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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

gap certification of previously certified Health IT Module(s).

(d) *Upgrades and enhancements.* An ONC-ACB may provide an updated certification to a previously certified Health IT Module(s).

(e) *Standards updates.* ONC-ACBs must provide an option for certification of Health IT Modules consistent with §171.405(b)(7) or (8) to any one or more of the criteria referenced in §170.405(a) based on newer versions of standards included in the criteria which have been approved by the National Coordinator for use in certification.

(f) [Reserved]

(g) *Health IT module dependent criteria.* When certifying a Health IT Module to the 2015 Edition health IT certification criteria, an ONC-ACB must certify the Health IT Module in accordance with the certification criteria at:

(1) Section 170.315(g)(3) if the Health IT Module is presented for certification to one or more listed certification criteria in §170.315(g)(3);

(2) Section 170.315(g)(4);

(3) Section 170.315(g)(5); and

(4) Section 170.315(g)(6) if the Health IT Module is presented for certification with C-CDA creation capabilities within its scope. If the scope of certification sought includes multiple certification criteria that require C-CDA creation, §170.315(g)(6) need only be tested in association with one of those certification criteria and would not be expected or required to be tested for each. If the scope of certification sought includes multiple certification criteria that require C-CDA creation, §170.315(g)(6) need only be tested in association with one of those certification criteria and would not be expected or required to be tested for each so long as all applicable C-CDA document templates have been evaluated as part of §170.315(g)(6) for the scope of the certification sought.

(5) Section 170.315(b)(10) when a health IT developer presents a Health IT Module for certification that can store electronic health information at the time of certification by the product, of which the Health IT Module is a part.

(h) *Privacy and security certification framework—(1) General rule.* When certi-

fying a Health IT Module to the 2015 Edition health IT certification criteria, an ONC-ACB can only issue a certification to a Health IT Module if the privacy and security certification criteria in paragraphs (h)(3)(i) through (ix) of this section have also been met (and are included within the scope of the certification).

(2) *Testing.* In order to be issued a certification, a Health IT Module would only need to be tested once to each applicable privacy and security criterion in paragraphs (h)(3)(i) through (ix) of this section so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification, except for the following:

(i) A Health IT Module presented for certification to §170.315(e)(1) must be separately tested to §170.315(d)(9); and

(ii) A Health IT Module presented for certification to §170.315(e)(2) must be separately tested to §170.315(d)(9).

(3) *Applicability.* (i) Section 170.315(a)(1) through (3), (5), (12), (14), and (15) are also certified to the certification criteria specified in §170.315(d)(1) through (7), (d)(12), and (13).

(ii) Section 170.315(a)(4), (9), (10), and (13) are also certified to the certification criteria specified in §170.315(d)(1) through (3), and (d)(5) through (7), (d)(12), and (13).

(iii) Section 170.315(b)(1) through (3) and (6) through (9) are also certified to the certification criteria specified in §170.315(d)(1) through (3) and (d)(5) through (8), (12), and (13);

(iv) Section 170.315(c) is also certified to the certification criteria specified in §170.315(d)(1), (d)(2)(i)(A), (B), (d)(2)(ii) through (v), (d)(3), (5), (12), and (13);

(v) Section 170.315(e)(1) is also certified to the certification criteria specified in §170.315(d)(1) through (3), (5), (7), (9), (12), and (13);

(vi) Section 170.315(e)(2) and (3) is also certified to the certification criteria specified in §170.315(d)(1), (d)(2)(i)(A) and (B), (d)(2)(ii) through (v), (d)(3), (5), (9), (12), and (13);

(vii) Section 170.315(f) is also certified to the certification criteria specified in §170.315(d)(1) through (3), (7), (12), and (13);

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(viii) Section 170.315(g)(7) through (10) is also certified to the certification criteria specified in §170.315(d)(1), (9), (12), and (13); and (d)(2)(i)(A) and (B), (d)(2)(ii) through (v), or (d)(10);

(ix) Section 170.315(h) is also certified to the certification criteria specified in §170.315(d)(1), (d)(2)(i)(A) and (B), (d)(2)(ii) through (v), (d)(3), (12), and (13); and

(i) [Reserved]

(j) *Direct Project transport method.* An ONC-ACB can only issue a certification to a Health IT Module for §170.315(h)(1) if the Health IT Module's certification also includes §170.315(b)(1).

(k) *Inherited certified status.* An ONC-ACB must accept requests for a newer version of a previously certified Health IT Module(s) to inherit the certified status of the previously certified Health IT Module(s) without requiring the newer version to be recertified.

(1) Before granting certified status to a newer version of a previously certified Health IT Module(s), an ONC-ACB must review an attestation submitted by the developer(s) of the Health IT Module(s) to determine whether any change in the newer version has adversely affected the Health IT Module(s)' capabilities for which certification criteria have been adopted.

(2) An ONC-ACB may grant certified status to a newer version of a previously certified Health IT Module(s) if it determines that the capabilities for which certification criteria have been adopted have not been adversely affected.

(1) *Conditions of certification attestations.* Ensure that the health IT developer of the Health IT Module has met its responsibilities under subpart D of this part.

(m) *Time-limited certification and certification status for certain 2015 Edition certification criteria.* An ONC-ACB may only issue a certification to a Health IT Module and permit continued certified status for:

(1) Section 170.315(a)(10) and (13) and §170.315(e)(2) for the period before January 1, 2022.

(2) Section 170.315(b)(6) for the period before December 31, 2023.

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(3) Section 170.315(g)(8) for the period before December 31, 2022.

[76 FR 1325, Dec. 7, 2011, as amended at 77 FR 54291, Sept. 4, 2012; 79 FR 54480, Sept. 11, 2014; 80 FR 62757, Oct. 16, 2015; 85 FR 25952, May 1, 2020; 85 FR 70085, Nov. 4, 2020]

§ 170.553 [Reserved]

§ 170.555 Certification to newer versions of certain standards.

(a) ONC-ACBs may certify Health IT Module(s) to a newer version of certain identified minimum standards specified at subpart B of this part, unless the Secretary prohibits the use of a newer version for certification.

(b) *Applicability of a newer version of a minimum standard.* (1) ONC-ACBs are not required to certify Health IT Module(s) according to newer versions of standards adopted and named in subpart B of this part, unless:

(i) The National Coordinator approves a newer version for use in certification and a health IT developer voluntarily elects to seek certification of its health IT in accordance with §170.405(b)(9) or update its certified health IT to the newer version in accordance with §170.405(b)(8); or

(ii) The new version is incorporated by reference in §170.299.

(2) A certified Complete EHR or certified Health IT Module may be upgraded to comply with newer versions of standards identified as minimum standards in subpart B of this part without adversely affecting its certification status, unless the Secretary prohibits the use of a newer version for certification.

[77 FR 54291, Sept. 4, 2012, as amended at 85 FR 25952, May 1, 2020]

§ 170.556 In-the-field surveillance and maintenance of certification for Health IT.

(a) *In-the-field surveillance.* Consistent with its accreditation under 170.523(a) to ISO/IEC 17065 and the requirements of this subpart, an ONC-ACB must initiate surveillance “in the field” as necessary to assess whether a certified Health IT Module continues to conform to the requirements in subparts A, B, C and E of this part once the certified