

certify all EHR Modules under the temporary certification program.

§ 170.450 EHR module testing and certification.

(a) When testing and certifying EHR Modules, an ONC-ATCB must test and certify in accordance with the applicable certification criterion or certification criteria adopted by the Secretary at subpart C of this part.

(b) An ONC-ATCB must provide the option for an EHR Module or a bundle of EHR Modules to be tested and certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Privacy and security testing and certification.* EHR Modules shall be tested and certified to all privacy and security certification criteria adopted by the Secretary unless the EHR Module(s) is/are presented for testing and certification in one of the following manners:

(1) The EHR Module(s) is/are presented for testing and certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR (as defined in 45 CFR 170.102), and one or more of the constituent EHR Modules is/are demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Module(s); or

(2) An EHR Module is presented for testing and certification, and the presenter can demonstrate and provide documentation to the ONC-ATCB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be tested and certified in accordance with such certification criterion.

(d) *Inherited certified status.* An ONC-ATCB must accept requests for a newer version of a previously certified EHR Module or bundle of EHR Modules to inherit the previously certified EHR Module's or bundle of EHR Modules certified status without requiring the newer version to be retested and recertified.

(1) Before granting certified status to a newer version of a previously certified EHR Module or bundle of EHR

Modules, an ONC-ATCB must review an attestation submitted by the developer of the EHR Module or presenter of the bundle of EHR Modules to determine whether the newer version has adversely affected any previously certified capabilities.

(2) An ONC-ATCB may grant certified status to a newer version of a previously certified EHR Module or bundle of EHR Modules if it determines that previously certified capabilities have not been adversely affected.

§ 170.455 Testing and certification to newer versions of certain standards.

(a) ONC-ATCBs may test and certify Complete EHRs and EHR Module to a newer version of certain identified minimum standards specified at subpart B of this part if the Secretary has accepted a newer version of an adopted minimum standard.

(b) Applicability of an accepted new version of an adopted minimum standard.

(1) ONC-ATCBs are not required to test and certify Complete EHRs and/or EHR Modules according to newer versions of an adopted minimum standard accepted by the Secretary until the incorporation by reference provision of the adopted version is updated in the FEDERAL REGISTER with a newer version.

(2) Certified EHR Technology may be upgraded to comply with newer versions of an adopted minimum standard accepted by the Secretary without adversely affecting the certification status of the Certified EHR Technology.

§ 170.457 Authorized testing and certification methods.

An ONC-ATCB must provide remote testing and certification for both development and deployment sites.

§ 170.460 Good standing as an ONC-ATCB.

An ONC-ATCB must maintain good standing by:

(a) Adhering to the Principles of Proper Conduct for ONC-ATCBs;

(b) Refraining from engaging in other types of inappropriate behavior, including an ONC-ATCB misrepresenting the

§ 170.465

scope of its authorization as well as an ONC-ATCB testing and certifying Complete EHRs and/or EHR Modules for which it does not have authorization; and

(c) Following all other applicable Federal and state laws.

§ 170.465 Revocation of authorized testing and certification body status.

(a) *Type-1 violations.* The National Coordinator may revoke an ONC-ATCB's status for committing a Type-1 violation. Type-1 violations include violations of law or temporary certification program policies that threaten or significantly undermine the integrity of the temporary certification program. These violations include, but are not limited to: False, fraudulent, or abusive activities that affect the temporary certification program, a program administered by HHS or any program administered by the Federal government.

(b) *Type-2 violations.* The National Coordinator may revoke an ONC-ATCB's status for failing to timely or adequately correct a Type-2 violation. Type-2 violations constitute non-compliance with § 170.460.

(1) *Noncompliance notification.* If the National Coordinator obtains reliable evidence that an ONC-ATCB may no longer be in compliance with § 170.460, the National Coordinator will issue a noncompliance notification with reasons for the notification to the ONC-ATCB requesting that the ONC-ATCB respond to the alleged violation and correct the violation, if applicable.

(2) *Opportunity to become compliant.* After receipt of a noncompliance notification, an ONC-ATCB is permitted up to 30 days to submit a written response and accompanying documentation that demonstrates that no violation occurred or that the alleged violation has been corrected.

(i) If the ONC-ATCB submits a response, the National Coordinator is permitted up to 30 days from the time the response is received to evaluate the response and reach a decision. The National Coordinator may, if necessary, request additional information from the ONC-ATCB during this time period.

45 CFR Subtitle A (10-1-10 Edition)

(ii) If the National Coordinator determines that no violation occurred or that the violation has been sufficiently corrected, the National Coordinator will issue a memo to the ONC-ATCB confirming this determination.

(iii) If the National Coordinator determines that the ONC-ATCB failed to demonstrate that no violation occurred or to correct the area(s) of non-compliance identified under paragraph (b)(1) of this section within 30 days of receipt of the noncompliance notification, then the National Coordinator may propose to revoke the ONC-ATCB's status.

(c) *Proposed revocation.* (1) The National Coordinator may propose to revoke an ONC-ATCB's status if the National Coordinator has reliable evidence that the ONC-ATCB committed a Type-1 violation; or

(2) The National Coordinator may propose to revoke an ONC-ATCB's status if, after the ONC-ATCB has been notified of a Type-2 violation, the ONC-ATCB fails to:

(i) To rebut the finding of a violation with sufficient evidence showing that the violation did not occur or that the violation has been corrected; or

(ii) Submit to the National Coordinator a written response to the non-compliance notification within the specified timeframe under paragraph (b)(2).

(d) *Suspension of an ONC-ATCB's operations.* (1) The National Coordinator may suspend the operations of an ONC-ATCB under the temporary certification program based on reliable evidence indicating that:

(i) The ONC-ATCB committed a Type-1 or Type-2 violation; and

(ii) The continued testing and certification of Complete EHRs and/or EHR Modules by the ONC-ATCB could have an adverse impact on the health or safety of patients.

(2) If the National Coordinator determines that the conditions of paragraph (d)(1) have been met, an ONC-ATCB will be issued a notice of proposed suspension.

(3) Upon receipt of a notice of proposed suspension, an ONC-ATCB will be permitted up to 3 days to submit a