Summary of:
Rule Health Information Technology Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology

Issued by: United States Department of Health and Human Services

Effective Date of Final Rule: August 27, 2010

Summary: All information contained herein is paraphrased for condensing and ease of reading purposes for the reader by Diane Matthews, MHA, of Laser Logics, Inc. Healthcare Division. The original content of the ruling is complex and of nearly 70 pages. This condensed summary is only intended for ease of use and reference by the end reader. A complete and official legal edition posted by the Federal Register see the official print version or the official electronic version on GPO's Federal Digital System (FDsys.gov). The entire ruling is available at The Federal Register (July 28, 2010) entitled the daily journal of the United States government: *Rule health information technology: Initial set of standards, implementation specifications, and certification criteria for electronic health record technology.*

Source: http://www.federalregister.gov/articles/2010/07/28/2010-17210/health-information-technology-initial-set-of-standards-implementation-specifications-and

Important Note: All references in the content herein to "we" is taken from the Ruling specified above directly and means "US Department of Health and Human Services".

Questions: For questions and information of how this ruling impacts a qualified medical provider, feel free to contact Diane Matthews, MHA of Laser Logics, Inc. Healthcare Division. The mission of Laser Logics, Inc. Healthcare Division is to provide informative, technical solutions to healthcare entities in their endeavor to implement a certified electronic health record. Our service offerings provide healthcare entities with a "turn-key solution" as a value added reseller of SuiteMed IMS, hardware, networking, security, implementation, customization, billing, training, and on-going after sale support.

Information: For further government information contact Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology, 202-690-7151.

General and Ambulatory Certification Criteria Summary for EHRs (§ 170.302 and § 170.304)

The Secretary adopts the following general certification criteria for Complete EHRs or EHR Modules. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically, unless designated as optional, and in accordance with all applicable specifications adopted in this part:

1. **Drug-drug, drug-allergy interaction checks.**
   - Notifications. Automatically and electronically generate and indicate in real-time, notifications at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, and computerized provider order entry (CPOE).
   - Adjustments. Provide certain users with the ability to adjust notifications provided for drug-drug and drug-allergy interaction checks.
   - Drug-formulary checks. Enable a user to electronically check if drugs are in a formulary or preferred drug list.

   Note: Certified EHR Technology to perform drug-drug and drug-allergy checks based on medication list and medication allergy list information included within Certified EHR Technology as structured data. Certified EHR Technology may also store health information in scanned documents, images, and other non-interoperable non-computable formats and, consequently, do not expect Certified EHR Technology to be capable of reading or accessing the information in these other formats for the purposes of performing drug-drug and drug-allergy checks.

   Presently, drug-test checking is not a required capability for eligible professionals and eligible hospitals to use in order to successfully meet the requirements of meaningful use Stage 1.

2. **Maintain up-to-date problem list**. Enable a user to electronically record, modify, and retrieve a patient's problem list for longitudinal care in accordance with:

   - The standard specified in § 170.207(a)(1); or
   - At a minimum, the version of the standard specified in § 170.207(a)(2).

   Note: CPOE: Inclusion of CPOE in the certification criterion is meant to indicate that notifications should occur based on new medication orders, in addition to a patient's current medications and medication allergies, as they are being entered. We believe that notifications will occur during the order-entry workflow.

   Note: A Certified EHR Technology must **be capable of using ICD-9 or SNOMED-CT®** when an eligible professional or eligible hospital seeks to maintain an up-to-date problem list.

   Note: Billing Codes ICD-9-CM is primarily used for billing and administrative purposes. SNOMED-CT® supports more clinical descriptions of patient problems or conditions. The certification criterion specifies that ICD-9CM or SNOMED-CT® be included in Certified EHR Technologya.

   We are discouraging the use of free text for documenting problem lists since this will limit the usefulness of problem lists for clinical reminders, decision support and other patient safety and quality reporting.

   While its use is not precluded, we do not believe that it is necessary to adopt the Current Dental Terminology as a condition of certification for all Complete EHRs and EHR Modules.

