

Dept. of Health and Human Services

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User's request to register their software application for use with the Certified API Developer's Health IT Module certified to §170.315(g)(10).

(ii) *Registration for production use.* A Certified API Developer must register and enable all applications for production use within five business days of completing its verification of an API User's authenticity, pursuant to paragraph (b)(1)(i) of this section.

(2) *Service base URL publication.* A Certified API Developer must publish the service base URLs for all Health IT Modules certified to §170.315(g)(10) that can be used by patients to access their electronic health information. The Certified API Developer must publicly publish the service base URLs:

(i) For all of its customers regardless of whether the Health IT Modules certified to §170.315(g)(10) are centrally managed by the Certified API Developer or locally deployed by an API Information Source; and

(ii) In a machine-readable format at no charge.

(3) *Rollout of (g)(10)-certified APIs.* A Certified API Developer with certified API technology previously certified to the certification criterion in §170.315(g)(8) must provide all API Information Sources with such certified API technology deployed with certified API technology certified to the certification criterion in §170.315(g)(10) by no later than December 31, 2022.

(4) *Compliance for existing certified API technology.* By no later than April 5, 2021, a Certified API Developer with Health IT Module(s) certified to the certification criteria in §170.315(g)(7), (8), or (9) must comply with paragraph (a) of this section, including revisions to their existing business and technical API documentation and make such documentation available via a publicly accessible hyperlink that allows any person to directly access the information without any preconditions or additional steps.

(c) *Definitions.* The following definitions apply to this section:

API Information Source means an organization that deploys certified API technology created by a "Certified API Developer;"

API User means a person or entity that creates or uses software applica-

tions that interact with the "certified API technology" developed by a "Certified API Developer" and deployed by an "API Information Source;"

Certified API Developer means a health IT developer that creates the "certified API technology" that is certified to any of the certification criteria adopted in §170.315(g)(7) through (10); and

Certified API technology means the capabilities of Health IT Modules that are certified to any of the API-focused certification criteria adopted in §170.315(g)(7) through (10).

[85 FR 25945, May 1, 2020, as amended at 85 FR 70084, Nov. 4, 2020]

§ 170.405 Real world testing.

(a) *Condition of Certification requirement.* A health IT developer with 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) must successfully test the real world use of those Health IT Module(s) for interoperability (as defined in 42 U.S.C.300jj(9) and §170.102) in the type of setting in which such Health IT Module(s) would be/is marketed.

(b) *Maintenance of Certification requirements—(1) Real world testing plan submission.* A health IT developer with Health IT Module(s) certified to any one or more of the criteria referenced in paragraph (a) of this section must submit to its ONC-ACB an annual real world testing plan addressing each of those certified Health IT Modules by a date determined by the ONC-ACB that enables the ONC-ACB to publish a publicly available hyperlink to the plan on CHPL no later than December 15 of each calendar year, beginning in 2021.

(i) The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.

(ii) The plan must include all health IT certified to any one or more of the criteria referenced in paragraph (a) of this section as of August 31 of the year in which the plan is submitted, and address the real world testing to be conducted in the calendar year immediately following plan submission.

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(iii) The plan must address the following for each of the certification criteria identified in paragraph (a) of this section that are included in each Health IT Module's scope of certification:

(A) The testing method(s)/methodology(ies) that will be used to demonstrate real world interoperability and conformance to the full scope of the certification criterion's requirements, including scenario- and use case-focused testing;

(B) The care setting(s) that will be tested for real world interoperability and an explanation for the health IT developer's choice of care setting(s) to test;

(C) For any standards and implementation specifications referenced by the criterion that the developer has chosen to certify to National Coordinator-approved newer versions pursuant to paragraph (b)(8) or (9) of this section, a description of how the developer will test and demonstrate conformance to all requirements of the criterion using all versions of the adopted standards to which each Health IT Module was certified as of August 31 of the year in which the real world testing plan is due.

(D) A schedule of key real world testing milestones;

(E) A description of the expected outcomes of real world testing;

(F) At least one measurement/metric associated with the real world testing; and

(G) A justification for the health IT developer's real world testing approach.

(2) *Real world testing results reporting.*

(i) If in the course of conducting real world testing the developer discovers one or more non-conformities with the full scope of any certification criterion under the Program, the developer must report that non-conformity to the ONC-ACB within 30 days.

