p> <p>(E) <u>Problems.</u> At a minimum, the version of the standard specified in § 170.207(a)(3);</p> <p>(F) <u>Encounter diagnoses.</u> The standard specified in § 170.207(m);</p> <p>(G) <u>Procedures.</u> The standard specified in § 170.207(b)(2) or § 170.207(b)(3);</p> <p>(H) <u>Laboratory test(s).</u> At a minimum, the version of the standard specified in § 170.207(g);</p> <p>(I) <u>Laboratory value(s)/result(s).</u> The value(s)/results of the laboratory test(s) performed;</p> <p>(J) <u>Medications.</u> At a minimum, the version of the standard specified in § 170.207(h); and</p> <p>(K) <u>Inpatient setting only.</u> Hospital admission and discharge dates and location; names of providers of care during hospitalization; discharge instructions; and reason(s) for hospitalization.</p> <p>(ii) <u>Transmit.</u> Enable a user to electronically transmit the summary care record created in paragraph (i) in accordance with:</p> <p>(A) The standards specified in § 170.202(a)(1) and (2).</p> <p>(B) <u>Optional.</u> The standard specified in § 170.202(a)(3).</p> <p>Standards § 170.205(a)(3) (Consolidated CDA); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(1) (smoking status types); § 170.207(a)(3) (SNOMED-CT® International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release); and § 170.202(a)(1) (Applicability Statement for Secure Health Transport); § 170.202(a)(2) (XDR and XDM for Direct Messaging); and § 170.202(a)(3) (SOAP-Based Secure Transport RTM version 1.0)</p>	<p><u>Exchange clinical information and patient summary of care record.</u></p> <p>(1) <i>Electronically record and transmit.</i> Enable a user to electronically record and transmit a patient summary of care record which includes, at a minimum, diagnostic test results, problem lists, medication lists, medication allergy list, procedures, care plans and patient instructions.</p> <p>(2) <i>Electronically receive and display.</i> Electronically receive and display a patient summary of care record which includes, at a minimum, diagnostic tests results, problem list, medication list, medication allergy list, procedures, care plans and patient instructions. [Include only if there is an alternative to the standard: Upon receipt of a patient summary of care record formatted according to the alternative standard, enable a user to review it in human readable format.]</p> <p>Workgroup Statement on Intent/Standards The data that is transmitted is in accordance with: (i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and (ii) For the following data elements the applicable standard must be used: (A) <i>Problems.</i> The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2); (B) <i>Procedure.</i> The standard specified in §170.207(b)(1) or §170.207(b)(2); (B) (C) <i>Laboratory test results.</i> At a minimum, the version of the standard specified in §170.207(c); and (C) (D) <i>Medications.</i> The standard specified in §170.207(d).</p> <p>No change to summary record standards discussed. Changes to vocabs would generally be reflective of changes elsewhere. LOINC where available ICD-10 RxNorm SNOMED CT</p>

Row	ONC Proposed 2014 Edition EHR Certification Criteria and Standards/Implementation Specifications	HITSC Recommended Certification Criteria and Standards/Implementation Specifications
17	<p>(f)(1) <u>Immunization information</u>. Enable a user to electronically record, change, and access immunization information.</p> <p>(f)(2) <u>Transmission to immunization registries</u>. Enable a user 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(i).</p> <p>Standards and Implementation Specifications § 170.205(e)(3) (HL7 2.5.1 and Implementation Guide for Immunization Messaging Release 1.3); and § 170.207(i) (CVX code set: August 15, 2011 version)</p> <ul style="list-style-type: none"> (f)(1) “Immunization information” is identified as an “unchanged” certification criterion. 	<p>ONC may consider splitting out submission if it would provide flexibility as follows:</p> <ol style="list-style-type: none"> 1. Electronically record, modify and retrieve immunization information in accordance with ... 2. Electronically submit immunization information in accordance with... <p>Per HITSC Surveillance Power Team move to solely HL7 2.5.1</p>
