

## Dept. of Health and Human Services

## § 170.505

the ONC Health IT Certification Program.

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

### § 170.502 Definitions.

For the purposes of this subpart:

*Applicant* means a single organization or a consortium of organizations that seeks to become an ONC-ACB or ONC-ATL by submitting an application to the National Coordinator for such status.

*Deployment site* means the physical location where a Health IT Module(s) or other type of health IT resides or is being or has been implemented.

*Development site* means the physical location where a Health IT Module(s) or other type of health IT was developed.

*Gap certification* means the certification of a previously certified Health IT Module(s) to:

(1) All applicable new and/or revised certification criteria adopted by the Secretary at subpart C of this part based on test results issued by a NVLAP-accredited testing laboratory under the ONC Health IT Certification Program or an ONC-ATL; and

(2) All other applicable certification criteria adopted by the Secretary at subpart C of this part based on the test results used to previously certify the Complete EHR or Health IT Module(s) under the ONC Health IT Certification Program.

*ONC-Authorized Certification Body or ONC-ACB* means an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to this subpart to perform the certification of Health IT Module(s), and/or other types of health IT under the ONC Health IT Certification Program.

*ONC-Authorized Testing Lab or ONC-ATL* means an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to this subpart to perform the testing of Health IT Modules to certification criteria adopted by the Secretary at subpart C of this part.

*Providing or provide an updated certification* means the action taken by an ONC-ACB to ensure that the developer

of a previously certified Health IT Module(s) shall update the information required by §170.523(k)(1)(i), after the ONC-ACB has verified that the certification criterion or criteria to which the Health IT Module(s) was previously certified have not been revised and that no new certification criteria are applicable to the Health IT Module(s).

*Remote certification* means the use of methods, including the use of web-based tools or secured electronic transmissions, that do not require an ONC-ACB to be physically present at the development or deployment site to conduct certification.

[76 FR 1325, Dec. 7, 2011, as amended at 77 FR 54291, Sept. 4, 2012; 81 FR 72464, Oct. 19, 2016; 85 FR 25950, May 1, 2020]

### §§ 170.503–170.504 [Reserved]

### § 170.505 Correspondence.

(a) Correspondence and communication with ONC or the National Coordinator shall be conducted by email, unless otherwise necessary or specified.

(1) Consideration for providing notice beyond email, such as by regular, express, or certified mail, will be based on, but not limited to, whether: The party requests use of correspondence beyond email; the party has responded via email to our communications; we have sufficient information from the party to ensure appropriate delivery of any other method of notice; and the matter involves an alleged violation within ONC's purview under §170.580 that indicates a serious violation under the ONC Health IT Certification Program with potential consequences of suspension, certification termination, or a certification ban.

(2) The official date of receipt of any email between ONC or the National Coordinator and an applicant for ONC-ACB status, an applicant for ONC-ATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart is the date on which the email was sent.

(b) In circumstances where it is necessary for an applicant for ONC-ACB status, an applicant for ONC-ATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart to correspond or communicate with ONC or

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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

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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;