

§ 170.535

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

45 CFR Subtitle A (10-1-23 Edition)

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