18	<p>(f)(5) <u>Inpatient setting only – reportable laboratory tests and values/results</u>. Enable a user to electronically record, change, and access reportable clinical laboratory tests and values/results.</p> <p>(f)(6) <u>Inpatient setting only – transmission of reportable laboratory tests and values/results</u>. Enable a user 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 § 170.207(g).</p> <p>Standards and Implementation Specifications § 170.205(g) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with errata); § 170.207(a)(3) (SNOMED CT® International Release January 2012); and § 170.207(g) (LOINC version 2.38)</p> <ul style="list-style-type: none"> (f)(5) “Inpatient setting only – reportable laboratory tests and values/results” is identified as an “unchanged” certification criterion. 	<p>ONC may consider splitting out submission if it would provide flexibility as follows:</p> <ol style="list-style-type: none"> 1. Electronically record, modify and retrieve reportable lab results information in accordance with ... 2. Electronically submit reportable lab results information in accordance with... <p>Maintain current standard and implementation guide. Vocab is LOINC when available.</p>

Row	ONC Proposed 2014 Edition EHR Certification Criteria and Standards/Implementation Specifications	HITSC Recommended Certification Criteria and Standards/Implementation Specifications
19	<p>(f)(3) <u>Public health surveillance</u>. Enable a user to electronically record, change, and access syndrome-based public health surveillance information.</p> <p>(f)(4) <u>Transmission to public health agencies</u>. Enable a user to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:</p> <p>(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).</p> <p>(ii) <u>Inpatient setting only</u>. The standard (and applicable implementation specifications) specified in § 170.205(d)(3).</p> <p>Standards and Implementation Specifications § 170.205(d)(2) (HL7 2.5.1) and § 170.205(d)(3) (HL7 2.5.1 and the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data HL7 Version 2.5.1)</p> <ul style="list-style-type: none"> (f)(3) “Public health surveillance” is identified as an “unchanged” certification criterion. 	<p>ONC may consider splitting out submission if it would provide flexibility as follows:</p> <ol style="list-style-type: none"> 1. Electronically record, modify and retrieve syndrome-based public health surveillance information in accordance with ... 2. Electronically submit syndrome-based public health surveillance information in accordance with... <p>Per HITSC Surveillance Power Team: (1) move to solely HL7 2.5.1. (2) Use Hospital Implementation Guide currently in final development for inpatient setting</p>

Row	ONC Proposed 2014 Edition EHR Certification Criteria and Standards/Implementation Specifications	HITSC Recommended Certification Criteria and Standards/Implementation Specifications
20	<p><u>Authentication, access control, and authorization.</u></p> <p>(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</p> <p>(ii) Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in (d)(1)(i), and the actions the user is permitted to perform with the EHR technology.</p> <ul style="list-style-type: none"> • Identified as an “unchanged” certification criterion. • Merged capabilities in §§ 170.302(o) and 170.302(t) for the 2014 Edition EHR certification criterion. • Preamble: “We also acknowledge, as recommended by the HITSC, that example standards and implementation specifications which could be followed in designing EHR technology to meet this certification criterion could include, but are not limited to: NIST Special Publication 800-63, Level 2 (single-factor authentication) and ASTM, E1986-09 (Information Access Privileges to Health Information).” 	<p><i>Access Control</i> No revisions required to support HITPC proposed MU Stage 2 objective and measure.</p> <p><u>Privacy and Security Workgroup</u></p> <p>IS: ASTM, E1986-09 (Information Access Privileges To Health Information)</p> <p><i>Authentication</i> No revisions required to support HITPC proposed MU Stage 2 objective and measure.</p> <p><u>Privacy and Security Workgroup</u></p> <p>(1) <u>Person Authentication.</u> EHR must be able to authenticate human users who assert an identity and present at least one proof of that identity.</p> <p>(2) <u>Entity Authentication.</u> EHR technology must authenticate the identity of external entities before sending any electronic health information to them, or receiving any electronic health information from them.</p> <p>STANDARD: NIST SP 800-63, Level 2 (single-factor authentication); ITU-T X.509</p>

