

reconsideration in accordance with § 170.504.

(d) *Final approval.*

(1) If the National Coordinator determines that an accreditation organization has met the standard specified in § 170.504(b), then that organization will be approved as the ONC-AA on a final basis. The accreditation organization that was selected as the ONC-AA on a preliminary basis pursuant to paragraph (c) of this section will be notified of this final decision and cannot request reconsideration or further review.

(2) If the National Coordinator determines that no accreditation organization has met the standard specified in § 170.504(b), then the organization that was selected as the ONC-AA on a preliminary basis pursuant to paragraph (c) of this section will be approved as the ONC-AA on a final basis.

(e) *ONC-AA ongoing responsibilities.* An ONC-AA must:

(1) Maintain conformance with ISO/IEC 17011:2004 (incorporated by reference in § 170.599);

(2) Verify that the certification bodies it accredits and ONC-ACBs conform to, at a minimum, ISO/IEC Guide 65:1996 (incorporated by reference in § 170.599);

(3) Ensure the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods;

(4) Verify that ONC-ACBs are performing surveillance in accordance with their respective annual plans; and

(5) Review ONC-ACB surveillance results to determine if the results indicate any substantive non-conformance by ONC-ACBs with the conditions of their respective accreditations.

(f) *ONC-AA status.*

(1) An accreditation organization has not been granted ONC-AA status unless and until it is notified by the National Coordinator that it has been approved as the ONC-AA on a final basis pursuant to paragraph (d) of this section.

(2) An ONC-AA's status will expire not later than 3 years from the date its status was granted by the National Coordinator.

(3) The National Coordinator will accept requests for ONC-AA status, in accordance with paragraph (b) of this section,

at least 180 days before the current ONC-AA's status is set to expire.

[76 FR 1325, Dec. 7, 2011, as amended at 76 FR 72642, Nov. 25, 2011]

**§ 170.504 Reconsideration process for requests for ONC-AA status.**

(a) An accreditation organization that submits a timely request for ONC-AA status in accordance with § 170.503 and is denied may request reconsideration of the decision to deny its request for ONC-AA status.

(b) *Submission requirement.* To request reconsideration, an accreditation organization is required to submit to the National Coordinator, within 15 days of receipt of a denial notice, a written statement with supporting documentation contesting the decision to deny its request for ONC-AA status. The submission must demonstrate that clear, factual errors were made in the review of its request for ONC-AA status and that the accreditation organization would have been selected as the ONC-AA pursuant to § 170.503(c) if those errors had been corrected. If the National Coordinator does not receive an accreditation organization's submission within the specified timeframe, then its request for reconsideration may be denied.

(c) *Review of submissions.* The National Coordinator is permitted up to 30 days to review all timely submissions that were received and determine whether an accreditation organization has met the standard specified in paragraph (b) of this section.

(d) *Decision.*

(1) If the National Coordinator determines that an accreditation organization has met the standard specified in paragraph (b) of this section, then that organization will be approved as the ONC-AA on a final basis. All other accreditation organizations will be notified that their requests for reconsideration have been denied.

(2) *Final decision.* A reconsideration decision issued by the National Coordinator is final and not subject to further review.

**§ 170.505 Correspondence.**

(a) Correspondence and communication with the National Coordinator shall be conducted by e-mail, unless

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otherwise necessary. The official date of receipt of any e-mail between the National Coordinator and an accreditation organization requesting ONC-AA status, the ONC-AA, an applicant for ONC-ACB status, or an ONC-ACB is the date on which the e-mail was sent.

(b) In circumstances where it is necessary for an accreditation organization requesting ONC-AA status, the ONC-AA, an applicant for ONC-ACB status, or an ONC-ACB to correspond or communicate with the National Coordinator by regular or express mail, the official date of receipt will be the date of the delivery confirmation.

### § 170.510 Types of certification.

Applicants may seek authorization from the National Coordinator to perform the following types of certification:

- (a) Complete EHR certification; and/or
- (b) EHR Module certification; and/or
- (c) Certification of other types of HIT for which the Secretary has adopted certification criteria under subpart C of this part.

### § 170.520 Application.

Applicants must include the following information in an application for ONC-ACB status and submit it to the National Coordinator for the application to be considered complete.

(a) The type of authorization sought pursuant to § 170.510. For authorization to perform EHR Module certification, applicants must indicate the specific type(s) of EHR Module(s) they seek authorization to certify. If qualified, applicants will only be granted authorization to certify the type(s) of EHR Module(s) for which they seek authorization.

(b) General identifying information including:

- (1) Name, address, city, state, zip code, and Web site of applicant; and
- (2) Designation of an authorized representative, including name, title, phone number, and e-mail address of the person who will serve as the applicant's point of contact.

(c) Documentation that confirms that the applicant has been accredited by the ONC-AA.

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(d) An agreement, properly executed by the applicant's authorized representative, that it will adhere to the Principles of Proper Conduct for ONC-ACBs.

### § 170.523 Principles of proper conduct for ONC-ACBs.

An ONC-ACB shall:

(a) Maintain its accreditation, or if a new ONC-AA is approved by the National Coordinator, obtain accreditation from the new ONC-AA within 12 months or a reasonable period specified by the National Coordinator and maintain such accreditation;

(b) Attend all mandatory ONC training and program update sessions;

(c) Maintain a training program that includes documented procedures and training requirements to ensure its personnel are competent to certify HIT;

(d) Report to ONC within 15 days any changes that materially affect its:

- (1) Legal, commercial, organizational, or ownership status;
- (2) Organization and management including key certification personnel;
- (3) Policies or procedures;
- (4) Location;
- (5) Personnel, facilities, working environment or other resources;
- (6) ONC authorized representative (point of contact); or
- (7) Other such matters that may otherwise materially affect its ability to certify HIT.

(e) Allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled), during normal business hours, any certifications performed to demonstrate compliance with the requirements of the permanent certification program;

(f) Provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified, which includes, at a minimum:

- (1) The Complete EHR or EHR Module developer name (if applicable);
- (2) The date certified;
- (3) The product version;
- (4) The unique certification number or other specific product identification;
- (5) The clinical quality measures to which a Complete EHR or EHR Module has been certified;