the National Coordinator by regular, express, or certified mail, the official date of receipt for all parties will be the date of the delivery confirmation to the address on record.

[85 FR 25950, May 1, 2020]

§ 170.510 Authorization scope for ONC–ACB status.

Applicants for ONC–ACB status may seek authorization from the National Coordinator to perform the following types of certification:

(a) Health IT Module certification; and/or

(b) Certification of other types of health IT for which the Secretary has adopted certification criteria under subpart C of this part.

[76 FR 1325, Dec. 7, 2011, as amended at 81 FR 72464, Oct. 19, 2016; 85 FR 25950, May 1, 2020]

§ 170.511 Authorization scope for ONC–ATL status.

Applicants may seek authorization from the National Coordinator to perform the testing of Complete EHRs or Health IT Modules to a portion of a certification criterion, one certification criterion, or many or all certification criteria adopted by the Secretary under subpart C of this part.

[81 FR 72464, Oct. 19, 2016]

§ 170.520 Application.

(a) *ONC–ACB 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.

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

(2) General identifying, information including:

(i) Name, address, city, state, zip code, and Web site of applicant; and

(ii) Designation of an authorized representative, including name, title, phone number, and email address of the person who will serve as the applicant's point of contact.

(3) Documentation that confirms that the applicant has been accredited to ISO/IEC 17065 (for availability, see § 170.599), with an appropriate scope, by any accreditation body that is a signatory to the Multilateral Recognition Arrangement (MLA) with the International Accreditation Forum (IAF).

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

(b) *ONC–ATL application.* Applicants must include the following information in an application for ONC–ATL status and submit it to the National Coordinator for the application to be considered complete.

(1) The authorization scope sought pursuant to § 170.511.

(2) General identifying, information including:

(i) Name, address, city, state, zip code, and Web site of applicant; and

(ii) Designation of an authorized representative, including name, title, phone number, and email address of the person who will serve as the applicant's point of contact.

(3) Documentation that confirms that the applicant has been accredited by NVLAP to the ONC Health IT Certification Program, including to ISO/IEC 17025 (incorporated by reference, *see* § 170.599).

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

[81 FR 72464, Oct. 19, 2016, as amended at 85 FR 25950, May 1, 2020]

§ 170.523 Principles of proper conduct for ONC–ACBs.

An ONC–ACB shall:

(a) *Accreditation.* Maintain its accreditation in good standing to ISO/IEC 17065 (incorporated by reference in § 170.599).

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

(c) *Training program.* Maintain a training program that includes documented procedures and training requirements to ensure its personnel are competent to certify health IT;

(d) *Reporting.* 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 health IT.

(e) *Onsite observation.* 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 ONC Health IT Certification Program;

(f) *Certified product listing.* Provide ONC, no less frequently than weekly, a current list of Health IT Modules, and/or EHR Modules that have been certified that includes, at a minimum:

(1) For the 2015 Edition health IT certification criteria and subsequent editions of health IT certification criteria:

(i) The Health IT Module developer name; product name; product version; developer Web site, physical address, email, phone number, and contact name;

(ii) The ONC–ACB Web site, physical address, email, phone number, and contact name, contact function/title;

(iii) The ATL Web site, physical address, email, phone number, and contact name, contact function/title;

(iv) Location and means by which the testing was conducted (*e.g.*, remotely with health IT developer at its headquarters location);

(v) The date(s) the Health IT Module was tested;

(vi) The date the Health IT Module was certified;

(vii) The unique certification number or other specific product identification;

(viii) The certification criterion or criteria to which the Health IT Module has been certified, including the test procedure and test data versions used, test tool version used, and whether any test data was altered (*i.e.*, a yes/no) and for what purpose;

(ix) The way in which each privacy and security criterion was addressed for the purposes of certification;

(x) The standard or mapping used to meet the quality management system certification criterion;

(xi) The standard(s) or lack thereof used to meet the accessibility-centered design certification criterion;

(xii) *Where applicable*, the hyperlink to access an application programming interface (API)'s documentation and terms of use;

(xiii) *Where applicable*, which certification criteria were gap certified;

(xiv) *Where applicable*, if a certification issued was a result of an inherited certified status request;

(xv) *Where applicable*, the clinical quality measures to which the Health IT Module has been certified;

(xvi) *Where applicable*, any additional software a Health IT Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary;

(xvii) *Where applicable*, the standard(s) used to meet a certification criterion where more than one is permitted;