   Most current EHR technology already includes the CPT-4 code sets.

3. **Maintain active medication list**. Enable a user to electronically record, modify, and retrieve a patient's active medication list as well as medication history for longitudinal care.

   Note: The term "retrieve" means the retrieval of information directly stored and managed by EHR Technology and that it does not mean the retrieval of information from external sources, unless explicitly stated otherwise. We also take this opportunity, in the context of our response regarding "longitudinal care" above, to clarify that "medication history" is intended to include a record of prior modifications to a patient's medications.

4. **Maintain active medication allergy list**. Enable a user to electronically record, modify, and retrieve a patient's active medication allergy list as well as medication allergy history for longitudinal care.

   Note: Non-medication allergies. Patient safety is one of HHS's top priorities. At the present time, the final meaningful use objective and measure focus on medication allergies.

5. **Record and chart vital signs.** Enable a user to electronically record, modify, and retrieve a patient's vital signs including, at a minimum:

   1. Height 2. Weight 3. Blood Pressure

   Note: Temperature and pulse have been removed from the certification criterion.

6. **Calculate body mass index (BMI)**. Automatically calculate and display body mass index (BMI) based on a patient's height and weight.

   Note: BMI it is only required that Certified EHR Technology be capable of calculating BMI. We do not believe that it is necessary, as a condition of certification, to specify how BMI should be coded.

7. **Plot and display growth charts**. Plot and electronically display, upon request, growth charts for patients 2-20 years old.

   Note: Children charting. The charting would then include: weight, length, pulse oximetry, head circumference, and blood pressure (with percentiles based on age and weight). For Stage 1, the related meaningful use objective addresses ages 2-20. In order to remain consistent with and support this objective, it is not necessary at this time to require a capability for charting any additional ages as a condition of certification.

   We expect a growth chart to plot the height, weight, and BMI over time, as compared to national norms. While the regulation text does not specifically require comparison to national norms, we understand that this type of information is typically provided along with the growth chart itself to provide greater relevance and meaning for the growth charts.

8. **Smoking status.** Enable a user to electronically record, modify, and retrieve the smoking status of a patient. Smoking status types must include: current every day smoker; current some day smoker; former smoker; never smoker; smoker, current status unknown; and unknown if ever smoked.

9. **Incorporate laboratory test results**:
   - Receive results.
   - Electronically receive clinical laboratory test results in a structured format and display such results in human readable format.
   - Display test report information. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).
   - Incorporate results. Electronically attribute, associate, or link a laboratory test result to a laboratory order or patient record.

   Note: It is not within the scope of this rule to dictate the standard by which laboratories transmit test results. The scope of this rule is the adoption of certification criteria that specify required capabilities of Certified EHR Technology (in this case, receiving laboratory information in structured format) and not, in this instance, specifying the standard by which laboratories must transmit test results. It is not required to specify the contexts under which laboratory test results are received. Rather, the capabilities required by this certification criterion, we specify that when laboratory test results are received in structured format that the results can be incorporated. Certified EHRs must provide the capability to receive clinical laboratory test results in a structured format as a condition of certification. It does not speak to how laboratories must send the test results.

   Note: Lab Result Batch Updates: An update to means that laboratory test result would be incorporated in EHR with the originating laboratory order or with a patient's record in any one of the methods specified. Requests for clarification and would permit batches of laboratory test results to be electronically linked to laboratory orders or patient records without manual intervention.

   Note: Lab Companies: EHRs must be capable of supporting electronic laboratory interfaces. We do not believe that the ability of a practice (regardless of size) to obtain an interface or other type of connection is an issue that is within the scope of this final rule to address.

   Note: Display Requirements: There is no required condition of certification any additional display requirements. Accordingly, we do not preclude the EHR developers from designing more specific displays of laboratory results that may need to be displayed in a more complex fashion.

   Note: Raw Lab Data: It is not required to enable an EHR to receive "raw or pre-final-report lab data" under this or any other adopted certification criterion.

