

Dept. of Health and Human Services

§ 170.581

(ii) An appeal, including all supporting documentation, must be filed within 30 days of the filing of the intent to appeal.

(4) *Effect of appeal.* (i) A request for appeal stays the termination of a certification issued to a Health IT Module, but the Health IT Module is prohibited from being marketed, licensed, or sold as “certified” during the stay.

(ii) A request for appeal does not stay the suspension of a Health IT Module.

(iii) A request for appeal stays a certification ban issued under § 170.581(a)(2).

(5) *Appointment of a hearing officer.* The National Coordinator will assign the case to a hearing officer to adjudicate the appeal on his or her behalf.

(i) The hearing officer may not review an appeal in which he or she participated in the initial suspension, termination, or certification ban determination or has a conflict of interest in the pending matter.

(ii) The hearing officer must be trained in a nationally recognized ethics code that articulates nationally recognized standards of conduct for hearing officers/officials.

(6) *Adjudication.* (i) The hearing officer may make a determination based on:

(A) The written record, which includes the:

(1) ONC determination and supporting information;

(2) Information provided by the health IT developer with the appeal filed in accordance with paragraphs (g)(1) through (3) of this section; and

(3) Information ONC provides in accordance with paragraph (g)(6)(v) of this section; or

(B) All the information provided in accordance with paragraph (g)(6)(i)(A) and any additional information from a hearing conducted in-person, via telephone, or otherwise.

(ii) The hearing officer will have the discretion to conduct a hearing if he/she:

(A) Requires clarification by either party regarding the written record under paragraph (g)(6)(i)(A) of this section;

(B) Requires either party to answer questions regarding the written record

under paragraph (g)(6)(i)(A) of this section; or

(C) Otherwise determines a hearing is necessary.

(iii) The hearing officer will neither receive witness testimony nor accept any new information beyond what was provided in accordance with paragraph (g)(6)(i) of this section.

(iv) The default process will be a determination in accordance with paragraph (g)(6)(i)(A) of this section.

(v) ONC will have an opportunity to provide the hearing officer with a written statement and supporting documentation on its behalf that clarifies, as necessary, its determination to suspend or terminate the certification or issue a certification ban.

(7) *Determination by the hearing officer.* (i) The hearing officer will issue a written determination to the health IT developer within 30 days of receipt of the appeal or within a timeframe agreed to by the health IT developer and ONC and approved by the hearing officer, unless ONC cancels the suspension or rescinds the termination determination.

(ii) The National Coordinator’s determination on appeal, as issued by the hearing officer, is final and not subject to further review.

[81 FR 72468, Oct. 19, 2016, as amended at 85 FR 25953, May 1, 2020]

§ 170.581 Certification ban.

(a) *Circumstances that may trigger a certification ban.* The certification of any of a health IT developer’s health IT is prohibited when:

(1) The certification of one or more of the health IT developer’s Health IT Modules is:

(i) Terminated by ONC under the ONC Health IT Certification Program;

(ii) Withdrawn from the ONC Health IT Certification Program by an ONC-ACB because the health IT developer requested it to be withdrawn (for reasons other than to comply with Program requirements) when the health IT developer’s health IT was the subject of a potential non-conformity or non-conformity as determined by ONC;

(iii) Withdrawn by an ONC-ACB because of a non-conformity with any of the certification criteria adopted by

§ 170.599

the Secretary under subpart C of this part;

(iv) Withdrawn by an ONC-ACB because the health IT developer requested it to be withdrawn (for reasons other than to comply with Program requirements) when the health IT developer's health IT was the subject of surveillance for a certification criterion or criteria adopted by the Secretary under subpart C of this part, including notice of pending surveillance; or

(2) ONC determines a certification ban is appropriate per its review under § 170.580(a)(2)(iii).

(b) *Notice of certification ban.* When ONC decides to issue a certification ban to a health IT developer, ONC will notify the health IT developer of the certification ban through a notice of certification ban. The notice of certification ban will include, but may not be limited to:

(1) An explanation of the certification ban;

(2) Information supporting the certification ban;

(3) Instructions for appealing the certification ban if banned in accordance with paragraph (a)(2) of this section; and

(4) Instructions for requesting reinstatement into the ONC Health IT Certification Program, which would lift the certification ban.

(c) *Effective date of certification ban.* (1) A certification ban will be effective immediately if banned under paragraph (a)(1) of this section.

(2) For certification bans issued under paragraph (a)(2) of this section, the ban will be effective immediately after the following applicable occurrence:

(i) The expiration of the 10-day period for filing a statement of intent to appeal in § 170.580(g)(3)(i) if the health IT developer does not file a statement of intent to appeal.

(ii) The expiration of the 30-day period for filing an appeal in § 170.580(g)(3)(ii) if the health IT developer files a statement of intent to appeal, but does not file a timely appeal.

(iii) A final determination to issue a certification ban per § 170.580(g)(7) if a health IT developer files an appeal timely.

45 CFR Subtitle A (10–1–23 Edition)

(d) *Reinstatement.* The certification of a health IT developer's health IT subject to the prohibition in paragraph (a) of this section may commence once the following conditions are met.

(1) A health IT developer must request ONC's permission in writing to participate in the ONC Health IT Certification Program.

(2) The request must demonstrate that the customers affected by the certificate termination, certificate withdrawal, or noncompliance with a Condition or Maintenance of Certification requirement have been provided appropriate remediation.

(3) For noncompliance with a Condition or Maintenance of Certification requirement, the noncompliance must be resolved.

(4) ONC is satisfied with the health IT developer's demonstration under paragraph (d)(2) of this section that all affected customers have been provided with appropriate remediation and grants reinstatement into the ONC Health IT Certification Program.

[85 FR 25954, May 1, 2020]

§ 170.599 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish a document in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW., Washington, DC 20201, call ahead to arrange for inspection at 202-690-7151, and is available from the source listed below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>.

(b) International Organization for Standardization, Case postale 56,