## Certification Guidance for EHR Technology Developers
## Serving Health Care Providers Ineligible for
## Medicare and Medicaid EHR Incentive Payments

### I.      Background

The Medicare and Medicaid EHR Incentive Programs, authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, have driven significant electronic health record (EHR) adoption by health care providers eligible to receive incentive payments.  Eligible professionals and hospitals must demonstrate "meaningful use" of EHR technology that has been certified under the ONC HIT Certification Program to qualify for the Medicare and Medicaid EHR incentive payments.  Despite this progress, many other types of health care providers equally important to the care continuum are not eligible to receive EHR incentive payments under the HITECH Act (e.g., certain mental and behavioral health professionals, and certain professionals who practice in long-term and post-acute care settings). These "ineligible" types of providers routinely interact with health care providers who are eligible for EHR incentive payments and face policy and technology challenges unique to their settings.

### II.     Purpose

This guidance is meant to serve as a building block for federal agencies and stakeholders to use as they work with different communities to achieve interoperable electronic health information exchange. It identifies the 2014 Edition EHR certification criteria from the ONC HIT Certification Program that specifically focus on interoperability – to enable electronic health information to be both exchanged and subsequently used by recipients.[1] While these certification criteria were specifically adopted to support health care providers seeking to achieve meaningful use, we believe that they are generally applicable to

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[1] ONC follows the definition of "interoperability" provided by the Institute for Electrical and Electronics Engineering Computer Dictionary which defines interoperability to mean: "the ability of two or more systems or components to exchange information and to use the information that has been exchanged." See IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries (New York, NY: 1990).

many health care settings. In addition, the capabilities expressed by some of these certification criteria could, if implemented by both eligible and ineligible types of providers, open critical communication lines between eligible and ineligible health care providers in order to support broad health care goals, such as care coordination and reduced hospital readmissions.

## III.    Interoperability-focused 2014 Edition EHR Certification Criteria

The following 2014 Edition EHR certification criteria address several use cases for which interoperable health information exchange may be beneficial between eligible and ineligible health care providers as well as between ineligible health care providers and knowledge resources, clinical laboratories, and public health agencies. Health care providers eligible to receive incentive payments under the Medicare and Medicaid EHR Incentive Programs will, depending on the stage of meaningful use they seek to achieve, need to have EHR technology certified to these criteria. We encourage EHR technology developers serving ineligible health care providers to also seek certification to these criteria.

**Table 1**. The three certification criteria listed in Table 1 specifically support interoperable summary care record exchange – a fundamental capability necessary to enable care coordination across different health care settings. To further emphasize the importance of summary care record exchange, ONC will list EHR technology certified to all three of the certification criteria identified in Table 1 on the Certified Health IT Product List (CHPL)[2] with an added designation to indicate the EHR technology's ability to support interoperable summary care record exchange.

| 2014 Edition EHR Certification Criterion | Short Description[3] |
|---|---|
| **45 CFR §170.314(b)(1)** **45 CFR §170.314(b)(2)** Transitions of Care | These two certification criteria require EHR technology to be, at a minimum, capable of: A) electronically creating and receiving summary care records with a common data set in accordance with the Consolidated Clinical Document Architecture (CCDA) standard; and B) electronically exchanging in accordance with the Direct transport specification. |
| **45 CFR §170.314(b)(4)** Clinical Information Reconciliation | Require EHR technology to allow a user to electronically reconcile the data that represent a patient's active medication, problem, and medication allergy list. |

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[2]  The CHPL is located at http://oncchpl.force.com/ehrcert?q=chpl.
[3] For more information about these certification criteria and the standards adopted and included within them, please visit: http://www.healthit.gov/policy-researchers-implementers/meaningful-use-stage-2-0/standards-hub

**Table 2.** The following certification criteria represent other EHR capabilities that support different types of interoperability functions.

