

§ 170.557 Authorized certification methods.

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

§ 170.560 Good standing as an ONC-ACB.

An ONC-ACB must maintain good standing by:

- (a) Adhering to the Principles of Proper Conduct for ONC-ACBs;
- (b) Refraining from engaging in other types of inappropriate behavior, including an ONC-ACB misrepresenting the scope of its authorization, as well as an ONC-ACB certifying Complete EHRs and/or EHR Module(s) for which it does not have authorization; and
- (c) Following all other applicable Federal and State laws.

§ 170.565 Revocation of ONC-ACB status.

(a) *Type-1 violations.* The National Coordinator may revoke an ONC-ACB's status for committing a Type-1 violation. Type-1 violations include violations of law or ONC HIT Certification Program policies that threaten or significantly undermine the integrity of the ONC HIT Certification Program. These violations include, but are not limited to: False, fraudulent, or abusive activities that affect the ONC HIT 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-ACB's status for failing to timely or adequately correct a Type-2 violation. Type-2 violations constitute non-compliance with § 170.560.

(1) *Noncompliance notification.* If the National Coordinator obtains reliable evidence that an ONC-ACB may no longer be in compliance with § 170.560, the National Coordinator will issue a noncompliance notification with reasons for the notification to the ONC-ACB requesting that the ONC-ACB respond to the alleged violation and correct the violation, if applicable.

(2) *Opportunity to become compliant.* After receipt of a noncompliance notification, an ONC-ACB 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-ACB 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-ACB during this time period.

(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-ACB confirming this determination.

(iii) If the National Coordinator determines that the ONC-ACB 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-ACB's status.

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

(2) The National Coordinator may propose to revoke an ONC-ACB's status if, after the ONC-ACB has been notified of a Type-2 violation, the ONC-ACB 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) of this section.

(d) *Suspension of an ONC-ACB's operations.* (1) The National Coordinator may suspend the operations of an ONC-ACB under the ONC HIT Certification Program based on reliable evidence indicating that:

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

(ii) The continued certification of Complete EHRs, EHR Module(s), and/or other types of HIT by the ONC-ACB

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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) of this section have been met, an ONC-ACB will be issued a notice of proposed suspension.

(3) Upon receipt of a notice of proposed suspension, an ONC-ACB will be permitted up to 3 days to submit a written response to the National Coordinator explaining why its operations should not be suspended.

(4) The National Coordinator is permitted up to 5 days from receipt of an ONC-ACB's written response to a notice of proposed suspension to review the response and make a determination.

(5) The National Coordinator may make one of the following determinations in response to the ONC-ACB's written response or if the ONC-ACB fails to submit a written response within the timeframe specified in paragraph (d)(3) of this section:

(i) Rescind the proposed suspension; or

(ii) Suspend the ONC-ACB's operations until it has adequately corrected a Type-2 violation; or

(iii) Propose revocation in accordance with §170.565(c) and suspend the ONC-ACB's operations for the duration of the revocation process.

(6) A suspension will become effective upon an ONC-ACB's receipt of a notice of suspension.

(e) *Opportunity to respond to a proposed revocation notice.* (1) An ONC-ACB may respond to a proposed revocation notice, but must do so within 10 days of receiving the proposed revocation notice and include appropriate documentation explaining in writing why its status should not be revoked.

(2) Upon receipt of an ONC-ACB's response to a proposed revocation notice, the National Coordinator is permitted up to 30 days to review the information submitted by the ONC-ACB and reach a decision.

(f) *Good standing determination.* If the National Coordinator determines that an ONC-ACB's status should not be revoked, the National Coordinator will notify the ONC-ACB's authorized representative in writing of this determination.

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(g) *Revocation.* (1) The National Coordinator may revoke an ONC-ACB's status if:

(i) A determination is made that revocation is appropriate after considering the information provided by the ONC-ACB in response to the proposed revocation notice; or

(ii) The ONC-ACB does not respond to a proposed revocation notice within the specified timeframe in paragraph (e)(1) of this section.

(2) A decision to revoke an ONC-ACB's status is final and not subject to further review unless the National Coordinator chooses to reconsider the revocation.

(h) *Extent and duration of revocation.* (1) The revocation of an ONC-ACB is effective as soon as the ONC-ACB receives the revocation notice.

(2) A certification body that has had its ONC-ACB status revoked is prohibited from accepting new requests for certification and must cease its current certification operations under the ONC HIT Certification Program.

(3) A certification body that has had its ONC-ACB status revoked for a Type-1 violation, is not permitted to reapply for ONC-ACB status under the ONC HIT Certification Program for a period of 1 year.

(4) The failure of a certification body that has had its ONC-ACB status revoked to promptly refund any and all fees for certifications of Complete EHRs and EHR Module(s) not completed will be considered a violation of the Principles of Proper Conduct for ONC-ACBs and will be taken into account by the National Coordinator if the certification body reapplies for ONC-ACB status under the ONC HIT Certification Program.

[76 FR 1325, Dec. 7, 2011, as amended at 77 FR 54291, Sept. 4, 2012]

§ 170.570 Effect of revocation on the certifications issued to Complete EHRs and EHR Module(s).

(a) The certified status of Complete EHRs and/or EHR Module(s) certified by an ONC-ACB that had its status revoked will remain intact unless a Type-1 violation was committed that calls into question the legitimacy of the certifications issued by the former ONC-ACB.