

(1) Adhering to the Principles of Proper Conduct for ONC-ACBs;

(2) 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 Health IT Module(s) for which it does not have authorization; and

(3) Following all other applicable federal and state laws.

(b) *ONC-ATL good standing.* An ONC-ATL must maintain good standing by:

(1) Adhering to the Principles of Proper Conduct for ONC-ATLs;

(2) Refraining from engaging in other types of inappropriate behavior, including an ONC-ATL misrepresenting the scope of its authorization, as well as an ONC-ATL testing health IT for which it does not have authorization; and

(3) Following all other applicable federal and state laws.

[81 FR 72466, Oct. 19, 2016; 85 FR 25953, May 1, 2020]

§ 170.565 Revocation of ONC-ACB or ONC-ATL status.

(a) *Type-1 violations.* The National Coordinator may revoke an ONC-ATL or ONC-ACB's status for committing a Type-1 violation. Type-1 violations include violations of law or ONC Health IT Certification Program policies that threaten or significantly undermine the integrity of the ONC Health IT Certification Program. These violations include, but are not limited to: False, fraudulent, or abusive activities that affect the ONC Health IT 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-ATL or 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-ATL or 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-ATL or ONC-ACB requesting that the ONC-ATL or 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-ATL or 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-ATL or 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-ATL or 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-ATL or ONC-ACB confirming this determination.

(iii) If the National Coordinator determines that the ONC-ATL or 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 non-compliance notification, then the National Coordinator may propose to revoke the ONC-ATL or ONC-ACB's status.

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

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

(i) 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-ATL or ONC-ACB's operations.* (1) The National Coordinator may suspend the operations of an ONC-ATL or ONC-ACB under the ONC Health IT Certification Program based on reliable evidence indicating that:

(i) *Applicable to both ONC-ACBs and ONC-ATLs.* The ONC-ATL or ONC-ACB committed a Type-1 or Type-2 violation;

(ii) *Applicable to ONC-ACBs.* The continued certification of Health IT Modules by the ONC-ACB could have an adverse impact on the health or safety of patients.

(iii) *Applicable to ONC-ATLs.* The continued testing of Health IT Modules by the ONC-ATL 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-ATL or ONC-ACB will be issued a notice of proposed suspension.

(3) Upon receipt of a notice of proposed suspension, an ONC-ATL or 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-ATL or 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-ATL or ONC-ACB's written response or if the ONC-ATL or 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-ATL or ONC-ACB's operations until it has adequately corrected a Type-2 violation; or

(iii) Propose revocation in accordance with paragraph (c) of this section and suspend the ONC-ATL or ONC-ACB's operations for the duration of the revocation process.

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

(e) *Opportunity to respond to a proposed revocation notice.* (1) An ONC-ATL or 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-ATL or 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 or ONC-ATL and reach a decision.

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

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

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

(ii) The ONC-ATL or 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-ATL or 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) *Effectuation.* The revocation of an ONC-ATL or ONC-ACB is effective as soon as the ONC-ATL or ONC-ACB receives the revocation notice.

(2) *ONC-ACB provisions.* (i) 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 Health IT Certification Program.

(ii) A certification body that has had its ONC-ACB status revoked for a Type-1 violation is not permitted to re-apply for ONC-ACB status under the

ONC Health IT Certification Program for a period of 1 year.

(iii) The failure of a certification body that has had its ONC-ACB status revoked to promptly refund any and all fees for certifications of Health IT 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 Health IT Certification Program.

(3) *ONC-ATL provisions.* (i) A testing lab that has had its ONC-ATL status revoked is prohibited from accepting new requests for testing and must cease its current testing operations under the ONC Health IT Certification Program.

(ii) A testing lab that has had its ONC-ATL status revoked for a Type-1 violation is not permitted to reapply for ONC-ATL status under the ONC Health IT Certification Program for a period of 1 year.

(iii) The failure of a testing lab that has had its ONC-ATL status revoked to promptly refund any and all fees for testing of health IT not completed will be considered a violation of the Principles of Proper Conduct for ONC-ATLs and will be taken into account by the National Coordinator if the testing lab reapplies for ONC-ATL status under the ONC Health IT Certification Program.

[81 FR 72466, Oct. 19, 2016, as amended at 85 FR 25953, May 1, 2020]

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

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

(b) If the National Coordinator determines that a Type-1 violation was committed by an ONC-ACB and/or ONC-ATL that called into question the legitimacy of certifications issued to health IT, then the National Coordinator would:

(1) Review the facts surrounding the revocation of the ONC-ACB's or ONC-ATL's status; and

(2) Publish a notice on ONC's Web site if the National Coordinator believes that the Health IT Module(s) certifications were based on unreliable testing and/or certification.

(c) If the National Coordinator determines that Health IT Module(s) certifications were based on unreliable testing and/or certification, the certification status of affected Health IT Module(s) would only remain intact for 120 days after the National Coordinator publishes the notice.

(1) The certification status of affected Health IT Module(s) can only be maintained after the 120-day timeframe by being re-tested by an ONC-ATL in good standing, as necessary, and re-certified by an ONC-ACB in good standing.

(2) The National Coordinator may extend the time that the certification status of affected Health IT Module(s) remains intact as necessary for the proper retesting and recertification of the affected health IT.

[81 FR 72467, Oct. 19, 2016, as amended at 85 FR 25953, May 1, 2020]

§ 170.575 [Reserved]

§ 170.580 ONC review of certified health IT.

(a) *Direct review*—(1) *Purpose.* ONC may directly review certified health IT or a health IT developer's actions or practices to determine whether either conform to the requirements of the ONC Health IT Certification Program.

(2) *Circumstances that may trigger review*—(i) *Certified health IT causing or contributing to unsafe conditions.* ONC may initiate direct review under this section if it has a reasonable belief that certified health IT may not conform to the requirements of the Program because the certified health IT may be causing or contributing to conditions that present a serious risk to public health or safety, taking into consideration—

(A) The potential nature, severity, and extent of the suspected conditions;

(B) The need for an immediate or coordinated governmental response; and