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21	<p><u>Auditable events and tamper-resistance.</u></p> <ul style="list-style-type: none"> (i) <u>Enabled by default.</u> The capability specified in paragraph (d)(2)(ii) must be enabled by default (i.e., turned on) and must only be permitted to be disabled (and re-enabled) by a limited set of identified users. (ii) <u>Record actions.</u> Record actions related to electronic health information, audit log status and, as applicable, encryption of end-user devices in accordance with the standard specified in § 170.210(e). (iii) <u>Audit log protection.</u> Actions recorded in accordance with paragraph (d)(2)(ii) must not be capable of being changed, overwritten, or deleted. (iv) <u>Detection.</u> Detect the alteration of audit logs. <p>Standard</p> <p>§ 170.210(e) <u>Record actions related to electronic health information, audit log status, and encryption of end-user devices.</u></p> <ul style="list-style-type: none"> (1) When EHR technology is used to record, create, change, access, or delete electronic health information, the following information must be recorded: <ul style="list-style-type: none"> (i) The electronic health information affected by the action(s); (ii) The date and time each action occurs in accordance with the standard specified at § 170.210(g); (iii) The actions(s) that occurred; (iv) Patient identification; and (v) User identification. (2) When the audit log is enabled or disabled, the following must be recorded: <ul style="list-style-type: none"> (i) The date and time each action occurs in accordance with the standard specified at § 170.210(g); and (ii) User identification. (3) As applicable, when encryption of electronic health information managed by EHR technology on end-user devices is enabled or disabled, the following must be recorded: <ul style="list-style-type: none"> (i) The date and time each actions occurs in accordance with the standard specified at § 170.210(g); and (ii) User identification. <ul style="list-style-type: none"> • Preamble: “As for the two recommended versions of the certification criterion, we propose a certification criterion that combines both recommended versions.” • Preamble: “Finally, we acknowledge, as recommended by the HITSC, that an example implementation specification which could be followed in designing EHR technology to meet these certification criteria could include, but is not limited to ASTM E2147-01, Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems.” • Please see the preamble of the proposed rule for further discussion. 	<p><u>Auditable events and tamper-resistance.</u></p> <ul style="list-style-type: none"> (1) <u>Record actions.</u> Record actions related to electronic health information in accordance with the standard specified in §170.210(b). (2) <u>Read-only.</u> Actions must be recorded in read-only format. (3) <u>Detection.</u> Detect the alteration of audit logs. <p><u>Privacy and Security Workgroup</u></p> <p><u>Activity auditing.</u></p> <ul style="list-style-type: none"> (1) <u>Detect and record auditable events.</u> (a) EHR must be able to detect auditable events. (b) EHR must be able to record information about security-relevant events, in accordance with the standard specified in §170.210(b). (2) <u>Protect audit information.</u> (a) EHR must assure that audit data cannot be modified, overwritten, or deleted. (b) EHR must be able to detect attempts to alter audit data. <p>STANDARD: Record audit data about security-relevant events.</p> <p>IS: ASTM E2147-01, Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems.</p>
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Row	ONC Proposed 2014 Edition EHR Certification Criteria and Standards/Implementation Specifications	HITSC Recommended Certification Criteria and Standards/Implementation Specifications
22	<p><u>Audit report(s)</u>. 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 elements specified in the standard at § 170.210(e).</p> <p>Standard § 170.210(e) <u>Record actions related to electronic health information, audit log status, and encryption of end-user devices.</u></p> <p>(4) When EHR technology is used to record, create, change, access, or delete electronic health information, the following information must be recorded:</p> <ul style="list-style-type: none"> (i) The electronic health information affected by the action(s); (ii) The date and time each action occurs in accordance with the standard specified at § 170.210(g); (iii) The actions(s) that occurred; (iv) Patient identification; and (v) User identification. <p>(5) When the audit log is enabled or disabled, the following must be recorded:</p> <ul style="list-style-type: none"> (i) The date and time each action occurs in accordance with the standard specified at § 170.210(g); and (ii) User identification. <p>(6) As applicable, when encryption of electronic health information managed by EHR technology on end-user devices is enabled or disabled, the following must be recorded:</p> <ul style="list-style-type: none"> (i) The date and time each actions occurs in accordance with the standard specified at § 170.210(g); and (ii) User identification. 	<p><u>Generate audit report(s)</u>. Enable a user to generate an audit report for a specific time period and to sort entries in the audit log according to any of the elements specified in the standard at 170.210(b).</p> <p><u>Privacy and Security Workgroup</u></p> <p><u>Generate audit report(s)</u>. EHR must enable a user to generate an audit report for a specific time period and to sort entries in the audit log according to any of the elements specified in the standard at 170.210(b).</p> <p>STANDARD: Record audit data about security-relevant events.</p> <p>IS: ASTM E2147-01, Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems.</p>

