



DEPARTMENT OF HEALTH AND HUMAN SERVICES

30-Day Submission Period for Requests for ONC-Approved Accreditor (ONC-AA)

Status

Agency: Office of the National Coordinator for Health Information Technology, Department of Health and Human Services.

Action: Notice.

Summary: This notice announces the 30-day period for submission of requests for ONC-Approved Accreditor (ONC-AA) status.

Dates: The 30-day submission period begins [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER] and will end on [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

For Further Information Contact: Alicia Morton, Director, ONC Health IT Certification Program, Office of the National Coordinator for Health Information Technology (ONC), 202-690-7151.

Supplementary Information:

In accordance with 45 CFR § 170.503(f)(2), an ONC-Approved Accreditor's (ONC-AA's) status will expire not later than 3 years from the date its status was granted by the National Coordinator for Health Information Technology (National Coordinator). The American National Standards Institute's (ANSI's) status as the ONC-AA for certifying bodies under the ONC Health IT Certification Program will expire on June 06, 2017. To ensure the continuity of the accreditation process and the ongoing responsibilities of the ONC-AA under the ONC Health IT Certification Program, we are seeking requests for ONC-AA status for the 3-year term that would follow the term of the current ONC-AA

(ANSI). Accordingly, this notice is issued pursuant to § 170.503(b), which requires the National Coordinator to publish a notice in the Federal Register to announce the 30-day period during which requests for ONC-AA status may be submitted. In order to be considered for ONC-AA status, an accreditation organization must submit a written request to the National Coordinator that includes the information required by § 170.503(b) within the 30-day period specified in this notice. Section 170.503(b) requires an accreditation organization to submit the following information to demonstrate its ability to serve as an ONC-AA:

- (1) A detailed description of the accreditation organization's conformance to ISO/IEC17011:2004 (incorporated by reference in § 170.599) and experience evaluating the conformance of certification bodies to ISO/IEC Guide 65:1996 (incorporated by reference in § 170.599);
- (2) A detailed description of the accreditation organization's accreditation requirements, as well as how those requirements would complement the Principles of Proper Conduct for ONC-Authorized Certification Bodies (ONC-ACBs) and ensure the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods;
- (3) Detailed information on the accreditation organization's procedures that would be used to monitor ONC-ACBs;
- (4) Detailed information, including education and experience, about the key personnel who review organizations for accreditation; and
- (5) Procedures for responding to, and investigating, complaints against ONC-ACBs.

Requests for ONC-AA status may be submitted by email to ONC-AA@hhs.gov and should include “Request for ONC-AA Status” in the subject line. Alternatively, requests for ONC-AA status may be submitted by regular or express mail to: Office of the National Coordinator for Health Information Technology, Attention: ONC Health IT Certification Program - Request for ONC-AA Status, 330 C Street S.W., Washington, D.C. 20201. In accordance with § 170.505, the official date of receipt of an email submission will be the date on which it was sent, and the official date of a submission by regular or express mail will be the date of the delivery confirmation. To clarify, email submissions may be sent up to and through 11:59 p.m. EST on the last day of the submission period. Additional information about requesting ONC-AA status and the ONC Health IT Certification Program can be found on the ONC website at:

<http://healthit.gov/certification>.

Authority: 42 U.S.C. 300jj–11.

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Technology.*

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