ONC-Authorized Certification Body Application

Pursuant to §170.520, organizations interested in participating in the ONC Health IT Certification Program as an ONC-Authorized Certification Body (ONC-ACB) must complete and submit an application for approval to the National Coordinator for Health Information Technology (National Coordinator). ONC-ACB status will expire three years from the date it is granted by the National Coordinator unless it is renewed in accordance with § 170.540(d). Pursuant to § 170.535, an applicant who is issued a denial notice may request that the National Coordinator reconsider the application only if the applicant can demonstrate that clear, factual errors were made in the review of its application and that the errors' correction could lead to the applicant obtaining ONC-ACB status.

Please indicate the type of application by selecting the appropriate box below (only select one):

☐ Application   ☐ Revised Application   ☐ Renewal   ☐ Request for reconsideration

Applications for ONC – ACB status should be submitted electronically via email to onc-acb@hhs.gov with each of the following components completed as instructed:

Application Components per § 170.520(a)	Action Required
Authorization Scope pursuant to §170.510	Provide Information
General Identifying Information	Provide Information
International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) (ISO/IEC) 17065 Accreditation Agreement to Adhere to the Principles of Proper Conduct for ONC-ACBs	Attach Documentation Sign Agreement

Authorization Scope

In the space below, indicate 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.

General Identifying Information

Organization Name(s):

Address:

City, State:

Zip Code:

ONC-Authorized Certification Body Application

Website URL:

Authorized Representative Name (Last, First):

Title:

Phone:

Mobile:

E-mail:

ISO/IEC 17065 Accreditation

Please attach documentation, with an appropriate scope, to the application submission confirming accreditation to ISO/IEC 17065.[1]

Principles of Proper Conduct for ONC-ACBs

Please confirm that you have read, understand, and agree that your organization will adhere to the Principles of Proper Conduct for ONC-ACBs, in accordance with § 170.523, by checking the box next to each Principle of Proper Conduct and signing and dating the attestation below.

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;

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[1] ISO/IEC 17065 accreditation must be by an accreditation body that is a signatory to the Multilateral Recognition Arrangement (MLA) with the International Accreditation Forum (IAF).

☐ (f) *Certified product listing.* Provide ONC, no less frequently than weekly, a current list of Health IT Modules, Complete EHRs, 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) The attestation required by §170.523(k)(2);

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

☐ *(g) 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

(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 testing that are withdrawn while its operations are suspended by the National Coordinator;

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

  (3) Previous testing that it performed if its conduct necessitates the retesting of Complete EHRs and/or Health IT Modules.

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

        (i) The disclaimer "This [Complete EHR or Health IT Module] is [specify Edition of EHR 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 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 feeds 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.

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

    (2) 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 use 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 the 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.

Once all checkboxes have been checked, print out and sign or insert your digital signature below.

As the Authorized Representative, I agree and am bound to the above conditions for participation. Further, I attest that all statements made in this document are correct to the best of my knowledge and are made in good faith.

Signature: _____

Name: _____

Date: _____

Organization: _____

☐   ☐

For Internal Use Only

Reset Internal Use Fields

Received by_____Date_____

Received by_____Date_____

Decision   Approved ☐ Denied

Status Effective Dates_____through_____

Recertification Date (60 days prior to expiration Date) _____

Recertification Notice sent_____by _____

Notes:

Reset ALL Fields