Row	ONC Proposed 2014 Edition EHR Certification Criteria and Standards/Implementation Specifications	HITSC Recommended Certification Criteria and Standards/Implementation Specifications
23	<p><u>Amendments.</u></p> <p>(i) Enable a user to electronically amend a patient’s health record to:</p> <p>(A) Replace existing information in a way that preserves the original information; and</p> <p>(B) Append patient supplied information, in free text or scanned, directly to a patient’s health record or by embedding an electronic link to the location of the content of the amendment.</p> <p>(ii) Enable a user to electronically append a response to patient supplied information in a patient’s health record.</p> <ul style="list-style-type: none"> • We requested public comment on whether EHR technology should be required to be capable of appending patient supplied information in both free text and scanned format or only one or these methods, to be certified to this proposed certification criteria. • Please see the preamble for further discussion. 	<p><u>Amendments.</u></p> <p>(1) Enable a user to electronically amend a data element or health record:</p> <p>a. To replace an existing data element or health record. These types of amendments must be recorded in a way that preserves the original information.</p> <p>b. To append patient supplied information, in free text or scanned image/document. These types of amendments must:</p> <p>i. Directly associate with the data element or health record that is to be amended; or</p> <p>ii. Provide an electronic link to or information about the location of the content of the amendment.</p> <p>(2) Enable a user to electronically append to a disputed data element or health record a formal rebuttal (authored by the user’s organization).</p> <p>(3) Make electronically available, upon a user’s request, a historical account of amendment(s).</p> <p><u>Privacy and Security Workgroup</u></p> <p>(1) EHR must provide the capability for an authorized provider to amend health information, while preserving the integrity of the data originally recorded in the health record.</p> <p>(2) EHR must provide the capability to attach to health information: (a) patient-asserted information, or an electronic link to patient-asserted information; and (b) a provider’s formal rebuttal to patient-asserted information.</p> <p>(3) EHR must maintain an audit trail of the amendments to health information (1 and 2 above).</p>

Row	ONC Proposed 2014 Edition EHR Certification Criteria and Standards/Implementation Specifications	HITSC Recommended Certification Criteria and Standards/Implementation Specifications
24	<p><u>Automatic log-off</u>. Terminate an electronic session after a predetermined time of inactivity.</p> <ul style="list-style-type: none"> Identified as an “unchanged” certification criterion. Preamble: “We are not revising or refining this certification criterion as part of the proposed 2014 Edition EHR certification criteria, but are clarifying that to terminate a session should not be confused with locking a session, where access to an active session is permitted after re-authentication. EHR technology must have the capability to terminate the session, including terminating the network connection.” 	<p>No revisions required to support HITPC proposed MU Stage 2 objective and measure.</p> <p>NOTE - Clarify whether intent is to “terminate” (end session) or “lock” (re-authenticate to access an active session)? Stage 1 test procedure was developed with termination in mind.</p> <p><u>Privacy and Security Workgroup</u></p> <p>(1) EHR must be able to initiate a session lock after a designated period of inactivity or upon receiving a request from a user. (2) Once a session has been locked, EHR must retain the session lock until the user reestablishes access using an authorized identifier and authenticator. (3) EHR must be able to terminate an electronic session (i.e., automatically log a user off) after an established period of inactivity. (4) EHR must provide the capability for a system administrator to set time periods for electronic session locking and termination.</p> <p>IS: NIST SP 800-53, Rev 3</p>