10. **Generate patient lists.** Enable a user to electronically select, sort, retrieve, and generate lists of patients according to, at a minimum, the data elements included in:
    - Problem list
    - Medication list
    - Demographics
    - Laboratory test results

    Note: No condition of certification that time periods is associated with a patient list, but presumably time (i.e., the age of the information) could be one factor that could also be used to sort lists (e.g., patients with XYZ problem recorded in the past 3 months).

11. **Medication reconciliation.** Enable a user to electronically compare two or more medication lists.

    Note: It is recognized that the technical foundation and safety checks are not currently in place for automated medication reconciliation. We did not intend to imply that automated reconciliation needed to occur through our use of the word "electronically." We used the term "electronically" to express our expectation that eligible professionals and eligible hospitals would be able to use Certified EHR Technology to complete this task. Accordingly, we have revised this certification criterion to require that Certified EHR Technology be capable of providing a user with the ability to electronically compare two or more medication lists (e.g., between an externally provided medication list and the current medication list in Certified EHR Technology).

12. **Submission to immunization registries.** Electronically record, modify, retrieve, and submit immunization information in accordance with the standard specified in § 170.205(e)(1) or § 170.205(e)(2); and at a minimum, the version of the standard specified in § 170.207(e).

    Note: Ability to transmit to public health entities as required by law. However, this is not currently a necessary requirement for certification.

    Note: The reference to "applicable stated-designated standard format" in the certification criterion. Additionally, we have reviewed this certification criterion and have determined that our reference to "immunization registries" is unnecessary. We are primarily concerned with Certified EHR Technology's ability to transmit the immunization information in a standardized format, and do not believe that it is necessary to specify a particular recipient in the certification criterion.

    HL7 Versions. HL7 2.3.1 and HL7 2.5.1. We understand that both standards are currently in use and for that reason we have permitted either to be used for purposes of certification. We also understand that eligible professionals and eligible hospitals will have to use the standard that the immunization registry or Immunization Information System in their jurisdiction can receive and, as a result, we have adopted the two most common standards utilized for the transmission of immunization information. We permit an EHR to be tested and certified to either HL7 2.3.1 or HL7 2.5.1. No other versions will be considered compliant with the adopted standards or certification criterion.

    CVX Codes: The CDC maintains an openly available list of updated CVX codes as well as a mapping of CVX codes to CPT codes on their Web site. Moreover, we believe that CVX codes are more appropriate than CPT codes because as the commenter referenced, CPT codes are used for billing purposes. In that regard, we believe that because there is a publicly available mapping between CVX and CPT, it would not be difficult or burdensome to map CPT codes to CVX codes. NDC codes were not adopted as a standard to represent immunizations and we do not believe that requiring their use for the purposes of demonstrating compliance with this certification criterion would be appropriate.

    CDC – Immunization Information: After consultation with the CDC, we believe that adopting implementation specifications for the transmission of immunization information would benefit EHR technology developers and users. General requests for greater specificity and our stated goal of greater interoperability, we believe that it would be appropriate to adopt the following implementation specifications for the submission of immunization data. For HL7 2.3.1 we have adopted the "Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol, Implementation Guide Version 2.2." For HL7 2.5.1, we have adopted the

"Implementation Guide for Immunization Messaging Release 1.0." We encourage migration to this newer implementation specification and believe that it will likely advance interoperability across the country and improve query capabilities.

State and Local Immunization Registries: We do not believe that it is necessary or appropriate to expand this certification criterion in this manner. We emphasize, though, that this should not preclude eligible professionals or eligible hospitals from using EHRs to submit other types of information as medically appropriate and if the recipient of the information is capable of receiving the data.

13. **Public health surveillance.** Electronically record, modify, retrieve, and submit syndrome-based public health surveillance information in accordance with the standard.

    Note: There are two content exchange standards for electronic submission to public health agencies for surveillance and reporting. No specific vocabulary is standard. Removed is reference to "public health agencies" as the recipient of information. Also, the term "transmit" is replaced with "submit." Implementation specs for HL7 2.5.1: Public Health Information Network HL7 Version 2.5 Message Version 1.0 and the Errata and Clarifications National Notification Message Structural Specification. These enable development focus on a more specific implementation of the **HL7 2.5.1** standard.

