

(b) If the National Coordinator determines that a Type-1 violation occurred that called into question the legitimacy of certifications conducted by the former ONC-ACB, then the National Coordinator would:

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

(2) Publish a notice on ONC's Web site if the National Coordinator believes that Complete EHRs and/or EHR Module(s) were improperly certified by the former ONC-ACB.

(c) If the National Coordinator determines that Complete EHRs and/or EHR Module(s) were improperly certified, the certification status of affected Complete EHRs and/or EHR Module(s) would only remain intact for 120 days after the National Coordinator publishes the notice. The certification status of affected Complete EHRs and/or EHR Module(s) can only be maintained thereafter by being re-certified by an ONC-ACB in good standing.

§ 170.575 Removal of the ONC-AA.

(a) *Conduct violations.* The National Coordinator may remove the ONC-AA for committing a conduct violation. Conduct 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) *Performance violations.* The National Coordinator may remove the ONC-AA for failing to timely or adequately correct a performance violation. Performance violations constitute a failure to adequately perform the ONC-AA's responsibilities as specified in § 170.503(e).

(1) *Noncompliance notification.* If the National Coordinator obtains reliable evidence that the ONC-AA may no longer be adequately performing its responsibilities specified in § 170.503(e), the National Coordinator will issue a noncompliance notification with reasons for the notification to the ONC-AA requesting that the ONC-AA re-

spond to the alleged violation and correct the violation, if applicable.

(2) *Opportunity to become compliant.* The ONC-AA is permitted up to 30 days from receipt of a noncompliance notification 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-AA submits a response, the National Coordinator is permitted up to 60 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-AA 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-AA confirming this determination. Otherwise, the National Coordinator may propose to remove the ONC-AA in accordance with paragraph (c) of this section.

(c) *Proposed removal.* (1) The National Coordinator may propose to remove the ONC-AA if the National Coordinator has reliable evidence that the ONC-AA has committed a conduct violation; or

(2) The National Coordinator may propose to remove the ONC-AA if, after the ONC-AA has been notified of an alleged performance violation, the ONC-AA fails to:

(i) Rebut the alleged 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.

(d) *Opportunity to respond to a proposed removal notice.* (1) The ONC-AA may respond to a proposed removal notice, but must do so within 20 days of receiving the proposed removal notice and include appropriate documentation explaining in writing why it should not be removed as the ONC-AA.

(2) Upon receipt of the ONC-AA's response to a proposed removal notice, the National Coordinator is permitted up to 60 days to review the information

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submitted by the ONC-AA and reach a decision.

(e) *Retention of ONC-AA status.* If the National Coordinator determines that the ONC-AA should not be removed, the National Coordinator will notify the ONC-AA in writing of this determination.

(f) *Removal.* (1) The National Coordinator may remove the ONC-AA if:

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

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

(2) A decision to remove the ONC-AA is final and not subject to further review unless the National Coordinator chooses to reconsider the removal.

(g) *Extent and duration of removal.* (1) The removal of the ONC-AA is effective upon the date specified in the removal notice provided to the ONC-AA.

(2) An accreditation organization that is removed as the ONC-AA must cease all activities under the ONC HIT Certification Program, including accepting new requests for accreditation under the ONC HIT Certification Program.

(3) An accreditation organization that is removed as the ONC-AA is prohibited from being considered for ONC-AA status for a period of 1 year from the effective date of its removal as the ONC-AA.

[76 FR 72643, Nov. 25, 2011, as amended at 77 FR 54291, Sept. 4, 2012]

§ 170.599 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call

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202-741-6030 or go to [http://www.archives.gov/federal_register/code_of_federal_regulations/](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html)

[ibr_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). Also, it is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201, call ahead to arrange for inspection at 202-690-7151, and is available from the source listed below.

(b) International Organization for Standardization, Case postale 56, CH-1211, Geneve 20, Switzerland, telephone +41-22-749-01-11, <http://www.iso.org>.

(1) ISO/IEC 17011:2004 Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies (Corrected Version), February 15, 2005, IBR approved for §170.503.

(2) ISO/IEC GUIDE 65:1996—General Requirements for Bodies Operating Product Certification Systems (First Edition), 1996, IBR approved for §170.503.

(3) [Reserved]

EFFECTIVE DATE NOTE: At 79 FR 54480, Sept. 11, 2014, §170.599 was amended by revising paragraphs (b)(1) and (2) and adding paragraph (b)(3), effective Oct. 14, 2014. For the convenience of the user, the added and revised text is set forth as follows:

§ 170.599 Incorporation by reference.

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(b) * * *

(1) ISO/IEC 17011:2004 Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies (Corrected Version), February 15, 2005, “ISO/IEC 17011,” IBR approved for §170.503.

(2) ISO/IEC GUIDE 65:1996—General Requirements for Bodies Operating Product Certification Systems (First Edition), 1996, “ISO/IEC Guide 65,” IBR approved for §170.503.

(3) ISO/IEC 17065:2012(E)—Conformity assessment—Requirements for bodies certifying products, processes and services (First Edition), 2012, “ISO/IEC 17065,” IBR approved for §170.503.

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