25	<p><u>Emergency access</u>. Permit an identified set of users to access electronic health information during an emergency.</p> <ul style="list-style-type: none"> Identified as an “unchanged” certification criterion. Preamble: “We are refining the 2011 Edition EHR certification criterion for emergency access codified at § 170.302(p) for the 2014 Edition EHR certification criteria by removing the parenthetical “who are authorized for emergency situations” from the certification criterion and including the phrase “identified set of users” to more clearly convey this certification criterion’s intent and to consistently use this phrase through every certification criterion where we intend for the same capability to be available. The purpose of this criterion is to provide certain users (“identified set of users”) with the ability to override normal access controls in the case of an emergency. The refinement to the criterion coupled with our explanation should provide sufficient clarity for testing and certifying to this certification criterion.” 	<p>No revisions required to support HITPC proposed MU Stage 2 objective and measure.</p>

Row	ONC Proposed 2014 Edition EHR Certification Criteria and Standards/Implementation Specifications	HITSC Recommended Certification Criteria and Standards/Implementation Specifications
26	<p><u>Encryption of data at rest.</u> Paragraph (d)(7)(i) or (d)(7)(ii) must be met to satisfy this certification criterion.</p> <p>(i) If EHR technology manages electronic health information on an end-user device and the electronic health information remains stored on the device after use of the EHR technology on that device has stopped, the electronic health information must be encrypted in accordance with the standard specified in § 170.210(a)(1). This capability must be enabled by default (i.e., turned on) and must only be permitted to be disabled (and re-enabled) by a limited set of identified users.</p> <p>(ii) Electronic health information managed by EHR technology never remains stored on end-user devices after use of the EHR technology on those devices has stopped.</p> <ul style="list-style-type: none"> • Preamble: “We did not include “decrypt” in the proposed certification criterion because we believe that the critical capability to require for certification is the act of encryption after use of the EHR technology on the end-user device has stopped. We presume that EHR technology developers would also include the capability to decrypt the electronic health information, when appropriate; otherwise subsequent use or access to the data would not be possible.” • Preamble: “As noted in the guidance provided by the HHS Office for Civil Rights, NIST Special Publication (SP) 800-111 serves as a resource to guide how encryption should be applied to end-user devices.” • Please see the preamble of the proposed rule for further discussion. 	<p>No revisions required to support HITPC proposed MU Stage 2 objective and measure.</p> <p>Annex A of FIPS 140-2</p> <p>Update as necessary for FIPS 140-3</p> <p>Privacy and Security Workgroup</p> <p><u>General encryption.</u> EHR must be able to encrypt and decrypt electronic health information in accordance with the standard specified in §170.210(a)(1).</p> <p><u>(1) Data-at-rest encryption.</u> EHR technology whose functionality includes the capability to manage electronic PHI on end-user device storage must be able to encrypt and decrypt data persisted on those end-user devices.</p> <p>STANDARD: FIPS Pub 140-2, Annex A [No change from Stage 1; FIPS Pub 140-3 is still in draft so we believe it would be premature to specify as the standard]</p> <p>IS: NIST SP 800-111</p>
27	<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> <p>Standard § 170.210(c) (verification that electronic health information has not been altered)</p> <ul style="list-style-type: none"> • Identified as an “unchanged” certification criterion. • See the proposed certification criterion for “auditable events and tamper resistance” at § 170.314(d)(2) for the “detection” capability. • Based on consultations with NIST, we determined it was appropriate to request public comment on moving from SHA-1 to SHA-2. See preamble discussion. 	<p><u>Integrity.</u></p> <p>(1) Create a message digest in accordance with the standard specified in 170.210(c).</p> <p>(2) 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> <p>Current standard requires A hashing algorithm with a security strength equal to or greater than SHA-1 as specified by NIST in FIPS PUB 180-3 – suggest replacing SHA-1 with SHA-2</p> <p>Privacy and Security Workgroup</p> <p>STANDARD: Change to “SHA-1, or SHA-1 plus SHA-2”</p>

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28	<p><u>Optional – accounting of disclosures.</u></p> <ul style="list-style-type: none"> Identified as an “unchanged” certification criterion. We request public comment on a variety of topics regarding this certification criterion. See section V.B “2014 Edition EHR Accounting of Disclosures Certification Criterion” of the preamble of the proposed rule. 	No recommendation.