| 2014 Edition EHR Certification Criterion | Short Description[4] |
|---|---|
| **45 CFR §170.314(a)(8)** Clinical Decision Support | Provides the option for EHR technology to be certified to the HL7 Context-Aware Knowledge Retrieval Standard ("Infobutton") standard to electronically retrieve linked-referential clinical decision support information from content/knowledge resources. |
| **45 CFR §170.314(a)(15)** Patient-Specific Education Resources | Requires EHR technology to be able to use "Infobutton" standard to electronically retrieve patient-specific education from content/knowledge resources. |
| **45 CFR §170.314(b)(3)** E-Prescribing | Requires EHR technology to be capable of electronically creating prescriptions and prescription-related information and electronically transmitting such information using the NCPDP SCRIPT version 10.6; with medications represented in RxNorm. |
| **45 CFR §170.314(b)(5)** Incorporate Laboratory Tests and Values/Results | Requires EHR technology designed for an ambulatory setting to be capable of electronically receiving, incorporating, and displaying clinical laboratory tests and values/results in accordance with the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface (LRI) and with laboratory tests represented in LOINC®. |
| **45 CFR §170.314(b)(6)** Transmission of Electronic Laboratory Tests and Values/Results to Ambulatory Providers | Requires EHR technology designed for an inpatient setting to be able to generate laboratory test reports for electronic transmission to ambulatory provider's EHR systems in accordance with the HL7 Version 2.5.1 Implementation Guide: S&I Framework LRI and with laboratory tests represented in LOINC®. |
| **45 CFR §170.314 (b)(7)** Data Portability | Requires EHR technology to be able to electronically create a set of export summaries for all patients, formatted in accordance with the CCDA. |
| **45 CFR §170.314(c)(1)-(3)** Clinical Quality Measures | Requires EHR technology to be capable of capturing, exporting, importing, calculating, and electronically submitting the information necessary for clinical quality measures. |
| **45 CFR §170.314(e)(1)** View, Download, and Transmit to 3rd Party | Requires EHR technology to be capable of providing secure online access to health information for patients and authorized representatives to electronically view, download their health information in accordance with the CCDA standard, and transmit such information in accordance with the Direct transport specification. |
| **45 CFR §170.314(e)(2)** Clinical Summaries | Requires EHR technology to enable a user to create a clinical summary in accordance with the CCDA standard in order to provide it to a patient. |
| **45 CFR §170.314(f)(2)** Transmission to Immunization Registries | Requires EHR technology to be able to electronically generate immunization information for electronic transmission using the HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4, and using the HL7 Standard Code Set CVX - Vaccines Administered vocabulary standard. |
| **45 CFR §170.314(f)(3)** Transmit Syndromic Surveillance to Public Health Agencies | Requires EHR technology to be able to electronically generate syndromic surveillance information for electronic transmission to public health agencies using the HL7 2.5.1 standard and, for the inpatient setting, a specific implementation guide. |

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[4] For more information about these certification criteria and the standards adopted and included within them, please visit: http://www.healthit.gov/policy-researchers-implementers/meaningful-use-stage-2-0/standards-hub

| 2014 Edition EHR Certification Criterion | Short Description[4] |
|---|---|
| **45 CFR §170.314(f)(4)** Transmit Lab Results to Public Health Agencies | Requires EHR technology to be capable of electronically generating reportable laboratory test values and results information for electronic transmission to public health agencies using the HL7 Version 2.5.1 Implementation Guide for Electronic Laboratory Reporting to Public Health as well as SNOMED CT® and LOINC®. |
| **45 CFR §170.314 (f)(6)** Optional -Transmit to Cancer Registries | Requires EHR technology to be able to electronically generate cancer case information for electronic transmission using the HL7 Clinical Document Architecture, Release 2.0, Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries and SNOMED CT® and LOINC®. |

## IV.     Privacy and Security-focused 2014 Edition EHR Certification Criteria

Table 3 below references the adopted privacy and security-focused 2014 Edition EHR certification criteria. These certification criteria help assure that electronic health information is protected when it is stored and transmitted as well as that only authorized personnel can access the information. Many of these certification criteria are generally applicable to EHR technology developed for any setting.  Thus, we encourage EHR technology developers that serve ineligible health care providers to seriously consider seeking certification to these certification criteria when doing so for the interoperability-focused certification criteria referenced above in Tables 1 and 2.

**Table 3.**

| 2014 Edition EHR Certification Criterion | Short Description |
|---|---|
| **45 CFR §170.314(d)(1)** Authentication, Access Control, and Authorization | Requires EHR technology to be capable of authenticating a user, authorizing them, and establishing their ability to access electronic health |
| **45 CFR §170.314(d)(2)** Auditable Events and Tamper-Resistance | Requires EHR technology to be capable of: <br>• Recording user actions related to electronic health information in an audit log in addition to when the audit log or the encryption status of electronic health information locally stored on end user devices is disabled or enabled. <br>• Being set by default to record actions related to electronic health information in an audit log, and recording audit log status or encryption status. <br>• Only enabling specific users to disable an audit log, if possible. <br>• Protecting actions and statuses related to the recording of electronic health information, audit log status, and encryption status from being changed, overwritten, or deleted by the EHR technology. <br>• Detecting when the audit log has been altered. |
| **45 CFR §170.314(d)(3)** Audit Report(s) | Requires EHR technology to be capable of : <br>• Enabling a user to generate an audit report for a specific time period, and <br>• Sort entries in the audit log according to the data elements specified in the audit log content standard |

| 2014 Edition EHR Certification Criterion | Short Description |
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| **45 CFR §170.314(d)(4)** Amendments | Requires EHR technology to be capable of enabling a user to capture a patient's (accepted or denied) request for an amendment to their electronic health information. |
| **45 CFR §170.314(d)(5)** Automatic Log-Off. | Requires EHR technology to be capable of preventing a user from gaining further access to an electronic session after a predetermined time of inactivity. |
| **45 CFR §170.314(d)(6)** Emergency Access | Requires EHR technology to be able to permit an identified set of users to access electronic health information during an emergency. |
| **45 CFR §170.314(d)(7)** End-User Device Encryption | Requires EHR technology to be capable of encrypting electronic health information (following security standards from the National Institute of Standards and Technology) when it is designed to store such information on end-user devices after use on those devices stops. |
| **45 CFR §170.314(d)(8)** Integrity | Requires EHR technology to be able to use secure hashing standards to verify that electronic health information has not been altered. |
| **45 CFR §170.314(d)(9)** Optional – Accounting of Disclosures | Requires EHR technology to be able to record treatment, payment, and health care operations disclosures. 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. |