14. **Patient-specific education resources**. Enable a user to electronically identify and provide patient-specific education resources according to, at a minimum, the data elements included in the patient's: problem list; medication list; and laboratory test results; as well as provide such resources to the patient.

15. **Administrative Transactions.** It is intended for adoption, administrative transactions standards and certification criteria to support meaningful use Stage 2 rulemaking, and expect health care providers and Complete EHR and EHR Module developers to take this into consideration leading up to 2013.

    Note: Transition to ASC X12N 5010 and ICD-10. The required compliance date of January 1, 2012 for ASC X12N version 5010 transactions we believe that after the ASC X12N version 5010 transition has occurred, and the October 1, 2013 compliance date for HIPAA covered entities to use ICD-10. In order to meet upcoming administrative simplification deadlines, most health care providers will have to upgrade their practice management systems or implement new ones. This will provide an important opportunity to align EHR technology capabilities and standards for administrative transactions with the administrative simplification provisions that the Affordable Care Act provides for health plans and clearinghouses.

16. **Automated measure calculation**. For each meaningful use objective with a percentage-based measure, electronically record the numerator and denominator and generate a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

    Note: PQRI Reporting (Physician Quality Reporting Initiative) 2008 Registry XML specifications apply only in the context of eligible professionals. Presently, CMS requires the submission of aggregate, summary level data for the purposes of meaningful use and not data at the patient-specific level.

    Note: Clinical quality measurement data. The collection of clinical quality measurement data and the calculation of results for submission to CMS should be performed by the Certified EHR however only be required to be tested and certified to developed electronic measure specifications.

17. **Access control**. Assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information.

18. **Emergency access.** Permit authorized users (who are authorized for emergency situations) to access electronic health information during an emergency. A person or entity's organizational policies and procedures may ensure timely notification of appropriate personnel.

19. **Automatic log-off.** Terminate an electronic session after a predetermined time of inactivity.

20. **Audit log.**
    - Record actions. Record actions related to electronic health information in accordance with the standard specified in § 170.210(b).
    - Generate audit log. Enable a user to generate an audit log 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).

Note: Auditing the action of printing, as it was originally envisioned, could be circumvented in such ways as to make the burden of trying to accurately audit such occurrences outweigh the benefit. Accordingly, we have removed "printed" from the standard. We have added "accessed" to the standard. We view the action of "access" to encompass "reading" or "viewing" and consequently have not included those terms as well. Finally, we believe that the action of "accessed" is a superset of actions which may include "export" and for that reason have not included, Additionally, to provide greater clarity, we have added in "and by whom" toward the end of the standard in order to more clearly specify that the actions recorded should be associated with the user identification that is recorded.

Audit logs require that deletions of electronic health information be recorded. "The date, time, patient identification, and user identification must be recorded when electronic health information is created, modified, accessed, or deleted; and an indication of which action(s) occurred and by whom must also be recorded." Audit logs can assist in the identification of security incidents, such as unauthorized access, as well as serve to deter users from conducting fraudulent or abusive activities and detect such activities. The purpose of adopted certification criteria is to specify the capabilities Complete EHRs and EHR Modules must include in order to be certified, not when such capabilities must be used. Accordingly, **we do not believe that it would be appropriate to specify in this certification criterion the time period for which an audit log should be "on."** Audit logs should be maintained in a secure manner. For this reason, we have preserved the capability we adopted in the Interim Final Rule as part of the integrity certification criterion that specified that Certified EHR Technology must be capable of detecting alterations to audit logs. We encourage the HIT Standards Committee to consider additional capabilities that could be specified related to audit logs.

21. **Integrity.**
    - Create a message digest in accordance with the standard specified in § 170.210(c).
    - 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.
    - Detection. Detect the alteration of audit logs.

