

§ 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