(xviii) *Where applicable*, any optional capabilities within a certification criterion to which the Health IT Module was tested and certified;

(xix) *Where applicable*, and for each applicable certification criterion, all of the information required to be submitted by Health IT Module developers to meet the safety-enhanced design certification criterion. Each user-centered design element required to be reported must be at a granular level (*e.g.*, task success/failure));

(xx) A hyperlink to the disclosures required by §170.523(k)(1) for the Health IT Module;

(xxi) [Reserved]

(xxii) *When applicable*, for each instance in which a Health IT Module failed to conform to its certification

731

and for which corrective action was instituted under §170.556 (provided no provider or practice site is identified):

(A) The specific certification requirements to which the technology failed to conform, as determined by the ONC–ACB;

(B) A summary of the deficiency or deficiencies identified by the ONC–ACB as the basis for its determination of non-conformity;

(C) When available, the health IT developer's explanation of the deficiency or deficiencies;

(D) The dates surveillance was initiated and completed;

(E) The results of randomized surveillance, including pass rate for each criterion in instances where the Health IT Module is evaluated at more than one location;

(F) The number of sites that were used in randomized surveillance;

(G) The date of the ONC–ACB's determination of non-conformity;

(H) The date on which the ONC–ACB approved a corrective action plan;

(I) The date corrective action began (effective date of approved corrective action plan);

(J) The date by which corrective action must be completed (as specified by the approved corrective action plan);

(K) The date corrective action was completed; and

(L) A description of the resolution of the non-conformity or non-conformities.

(2) [Reserved]

(g) *Records retention.* (1) Retain all records related to the certification of Complete EHRs and Health IT Modules to an edition of certification criteria beginning with the codification of an edition of certification criteria in the Code of Federal Regulations through a minimum of 3 years from the effective date that removes the applicable edition from the Code of Federal Regulations; and

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

(h) *Certification decision.* Only certify Health IT Modules that have been:

(1) Tested, using test tools and test procedures approved by the National Coordinator, by an:

(i) ONC–ATL;

(ii) ONC–ATL, National Voluntary Laboratory Accreditation Program-accredited testing laboratory under the ONC Health IT Certification Program, and/or an ONC–ATCB for the purposes of performing gap certification; or

(2) Evaluated by it for compliance with a conformance method approved by the National Coordinator.

(i) *Surveillance.* Conduct surveillance of certified health IT in accordance with its accreditation, §170.556, and the following requirements:

(1) Submit an annual surveillance plan to the National Coordinator.

(2) Report, at a minimum, on a quarterly basis to the National Coordinator the results of its surveillance, including surveillance results that identify:

(i) The names of health IT developers;

(ii) Names of products and versions;

(iii) Certification criteria and ONC Health IT Certification Program requirements surveilled;

(iv) The type of surveillance (*i.e.,* reactive or randomized);

(v) The dates surveillance was initiated and completed; and

(vi) As applicable, the number of sites that were used in randomized surveillance.

(3) Annually submit a summative report of surveillance results to the National Coordinator.

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

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

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

(3) Previous certifications that it performed if its conduct necessitates the recertification of Complete EHRs and/or Health IT Module(s);

(k) *Disclosures.* Ensure adherence to the following requirements when issuing any certification and during surveillance of Health IT Modules the ONC–ACB has certified.

(1) *Mandatory Disclosures.* A health IT developer must conspicuously include the following on its website and in all marketing materials, communications

732

statements, and other assertions related to the Health IT Module's certification:

(i) The disclaimer "This Health IT Module is [specify Edition of health IT certification criteria] compliant and has been certified by an ONC–ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services."

(ii) For a Health IT Module certified to the 2015 Edition health IT certification criteria, the information specified by paragraphs (f)(1)(i), (vi) through (viii), (xv), and (xvi) of this section as applicable for the specific Health IT Module.

(iii) In plain language, a detailed description of all known material information concerning additional types of costs or fees that a user may be required to pay to implement or use the Health IT Module's capabilities, whether to meet provisions of HHS programs requiring the use of certified health IT or to achieve any other use within the scope of the health IT's certification. The additional types of costs or fees required to be disclosed include but are not limited to costs or fees (whether fixed, recurring, transaction-based, or otherwise) imposed by a health IT developer (or any third party from whom the developer purchases, licenses, or obtains any technology, products, or services in connection with its certified health IT) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which health IT is certified; or in connection with any data generated in the course of using any capability to which health IT is certified.