Note: "A hashing algorithm with a security strength equal to or greater than SHA-1 must be used to verify that electronic health information has not been altered." More information on SHA-1 and other secure hash algorithms can be found in FIPS 180-3.

Secure Transmissions. Meaningful use requires the electronic exchange of health information and the protection of such information. We believe that the only practical and effective way that EHR information can be exchanged in a meaningful manner is if the integrity of the information can be maintained. Information "integrity" is also one of the three pillars of securing or "protecting" electronic information.

22. **Authentication.** Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information.

    Note: The burden associated with cross enterprise authentication is unnecessarily high and cross-network authentication should not be a condition of certification at the present time. As a result, we have removed this specific part of the certification criterion and the associated standard.

    User name and password or biometrics - we do not believe that it is appropriate to specify, as a condition of certification, the types of factors that users could utilize to authenticate themselves.

23. **General encryption.** Encrypt and decrypt electronic health information in accordance with the standard specified in § 170.210(a)(1), unless the Secretary determines that the use of such algorithm would pose a significant security risk for Certified EHR Technology.

24. **Encryption when exchanging electronic health information**. Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in § 170.210(a)(2).

    Note: We require that Certified EHR Technology must be capable of encrypting electronic health information. We do not specify the policies surrounding the use of encryption by an eligible professional or eligible hospital nor do we specify that it should only apply to devices. Rather we intend for Certified EHR Technology to be technologically capable of encryption, thereby allowing, if desired or required, an eligible professional or eligible hospital who adopts Certified EHR Technology to use this capability. Because of the flexibility in the adopted standard, however, how encryption is technically implemented is up to the Complete EHR or EHR Module developer to determine within the parameters of Annex A of FIPS 140-2. Given the changes we have made to the general encryption standard, we believe that the full range of the most secure encryption algorithms are available for Complete EHR and EHR Module developers to implement.

    User-defined preferences in the Interim Final Rule means that users would have the ability to elect when they wanted encryption to occur, for example, at log-off. We recognize that organizational policies, software as service models and other architectures in which Certified EHR Technology may be implemented, could lead to encryption being instituted in significantly different ways and, as a result, we have removed the reference to “user-defined preferences.”

25. **Optional. Accounting of disclosures.** Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).

26. **Computerized provider order entry (CPOE)**. Enable a user to electronically record, store, retrieve, and modify, at a minimum, the following order types:

    - Medications
    - Laboratory
    - Radiology/imaging

    Note: “provider referrals” from the certification criterion. It is not within the scope of this rulemaking to specify the persons who would need to use CPOE.

    Regarding incorporating laboratory test results, it is required that the EHR be capable of electronically attributing, associating, or linking a laboratory test result to a laboratory order or patient record. **Bidirectional exchange (including electronic transmission of laboratory orders) is not a requirement of meaningful use Stage 1** and is beyond the scope of this rule.

Imaging and radiology reports. The adopted certification criteria related to CPOE pertain only to the ordering, and not to the delivery of results (reports or images). There are no adopted standards for radiology reports or images; however, both the CCR and CCD can be used to convey narrative text and objects such as scanned documents.

27. **Electronic prescribing.** Enable a user to electronically generate and transmit prescriptions and prescription-related information in accordance with standards specified in § 170.205(b)(1) or § 170.205(b)(2); and § 170.207(d).

    Note: Electronic prescribing. Standard. The National Council for the Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT standard, Implementation Guide, Version 8, Release 1 (Version 8.1) October 2005 (incorporated by reference in § 170.299) or Standard. NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 (incorporated by reference in § 170.299).

    Note: An EHR would be compliant with this certification criterion if it has the capability of generating and transmitting prescription and prescription-related information according to NCPDP SCRIPT 8.1 while also using the adopted vocabulary standard, or if it is capable of generating and transmitting prescriptions and prescription-related information according to NCPDP SCRIPT 10.6.

    Some pharmacies may be unable to receive electronic prescriptions at the present time, this does not affect the capability that an EHR must provide. Inserted is “where applicable” would be beneficial because it would make the criterion unnecessarily ambiguous. This phrase would relate to when electronic prescribing should be conducted, not how it should be done, which is the focus of this certification criterion.