29	<p><u>Inpatient setting only – advance directives.</u> Enable a user to electronically record whether a patient has an advance directive.</p> <ul style="list-style-type: none"> Identified as an “unchanged” certification criterion. 	<p>Inpatient and Ambulatory</p> <p><u>Advance directives.</u> Enable a user to electronically:</p> <ol style="list-style-type: none"> Record whether a patient has an advance directive; Store an advance directive; and Provide access to a copy of the advance directive in human readable format. <p>Workgroup Statement on Intent: We expect that the EHR would be capable of recording and storing historical advance directives as well as the current version. We consider scanned images and similar non- structured electronic files acceptable formats for this requirement. Furthermore the copy provided does not have to be in a structured format.</p>
30	<p><u>Imaging.</u> Electronically indicate to a user the availability of a patient’s images and/or narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable immediate electronic access to such images and narrative interpretations.</p>	N/A
31	<p><u>Family health history.</u> Enable a user to electronically record, change, and access a patient’s family health history.</p>	N/A
32	See Rows 2A and 2B.	See Rows 2A and 2B.

Row	ONC Proposed 2014 Edition EHR Certification Criteria and Standards/Implementation Specifications	HITSC Recommended Certification Criteria and Standards/Implementation Specifications
33	See Row 19.	See Row 19.
34	<p>(f)(7) <u>Ambulatory setting only – cancer case information</u>. Enable a user to electronically record, change, and access cancer case information.</p> <p>(f)(8) <u>Ambulatory setting only – transmission to cancer registries</u>. Enable a user to electronically create cancer case information for electronic transmission in accordance with:</p> <ul style="list-style-type: none"> (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 § 170.207(g). <p>Standards and Implementation Specifications § 170.205(i) (HL7 CDA, Release 2 and Implementation Guide for Healthcare Provider Reporting to Central Cancer Registries, Draft, February 2012); § 170.207(a)(3) (SNOMED CT® International Release January 2012); and § 170.207(g) (LOINC version 2.38)</p>	N/A
35	N/A	N/A
36	<u>Automated numerator recording</u> . For each meaningful use objective with a percentage-based measure, electronically record the numerator.	N/A
37	<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.	No recommended revisions.
38	<p><u>Non-percentage-based measure use report</u>.</p> <ul style="list-style-type: none"> (i) For each capability included in EHR technology that is also associated with a meaningful use objective and measure that is not percentage based, electronically record the date and time in accordance with the standard specified at § 170.210(g) when the capability was enabled, disabled, and/or executed. (ii) Enable a user to electronically create a report of the information recorded as part of paragraph (g)(3)(i). <p>Standard § 170.210(g) (synchronized clocks)</p>	N/A

Row	ONC Proposed 2014 Edition EHR Certification Criteria and Standards/Implementation Specifications	HITSC Recommended Certification Criteria and Standards/Implementation Specifications
39	<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); § 170.314(a)(2); § 170.314(a)(6); § 170.314(a)(7); § 170.314(a)(8); § 170.314(a)(17); § 170.314(b)(3); and § 170.314(b)(4).</p>	N/A
40	<p>(c)(1) <u>Clinical quality measures – capture and export</u>.</p> <p>(i) <u>Capture</u>. Electronically record all of the data elements that are represented in the standard specified in § 170.204(c).</p> <p>(ii) <u>Export</u>. Electronically export a data file that includes all of the data elements that are represented in the standard specified in § 170.204(c).</p> <p>(c)(2) <u>Clinical quality measures – incorporate and calculate</u>.</p> <p>(i) <u>Incorporate</u>. Electronically incorporate all of the data elements necessary to calculate each of the clinical quality measures included in the EHR technology.</p> <p>(ii) <u>Calculate</u>. Electronically calculate each clinical quality measure that is included in the EHR technology.</p> <p>(c)(3) <u>Clinical quality measures – reporting</u>. Enable a user to electronically create for transmission clinical quality measurement results in a data file defined by CMS.</p> <p>Standard § 170.204(c) (NQF Quality Data Model)</p>	No recommended certification criteria. ONC should consult with CMS as appropriate.

