§ 170.306 Specific certification criteria for Complete EHRs or EHR Modules designed for an inpatient setting.

The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules designed to be used in an inpatient setting. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) Computerized provider order entry. Enable a user to electronically record, store, retrieve, and modify, at a minimum, the following order types:
   (1) Medications;
   (2) Laboratory; and
   (3) Radiology/imaging.

(b) Record demographics. Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, date of birth, and date and preliminary cause of death in the event of mortality. Enable race and ethnicity to be recorded in accordance with the standard specified at §170.207(f).

(c) Clinical decision support—(1) 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; medication allergy list; and laboratory test results.

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

(d) Electronic copy of discharge instructions. Enable a user to create an electronic copy of a patient’s discharge instructions and on electronic media or through some other electronic means in accordance with:

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

(2) Procedures. The standard specified in §170.207(b)(1) or §170.207(b)(2);

(3) Laboratory test results. At a minimum, the version of the standard specified in §170.207(c); and

(4) Medications. The standard specified in §170.207(d).

(2) Enable a user to create an electronic copy of a patient’s discharge summary in human readable format and on electronic media or through some other electronic means.

(e) Electronic copy of discharge instructions. Enable a user to create an electronic copy of discharge instructions for a patient, in human readable format, at the time of discharge on electronic media or through some other electronic means.

(f) Exchange clinical information and patient summary record—(1) Electronically receive and display. Electronically receive and display a patient’s summary record from other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, and procedures in accordance with the standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2).

Upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format.
§ 170.400  Electronically transmit. Enable a user to electronically transmit a patient’s summary record to other providers and organizations including, at a minimum, diagnostic results, problem list, medication list, medication allergy list, and procedures 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) Problems. The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);

(B) Procedures. The standard specified in §170.207(b)(1) or §170.207(b)(2);

(C) Laboratory test results. At a minimum, the version of the standard specified in §170.207(c); and

(D) Medications. The standard specified in §170.207(d).

(g) Reportable lab results. Electronically record, modify, retrieve, and submit reportable clinical lab results in accordance with the standard (and applicable implementation specifications) specified in §170.205(c) and, at a minimum, the version of the standard specified in §170.207(c).

(h) Advance directives. Enable a user to electronically record whether a patient has an advance directive.

(i) Calculate and submit clinical quality measures—(1) Calculate. Electronically calculate all of the clinical quality measures specified by CMS for eligible hospitals and critical access hospitals.

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

Subpart D—Temporary Certification Program for HIT

SOURCE: 75 FR 36203, June 24, 2010, unless otherwise noted.

§ 170.400  Basis and scope.

This subpart implements section 3001(c)(5) of the Public Health Service Act, and sets forth the rules and procedures related to the temporary certification program for health information technology administered by the National Coordinator for Health Information Technology.

§ 170.401  Applicability.

This subpart establishes the processes that applicants for ONC-ATCB status must follow to be granted ONC-ATCB status by the National Coordinator, the processes the National Coordinator will follow when assessing applicants and granting ONC-ATCB status, the requirements that ONC-ATCBs must follow to remain in good standing, and the requirements of ONC-ATCBs for testing and certifying Complete EHRs and/or EHR Modules in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part.

§ 170.402  Definitions.

For the purposes of this subpart:

Applicant means a single organization or a consortium of organizations that seeks to become an ONC-ATCB by requesting and subsequently submitting an application for ONC-ATCB status to the National Coordinator.

Deployment site means the physical location where a Complete EHR or EHR Module resides or is being or has been implemented.

Development site means the physical location where a Complete EHR or EHR Module was developed.

ONC-ATCB or ONC-Authorized Testing and Certification Body means an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to this subpart to perform the testing and certification of Complete EHRs and/or EHR Modules under the temporary certification program.

Remote testing and certification means the use of methods, including the use of web-based tools or secured electronic transmissions, that do not require an ONC-ATCB to be physically present at the development or deployment site to conduct testing and certification.

§ 170.405  Correspondence.

(a) Correspondence and communication with the National Coordinator shall be conducted by e-mail, unless otherwise necessary. The official date of receipt of any e-mail between the

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