    Weight-based dosing calculation with intelligent rounding, we do not believe that it necessary to require it as a condition of certification at the present time. Again, this does not preclude Complete EHR and EHR Module developers from including this capability.

    Controlled Substances: The Drug Enforcement Agency has since published an interim final rule (75 FR 16236) on the requirements related to the electronic prescribing of controlled substances. At the present time, we do not require as a condition of certification for Complete EHRs and EHR Modules that they be capable of enabling compliance with the current DEA provisions for the electronic prescribing of controlled substances.

28. **Record demographics.** Enable a user to electronically record, modify, and retrieve patient demographic data Enable race and ethnicity to be recorded in accordance with the standard specified at § 170.207(f), including:

    - preferred language
    - gender
    - race
    - ethnicity
    - date of birth

    Note: Race and Ethnicity. Standard. The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, October 30, 1997 (available at http://www.whitehouse.gov/omb/rewrite/fedreg/ombdir15.html).

29. **Patient reminders**. Enable a user to electronically generate a patient reminder list for preventive or follow-up care according to patient preferences based on, at a minimum, the data elements included in:

    - Problem list
    - Medication list
    - Medication allergy list
    - Demographics
    - Laboratory test results

    Note: EHRs should be able to leverage the information to assist eligible providers and staff a patient reminder list. Removed is "upon request" from the certification as the action of requesting a list is implied by the certification and the meaningful use measure. EHR is to be capable of generating a patient reminder list for an eligible professional and staff. The meaningful use measure establishes the requirement for an eligible professional to take action once the reminder list has been generated.

    Preferred language is included in demographics and we do not believe that it is necessary to expressly call it out as part of this certification criterion.

30. **Clinical decision support**:

    - Implement rules. Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results.

    - Notifications. Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.

    Note: For notifications "real-time" means at the point of clinical decision making (i.e., notifications must be provided when an eligible provider is using EHR and not run overnight and provided in the morning, for instance). The tracking of alerts is not required at this time.

31. **Electronic copy of health information**. Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in:

    - Human readable format; and
    - On electronic media or through some other electronic means
    - For the following data elements the applicable standard must be used:
        1) Problems 2) Laboratory test results 3)Medications

    Note: Human readable format means a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation.

    It is not specified that electronic media such as thumb drives or CDs must be used. An eligible hospital will be able to determine, consistent with its security posture, if certain electronic media is permissible and if so, what types. It will also be able to determine the means and location through which an electronic copy may be provided, e.g., at the records management department or office i.e. patient portal would be an acceptable mechanism to provide an electronic copy. The time period for which the electronic copy must cover as a condition of certification.

Durable Medical Supplies: Tracking of durable medical equipment is not required at this time.

An EHR is required to be capable of generating an electronic copy of health information that includes the minimum elements required as a condition of certification. It is not specified the timeframe such information must encompass, but we would expect that it would include, at a minimum, the most current information that is available and accessible within the EHR.

The certification criterion removes "procedures" as well as "immunizations," to be more consistent with the final meaningful use objective and measure and for greater clarity.

There is no method specified by which an individual must receive an electronic copy of the specified health information, only that the EHR be capable of electronically generating an electronic copy in human readable format. While an EHR must be capable of creating an electronic copy of a patient's health information as specified in this certification criterion, we encourage Complete EHR and EHR Module developers to also include the capability to generate an electronic copy in a manner that allows eligible professionals (and eligible hospitals as this capability relates to inpatient setting) to comply with applicable provisions of the HIPAA Privacy and Security Rules.

CCD or CCR format: In order to meet this certification criterion, Certified EHR Technology must be able to generate an electronic copy that is in human readable format and as a CCD or CCR. If Certified EHR Technology is capable of generating one copy that could meet both of these requirements, we would consider that to be a compliant implementation of this capability. CCD and XDS (HITSP/TP13)/FTP/e-mail of a document would meet the certification criterion requirements. Removed is the adopted transport standards, we do not require as a condition of certification that a specific transport standard be used to transmit a generated CCD.