Row	ONC Proposed 2014 Edition EHR Certification Criteria and Standards/Implementation Specifications	HITSC Recommended Certification Criteria and Standards/Implementation Specifications
41	<p><u>Electronic notes</u>. Enable a user to electronically record, change, access, and search electronic notes.</p>	<p><u>Electronic notes</u> Enable a user to electronically record, retrieve, and search a physician, physician assistant, or nurse practitioner’s note.</p> <p>Workgroup Note Defer final definition for “eligible hospital days” to CMS. Potential “eligible hospital days” definition: The number of days of care charged to a beneficiary for inpatient hospital care services is always in units of full days. A day begins at midnight and ends 24 hours later. The midnight-to-midnight method is to be used in counting days of care for Medicare reporting purposes.</p> <p>Consideration/clarification: Does the definition need to be broadened to support the ED treat and release patients? Patients discharged from the ED should probably use a per visit measurement methodology</p> <p>Per the Meaningful Use Workgroup, free text is fine. It just cannot be scanned. So we do not need a detailed standard for the note structure. It could be a visit note, progress note, admit note, consult note, or any other similar clinical note.</p>
42	<p><u>Inpatient setting only – transmission of electronic laboratory tests and values/results to ambulatory providers</u>. Enable a user to electronically create laboratory tests and values/results for electronic transmission in accordance with: (i) The standard (and applicable implementation specifications) specified in § 170.205(k); and (ii) At a minimum, the version of the standard specified in § 170.207(g).</p> <p>Standards and Implementation Specifications § 170.205(k) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Lab Results Interface, Release 1 (US Realm); and § 170.207(g) (LOINC version 2.38)</p>	<p>(inpatient setting) <u>Send laboratory test results</u>. Electronically send clinical laboratory test results to outpatient providers using the specified standard.</p> <p>ONC should consider the S&I-referenced LRI Implementation Guide</p> <p>Workgroup Statement on Intent: The included results in the denominator are only those lab test results completed for outpatient services and excludes the results generated for inpatient services. Similarly, the denominator should include all those test results that are electronically entered into the hospital lab system, either through electronic submission from the outpatient provider or manually entered into the electronic lab system by the hospital employee. The denominator would exclude any lab services provided as third party or outsources services to other hospitals or similar entities.</p>

Row	ONC Proposed 2014 Edition EHR Certification Criteria and Standards/Implementation Specifications	HITSC Recommended Certification Criteria and Standards/Implementation Specifications
43	<p><u>Problem list</u>. Enable a user to electronically record, change, and access a patient’s problem list for longitudinal care in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3).</p> <p>Standards § 170.207(a)(3) (SNOMED CT® International Release January 2012)</p> <ul style="list-style-type: none"> • The rule proposes only SNOMED CT® (not ICD-9-CM or ICD-10-CM). • See the preamble of the proposed rule for discussion of “longitudinal care.” 	<p>Revise to replace ICD-9-CM with ICD-10-CM contingent on the implementation date for ICD-10-CM remains October 1, 2013 and is not delayed. Maintain SNOMED CT with appropriate version.</p> <p>Workgroup Note Need a clear definition for longitudinal care. Patient-centric definition should reflect longitudinal care across the continuum of care in both ambulatory (multiple encounters) and inpatient (multiple hospitalizations).</p> <p>Definition is used in rows 43, 44, and 45.</p>
44	<p><u>Medication list</u>.</p> <ul style="list-style-type: none"> • Identified as an “unchanged” certification criterion. 	<p>No revisions required to support HITPC proposed MU Stage 2 objective and measure.</p>
45	<p><u>Medication allergy list</u>.</p> <ul style="list-style-type: none"> • Identified as an “unchanged” certification criterion. 	<p>No revisions required to support HITPC proposed MU Stage 2 objective and measure.</p> <p>Workgroup Statement on Intent We recognize that an EHR will likely include both medication allergies and adverse medication reaction information in the same location. We are assuming that both types of information are included in this requirement.</p>
46	<p>No proposed certification criterion. Please see the preamble discussion in the proposed rule for the “patient reminders” certification criterion.</p>	<p>(ambulatory setting) <u>Patient communication medium preference</u>. Enable a user to electronically record, modify, and retrieve the patient’s communication medium preference.</p> <p>Workgroup Note</p> <ul style="list-style-type: none"> • No known communication medium standard. • Should we include examples of communication medium (e.g., paper, email, PHR or portal)? • Preferred language is captured under demographics (§ 170.304(c)) • Patient reminders are to be according to patient preferences (§ 170.304(d)), but the patient’s preferred communication medium is not currently required to be recorded.