(iv) The types of information required to be disclosed under paragraph (k)(iii) of this section include but are not limited to:

(A) Additional types of costs or fees (whether fixed, recurring, transaction-based, or otherwise) imposed by a health IT developer (or any third-party from whom the developer purchases, licenses, or obtains any technology, products, or services in connection with its certified health IT) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which health IT is certified; or in connection with any data generated in the course of using any capability to which health IT is certified.

(B)–(C) [Reserved]

(v) Health IT self-developers are excluded from the requirements of paragraph (k)(1)(iii) of this section.

(2)–(3) [Reserved]

(4) A certification issued to a Health IT Module based solely on the applicable certification criteria adopted by the ONC Health IT Certification Program must be separate and distinct from any other certification(s) based on other criteria or requirements.

(l) *Certification and Design Mark.* Display the ONC Certified health IT Certification and Design Mark on all certifications issued under the ONC Health IT Certification Program in a manner that complies with the Criteria and Terms of Use for the ONC Certified health IT Certification and Design Mark, and ensure that use of the mark by health IT developers whose products are certified under the ONC Health IT Certification Program is compliant with the Criteria and Terms of Use for the ONC Certified health IT Certification and Design Mark.

(m) *Adaptations and updates.* On a quarterly basis each calendar year, obtain a record of:

(1) All adaptations of certified Health IT Modules;

(2) All updates made to certified Health IT Modules affecting the capabilities in certification criteria to which the "safety-enhanced design" criteria apply;

(3) All uses cases for § 170.315(d)(13);

(4) All updates made to certified Health IT Modules in compliance with § 170.405(b)(3); and

(5) All updates to certified Health IT Modules and all certifications of Health IT Modules issued including voluntary use of newer standards versions per § 170.405(b)(8) or (9). Record of these updates may be obtained by aggregation of ONC–ACB documentation of certification activity.

(n) *Complaints reporting.* Submit a list of complaints received to the National Coordinator on a quarterly basis each

calendar year that includes the number of complaints received, the nature/substance of each complaint, and the type of complainant for each complaint.

(o) *Scope reduction.* Be prohibited from reducing the scope of a Health IT Module's certification when it is under surveillance or under a corrective action plan.

(p) *Real world testing.* (1) Review and confirm that applicable health IT developers submit real world testing plans in accordance with § 170.405(b)(1).

(2) Review and confirm that applicable health IT developers submit real world testing results in accordance with § 170.405(b)(2).

(3) Submit real world testing plans by December 15 of each calendar year and results by March 15 of each calendar year to ONC for public availability.

(q) *Attestations.* Review and submit health IT developer Conditions and Maintenance of Certification requirements attestations made in accordance with § 170.406 to ONC for public availability.

(r) *Test results from ONC–ATLs.* Accept test results from any ONC–ATL that is:

(1) In good standing under the ONC Health IT Certification Program, and

(2) Compliant with its ISO/IEC 17025 accreditation requirements as required by 170.524(a).

(s) *Information for direct review.* Report to ONC, no later than a week after becoming aware of, any information that could inform whether ONC should exercise direct review under § 170.580(a).

(t) *Health IT Module voluntary standards and implementation specifications updates notices.* Ensure health IT developers opting to take advantage of the flexibility for voluntary updates of standards and implementation specifications in certified Health IT Modules per § 170.405(b)(8) provide timely advance written notice to the ONC–ACB and all affected customers.

(1) Maintain a record of the date of issuance and the content of developers' § 170.405(b)(8) notices; and

(2) Timely post content or make publicly accessible via the CHPL each § 170.405(b)(8) notice received, publicly on the CHPL attributed to the certified Health IT Module(s) to which it applies.

§ 170.524 Principles of proper conduct for ONC–ATLs.

An ONC–ATL shall:

(a) *Accreditation.* Maintain its NVLAP accreditation for the ONC Health IT Certification Program, including accreditation to ISO/IEC 17025 (incorporated by reference, *see* § 170.599);

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

(c) *Training program.* Maintain a training program that includes documented procedures and training requirements to ensure its personnel are competent to test health IT;

(d) *Reporting.* 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 testing 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 test health IT.

(e) *Onsite observation.* Allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled), during normal business hours, any testing performed pursuant to the ONC Health IT Certification Program;

(f) *Records retention.* (1) Retain all records related to the testing of Complete EHRs and/or Health IT Modules to an edition of certification criteria beginning with the codification of an edition of certification criteria in the Code of Federal Regulations through a minimum of three years from the effective date that removes the applicable edition from the Code of Federal Regulations; and

734