(ii) For real world testing activities conducted during the immediately preceding calendar year, a health IT developer must submit to its ONC-ACB an annual real world testing results report addressing each of its certified Health IT Modules that include certification criteria referenced in paragraph (a) of this section by a date determined

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by the ONC-ACB that enables the ONC-ACB to publish a publicly available hyperlink to the results report on CHPL no later than March 15 of each calendar year, beginning in 2023. The real world testing results must report the following for each of the certification criteria identified in paragraph (a) of this section that are included in the Health IT Module's scope of certification:

(A) The method(s) that was used to demonstrate real world interoperability;

(B) The care setting(s) that was tested for real world interoperability;

(C) The voluntary updates to standards and implementation specifications that the National Coordinator has approved through the Standards Version Advancement Process;

(D) A list of the key milestones met during real world testing;

(E) The outcomes of real world testing including a description of any challenges encountered during real world testing; and

(F) At least one measurement/metric associated with the real world testing.

(3) *USCDI Updates.* A health IT developer with health IT certified to §170.315(b)(1), (b)(2), (e)(1), (g)(6) and/or (g)(9) on May 1, 2020, must:

(i) Update their certified health IT to be compliant with the revised versions of these criteria adopted in this final rule; and

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(3)(i) of this section by December 31, 2022.

(4) *C-CDA Companion Guide Updates.* A health IT developer with health IT certified to §170.315(b)(1), (b)(2), (b)(9), (e)(1), (g)(6), and/or (g)(9) prior to May 1, 2020, must:

(i) Update their certified health IT to be compliant with the revised versions of the Program criteria in the 2015 Edition; and

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(4)(i) of this section by December 31, 2022.

(5) *Electronic prescribing.* A health IT developer with health IT certified to

§170.315(b)(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(b)(3)(ii); and

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(5)(i) of this section by December 31, 2022.

(6) *Security tags.* A health IT developer with health IT certified to §170.315(b)(7) and/or §170.315(b)(8) prior to May 1, 2020, must:

(i) Update their certified health IT to be compliant with the revised versions of the criteria adopted in §170.315(b)(7) and/or the revised versions of the criteria adopted in §170.315(b)(8); and

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(6)(i) of this section by December 31, 2022.

(7) *ASTM updates.* A health IT developer with health IT certified to §170.315(d)(2), (3), and/or (d)(10) prior to May 1, 2020, must:

(i) Update their certified health IT to be compliant with §170.210(e)(1) and the standard specified in §170.210(h); and

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(7)(i) of this section by December 31, 2022.

(8) *Standards Version Advancement Process—voluntary updates of certified health IT to newer versions of standards and implementation specifications.* A health IT developer subject to this paragraph (b) is permitted to update Health IT Module(s) certified to any one or more of the certification criteria referenced in paragraph (a) of this section to a newer version of any adopted standard or implementation specification included in the criterion, provided that newer version is approved by the National Coordinator for use in certifications issued under the ONC Health IT Certification Program. A developer that pursues such updates to its certified Health IT Module(s) must:

(i) Provide advance notice to all affected customers and its ONC-ACB—

(A) Expressing its intent to update the certified Health IT Module(s) to the National Coordinator-approved advanced version of the standard implementation specification;

(B) The developer's expectations for how the update(s) will affect real world interoperability for the Health IT Module(s);

(C) Whether the developer intends to continue to support the certificate(s) for the existing certified Health IT Module(s) version(s) for some period of time and how long or if the existing certified Health IT Module(s) version(s) will be deprecated; and

(ii) Successfully demonstrate conformance with approved more recent versions of the standard(s) or implementation specification(s) included in each certification criterion under which the developer chooses to update its certified Health IT Module(s).

(iii) Maintain the updated certified Health IT Module(s) in full conformance with all applicable Program requirements.

(9) *Standards Version Advancement Process—voluntary certification to newer versions of standards and implementation specifications.* A Health IT developer is permitted to seek certification for its Health IT Module(s) to any one or more of the certification criteria referenced in paragraph (a) of this section using a newer version of any adopted standard(s) or implementation specification(s) included in the criterion without first obtaining certification to the version of that adopted standard or implementation specification that is incorporated by reference in §170.299, provided that the newer version is approved by the National Coordinator for use in certifications issued under the ONC Health IT Certification Program. Developers may, for each standard and implementation specification included in each criterion, choose on an itemized basis whether to seek certification to the version incorporated by reference in §170.299, or to one or more newer version(s) approved by the National Coordinator for use in Health IT Module certifications issued pursuant to section 3001(c)(5) of the Public Health Service Act, or to both.

(10) *Clinical quality measures—report.* A health IT developer with health IT

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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]

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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