Row	ONC Proposed 2014 Edition EHR Certification Criteria and Standards/Implementation Specifications	HITSC Recommended Certification Criteria and Standards/Implementation Specifications
47	<ul style="list-style-type: none"> Preamble: “Additionally, because we have proposed requiring the capability to perform transmissions in accordance with these transport standards (which provide for encryption and integrity protection) in this criterion [“view, download, and transmit to 3rd party”] and in the “transitions of care – create and transmit summary care record” certification criterion, we have determined that it is not necessary to include in the 2014 Edition EHR certification criteria the “encrypting when exchanging” certification criterion adopted in the 2011 Edition EHR certification criteria (§ 170.302(v)). We believe that to include the 2011 Edition EHR certification criterion would be redundant and that our proposed approach more explicitly ties security to a particular transmission.” Please also see the proposed “secure messaging” certification criterion at § 170.314(e)(3). 	<p>No revisions required to support HITPC proposed MU Stage 2 objective and measure.</p> <p>Privacy and Security Workgroup</p> <p><u>Encryption when exchanging electronic health information.</u> EHR technology must assure that all health information exchanged with external entities is encrypted and integrity-protected. Maintain current standard.</p> <p>STANDARDS: FIPS Pub 140-2, Annex A; IETF RFC 2246 (TLS 1.0); IETF RFC 2401 (IPsec)</p> <p>IS: NIST SP 800-52 (TLS); NIST SP 800-77 (IPsec VPN); NIST SP 800-113 (SSL VPN); other transport or network layer protocols validated i.a.w. FIPS Pub 140-2</p> <p>NwHIN transport standards</p>
48	See Row 11 (“view, download, and transmit to 3 rd party” certification criterion).	<p>These capabilities are recommended to be incorporated into the certification criterion in Row 11 (“view, download, and transmit to 3rd party” certification criterion).</p> <p>Privacy and Security Workgroup</p> <p>EHR must be able to authenticate the identity of an authorized patient or their personal representative using single-factor authentication (or stronger) based on the standard specified.</p> <p>STANDARD: NIST SP 800-63, Level 2 (single-factor authentication)</p>
49	See Row 11 (“view, download, and transmit to 3 rd party” certification criterion).	<p>These capabilities are recommended to be incorporated into the certification criterion in Row 11 (“view, download, and transmit to 3rd party” certification criterion).</p> <p>Privacy and Security Workgroup</p> <p>Covered by general audit criteria.</p>

Row	ONC Proposed 2014 Edition EHR Certification Criteria and Standards/Implementation Specifications	HITSC Recommended Certification Criteria and Standards/Implementation Specifications
50	See Row 11 (“view, download, and transmit to 3 rd party” certification criterion).	<p>These capabilities are recommended to be incorporated into the certification criterion in Row 11 (“view, download, and transmit to 3rd party” certification criterion).</p> <p>Privacy and Security Workgroup</p> <p>EHR must be able to create and include data-provenance information with any health data downloaded by the patient (e.g., lab that reported test results) or sent to a patient’s PHR.</p>
51	See Row 11 (“view, download, and transmit to 3 rd party” certification criterion).	<p>These capabilities are recommended to be incorporated into the certification criterion in Row 11 (“view, download, and transmit to 3rd party” certification criterion).</p> <p>Privacy and Security Workgroup</p> <p>EHR must enable the patient to download a copy of his or her health information over a secured communication channel.</p>