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deficiencies, including a detailed description of how the developer will assess the scope and impact of the problem, including identifying all potentially affected customers; how the developer will promptly ensure that all potentially affected customers are notified of the problem and plan for resolution; how and when the developer will resolve issues for individual affected customers; and how the developer will ensure that all issues are in fact resolved.

(v) The timeframe under which corrective action will be completed.

(vi) An attestation by the developer that it has completed all elements of the approved corrective action plan.

(4) When the ONC–ACB receives a proposed corrective action plan (or a revised proposed corrective action plan), the ONC–ACB shall either approve the corrective action plan or, if the plan does not adequately address the elements described by paragraph (d)(3) of this section and other elements required by the ONC–ACB, instruct the developer to submit a revised proposed corrective action plan.

(5) *Suspension.* Consistent with its accreditation to ISO/IEC 17065 and procedures for suspending a certification, an ONC–ACB shall initiate suspension procedures for a Health IT Module:

(i) 30 days after notifying the developer of a non-conformity pursuant to paragraph (d)(1) of this section, if the developer has not submitted a proposed corrective action plan;

(ii) 90 days after notifying the developer of a non-conformity pursuant to paragraph (d)(1) of this section, if the ONC–ACB cannot approve a corrective action plan because the developer has not submitted a revised proposed corrective action plan in accordance with paragraph (d)(4) of this section; and

(iii) Immediately, if the developer has not completed the corrective actions specified by an approved corrective action plan within the time specified therein.

(6) *Withdrawal.* If a or certified Health IT Module's certification has been suspended, an ONC–ACB is permitted to initiate certification withdrawal procedures for the Health IT Module (consistent with its accreditation to ISO/IEC 17065 and procedures for withdrawing a certification) when the health IT developer has not completed the actions necessary to reinstate the suspended certification.

(e) *Reporting of surveillance results requirements*—(1) *Rolling submission of in-the-field surveillance results.* The results of in-the-field surveillance under this section must be submitted to the National Coordinator, at a minimum, on a quarterly basis in accordance with § 170.523(i)(2).

(2) *Confidentiality of locations evaluated.* The contents of an ONC–ACB's surveillance results submitted to the National Coordinator must not include any information that would identify any user or location that participated in or was subject to surveillance.

(3) *Reporting of corrective action plans.* When a corrective action plan is initiated for a Health IT Module, an ONC–ACB must report the Health IT Module and associated product and corrective action information to the National Coordinator in accordance with § 170.523(f)(1)(xxii) or (f)(2)(xi), as applicable.

(f) *Relationship to other surveillance requirements.* Nothing in this section shall be construed to limit or constrain an ONC–ACB's duty or ability to perform surveillance, including in-the-field surveillance, or to suspend or terminate the certification, of any certified Health IT Module as required or permitted by this subpart and the ONC–ACB's accreditation to ISO/IEC 17065.

[80 FR 62758, Oct. 16, 2015, as amended at 80 FR 76872, Dec. 11, 2015; 81 FR 72466, Oct. 19, 2016; 85 FR 25952, May 1, 2020]

§ 170.557 Authorized testing and certification methods.

(a) *ONC–ATL applicability.* An ONC–ATL must provide remote testing for both development and deployment sites.

(b) *ONC–ACB applicability.* An ONC–ACB must provide remote certification for both development and deployment sites.

[81 FR 72466, Oct. 19, 2016]

§ 170.560 Good standing as an ONC–ACB or ONC–ATL.

(a) *ONC–ACB good standing.* An ONC–ACB must maintain good standing by:

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(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 noncompliance 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 noncompliance 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 noncompliance notification within the specified timeframe under paragraph (b)(2) of this section.

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