Continuity of Care Record (CCR) standard for patient summary records. The CCR patient summary record id adopted for both the CCR and CCD as patient summary record standards.

Historical data from paper records should be treated for the purpose of certification. If historical data is on paper, the standards for display are inapplicable. Data from paper records is not a relevant factor for the purposes of testing and certification.

32. **Timely access.** Enable a user to provide patients with online access to their clinical information, including, at a minimum, lab test results, problem list, medication list, and medication allergy list.

33. **Clinical summaries.** Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list. If the clinical summary is provided electronically it must be:
    - Provided in human readable format; and
    - Provided on electronic media or through some other electronic means in accordance with:
        - The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and
        - For the following data elements the applicable standard must be used:
            i. Problems. The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2);
            ii. Laboratory test results. At a minimum, the version of the standard specified in § 170.207(c); and
            iii. Medications. The standard specified in § 170.207(d).

34. **Exchange clinical information and patient summary record.** The Secretary adopts the following content exchange standards and associated implementation specifications:

Electronic submission of lab results to public health agencies. Standard HL7 2.5.1 (incorporated by reference in § 170.299). Implementation specifications HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (incorporated by reference in § 170.299).

Electronic submission to public health agencies for surveillance or reporting. (1) Standard. HL7 2.3.1 (incorporated by reference in § 170.299).

Standard. HL7 2.5.1 (incorporated by reference in § 170.299). Implementation specifications. Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0 and Errata and Clarifications National Notification Message Structural Specification (incorporated by reference in § 170.299).

Electronic submission to immunization registries. (1) Standard. HL7 2.3.1 (incorporated by reference in § 170.299). Implementation specifications. Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2 (incorporated by reference in § 170.299). Standard. HL7 2.5.1 (incorporated by reference in § 170.299). Implementation specifications. HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0 (incorporated by reference in § 170.299).

Electronically receive and display. Electronically receive and display a patient's summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, and medication allergy list in accordance with the standard.

Patient summary record: Standard. Health Level Seven Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) (incorporated by reference in § 170.299). Implementation specifications. The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32 (incorporated by reference in § 170.299).

- Upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format.

Electronically transmit. Enable a user to electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in accordance with:

- The standard specified in § 170.205(a)(1) or § 170.205(a)(2); and
- For the following data elements the applicable standard must be used:
  - Problems. The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2);
  - Laboratory test results. At a minimum, the version of the standard specified in § 170.207(c); and
  - Medications. The standard specified in § 170.207(d).

35. **Calculate and submit clinical quality measures.**

- Electronically calculate all of the core clinical measures specified by CMS for eligible professionals.
- Electronically calculate, at a minimum, three clinical quality measures specified by CMS for eligible professionals, in addition to those clinical quality measures specified in paragraph (1)(i).

- Submission. Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in § 170.205(f).

Certified EHR Technology means a Complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator. "Initial EHR Certification Bodies Named: Key step in national initiative toward adoption of electronic health records **The Certification Commission for Health Information Technology (CCHIT), Chicago, Ill. and the Drummond Group Inc. (DGI)**, Austin, Texas, were named today [August 30, 2010] by the Office of the National Coordinator for Health Information Technology (ONC) as the first technology review bodies that have been authorized to test and certify electronic health record (EHR) systems for compliance with the standards and certification criteria that were issued by the U.S. Department of Health and Human Services earlier this year. Source: http://www.hhs.gov/news/press/2010pres/08/20100830d.html

Note: CCHIT listing of certified EHRs see http://www.cchit.org/products/Ambulatory viable Ambulatory certified EHR systems by CCHIT will be those listed for years 2008 – 2011 at present.

Source: The Federal Register (July 28, 2010). The daily journal of the United States government: *Rule health information technology: Initial set of standards, implementation specifications, and certification criteria for electronic health record technology.* Retrieved from http://www.federalregister.gov/articles/2010/07/28/2010-17210/health-information-technology-initial-set-of-standards-implementation-specifications-and

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