

§ 170.406

certified to §170.315(c)(3) prior to June 30, 2020, must:

(i) Update their certified health IT to be compliant with the revised versions of this criteria adopted in §170.315(c)(3); and

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(10)(i) of this section by December 31, 2022.

[85 FR 25945, May 1, 2020, as amended at 85 FR 43711, July 20, 2020; 85 FR 70084, Nov. 4, 2020; 85 FR 78236, Dec. 4, 2020]

§ 170.406 Attestations.

(a) *Condition of Certification requirement.* A health IT developer, or its authorized representative that is capable of binding the health IT developer, must provide the Secretary an attestation of compliance with the following Conditions and Maintenance of Certification requirements:

(1) Section 170.401;

(2) Section 170.402, but only for §170.402(a)(4) and (b)(2) if the health IT developer certified a Health IT Module(s) that is part of a health IT product which can store electronic health information;

(3) Section 170.403;

(4) Section 170.404 if the health IT developer has a Health IT Module(s) certified to any of the certification criteria adopted in §170.315(g)(7) through (10); and such health IT developer must also ensure that health IT allows for health information to be exchanged, accessed, and used, in the manner described in §170.404; and

(5) Section 170.405 if a health IT developer has a Health IT Module(s) certified to any one or more 2015 Edition certification criteria in §170.315(b), (c)(1) through (3), (e)(1), (f), (g)(7) through (10), and (h).

(b) *Maintenance of Certification requirement.* (1) A health IT developer, or its authorized representative that is capable of binding the health IT developer, must provide the attestation specified in paragraph (a) of this section semiannually for any Health IT Modules that have or have had an active certification at any time under the ONC Health IT Certification Program during the prior six months.

(2) [Reserved]

45 CFR Subtitle A (10–1–23 Edition)

Subpart E—ONC Health IT Certification Program

SOURCE: 76 FR 1325, Dec. 7, 2011, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to subpart E of part 170 appear at 80 FR 62755, Oct. 16, 2015.

§ 170.500 Basis and scope.

This subpart implements section 3001(c)(5) of the Public Health Service Act and sets forth the rules and procedures related to the ONC Health IT Certification Program for health information technology (health IT) administered by the National Coordinator for Health Information Technology.

[76 FR 1325, Dec. 7, 2011, as amended at 77 FR 54291, Sept. 4, 2012]

§ 170.501 Applicability.

(a) This subpart establishes the processes that applicants for ONC-ACB status must follow to be granted ONC-ACB status by the National Coordinator; the processes the National Coordinator will follow when assessing applicants and granting ONC-ACB status; the requirements that ONC-ACBs must follow to maintain ONC-ACB status; and the requirements of ONC-ACBs for certifying Health IT Module(s), and other types of health IT in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part.

(b) This subpart establishes the processes that applicants for ONC-ATL status must follow to be granted ONC-ATL status by the National Coordinator; the processes the National Coordinator will follow when assessing applicants and granting ONC-ATL status; the requirements that ONC-ATLs must follow to maintain ONC-ATL status; and the requirements of ONC-ATLs for testing Health IT Modules in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part.

(c) [Reserved]

(d) This subpart establishes the processes the National Coordinator will follow when exercising direct review of certified health IT and related requirements for ONC-ACBs, ONC-ATLs, and developers of health IT certified under

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