

(2) Make the records available to HHS upon request during the retention period described in paragraph (f)(1) of this section;

(g) *Approved testing methods.* Only test health IT using test tools and test procedures approved by the National Coordinator; and

(h) *Refunds.* Promptly refund any and all fees received for:

(1) Requests for testing that are withdrawn while its operations are suspended by the National Coordinator;

(2) Testing that will not be completed as a result of its conduct; and

(3) Previous testing that it performed if its conduct necessitates the retesting of Health IT Modules.

[81 FR 72465, Oct. 19, 2016, as amended at 85 FR 25951, May 1, 2020]

§ 170.525 Application submission.

(a) An applicant for ONC-ACB or ONC-ATL status must submit its application either electronically via email (or Web site submission if available), or by regular or express mail.

(b) An application for ONC-ACB or ONC-ATL status may be submitted to the National Coordinator at any time.

[81 FR 72465, Oct. 19, 2016]

§ 170.530 Review of application.

(a) *Method of review and review time-frame.* (1) Applications will be reviewed in the order they are received.

(2) The National Coordinator is permitted up to 30 days from receipt to review an application that is submitted for the first time.

(b) *Application deficiencies.* (1) If the National Coordinator identifies an area in an application that requires the applicant to clarify a statement or correct an error or omission, the National Coordinator may contact the applicant to make such clarification or correction without issuing a deficiency notice. If the National Coordinator has not received the requested information after five days, the National Coordinator may issue a deficiency notice to the applicant.

(2) If the National Coordinator determines that deficiencies in the application exist, the National Coordinator will issue a deficiency notice to the applicant and return the application. The

deficiency notice will identify the areas of the application that require additional information or correction.

(c) *Revised application.* (1) An applicant is permitted to submit a revised application in response to a deficiency notice. An applicant may request from the National Coordinator an extension for good cause of the 15-day period provided in paragraph (c)(2) of this section to submit a revised application.

(2) In order for an applicant to continue to be considered for ONC-ACB or ONC-ATL status, the applicant's revised application must address the specified deficiencies and be received by the National Coordinator within 15 days of the applicant's receipt of the deficiency notice, unless the National Coordinator grants an applicant's request for an extension of the 15-day period based on a finding of good cause. If a good cause extension is granted, then the revised application must be received by the end of the extension period.

(3) The National Coordinator is permitted up to 15 days to review a revised application once it has been received and may request clarification of statements and the correction of errors or omissions in a revised application during this time period.

(4) If the National Coordinator determines that a revised application still contains deficiencies, the applicant will be issued a denial notice indicating that the applicant cannot re-apply for ONC-ACB or ONC-ATL status for a period of six months from the date of the denial notice. An applicant may request reconsideration of this decision in accordance with § 170.535.

(d) *Satisfactory application.* (1) An application will be deemed satisfactory if it meets all the application requirements, as determined by the National Coordinator.

(2) The National Coordinator will notify the applicant's authorized representative of its satisfactory application and its successful achievement of ONC-ACB or ONC-ATL status.

(3) Once notified by the National Coordinator of its successful achievement of ONC-ACB or ONC-ATL status, the applicant may represent itself as an ONC-ACB or ONC-ATL (as applicable)

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and begin certifying or testing (as applicable) health information technology consistent with its authorization.

[76 FR 1325, Dec. 7, 2011, as amended at 81 FR 72465, Oct. 19, 2016]

§ 170.535 ONC-ACB and ONC-ATL application reconsideration.

(a) *Basis for reconsideration request.* An applicant may request that the National Coordinator reconsider a denial notice only if the applicant can demonstrate that clear, factual errors were made in the review of its application and that the errors' correction could lead to the applicant obtaining ONC-ACB or ONC-ATL status.

(b) *Submission requirement.* An applicant is required to submit, within 15 days of receipt of a denial notice, a written statement to the National Coordinator contesting the decision to deny its application and explaining with sufficient documentation what factual error(s) it believes can account for the denial. If the National Coordinator does not receive the applicant's reconsideration request within the specified timeframe, its reconsideration request may be rejected.

(c) *Reconsideration request review.* If the National Coordinator receives a timely reconsideration request, the National Coordinator is permitted up to 15 days from the date of receipt to review the information submitted by the applicant and issue a decision.

(d) *Decision.* (1) If the National Coordinator determines that clear, factual errors were made during the review of the application and that correction of the errors would remove all identified deficiencies, the applicant's authorized representative will be notified of the National Coordinator's determination and the applicant's successful achievement of ONC-ACB or ONC-ATL status.

(2) If, after reviewing an applicant's reconsideration request, the National Coordinator determines that the applicant did not identify factual errors or that the correction of the factual errors would not remove all identified deficiencies in the application, the National Coordinator may reject the applicant's reconsideration request.

(3) *Final decision.* A reconsideration decision issued by the National Coordinator

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is final and not subject to further review.

[76 FR 1325, Dec. 7, 2011, as amended at 81 FR 72466, Oct. 19, 2016]

§ 170.540 ONC-ACB and ONC-ATL status.

(a) *Acknowledgement and publication.* The National Coordinator will acknowledge and make publicly available the names of ONC-ACBs and ONC-ATLs, including the date each was authorized and the type(s) of certification or scope of testing, respectively, each has been authorized to perform.

(b) *Representation.* Each ONC-ACB or ONC-ATL must prominently and unambiguously identify the scope of its authorization on its Web site and in all marketing and communications statements (written and oral) pertaining to its activities under the ONC Health IT Certification Program.

(c) *Renewal.* An ONC-ACB or ONC-ATL is required to renew its status every three years. An ONC-ACB or ONC-ATL is required to submit a renewal request, containing any updates to the information requested in § 170.520, to the National Coordinator 60 days prior to the expiration of its status.

(d) *Expiration.* An ONC-ACB's or ONC-ATL's status will expire three years from the date it was granted by the National Coordinator unless it is renewed in accordance with paragraph (c) of this section.

[81 FR 72466, Oct. 19, 2016]

§ 170.545 [Reserved]

§ 170.550 Health IT Module certification.

(a) *Certification scope.* When certifying Health IT Module(s), an ONC-ACB must certify in accordance with the applicable certification criteria adopted by the Secretary at subpart C of this part.

(b) *Health IT product scope options.* An ONC-ACB must provide the option for an Health IT Module(s) to be certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Gap certification.* An ONC-ACB may provide the option for and perform