
42 U.S. Code § 263b

Certification of mammography facilities

(a) Definitions

As used in this section:

(1) Accreditation body

The term “accreditation body” means a body that has been approved by the Secretary under subsection (e) (1)(A) to accredit mammography facilities.

(2) Certificate

The term “certificate” means the certificate described in subsection (b)(1).

(3) Facility

(A) In general

The term “facility” means a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility as determined by the Secretary, that conducts breast cancer screening or diagnosis through mammography activities. Such term does not include a facility of the Department of Veterans Affairs.

(B) Activities

For the purposes of this section, the activities of a facility include the operation of equipment to produce the mammogram, the processing of the film, the initial interpretation of the mammogram and the viewing conditions for that interpretation. Where procedures such as the film processing, or the interpretation of the mammogram are performed in a location different from where the mammogram is performed, the facility performing the mammogram shall be responsible for meeting the quality standards described in subsection (f).

(4) Inspection

The term “inspection” means an onsite evaluation of the facility by the Secretary, or State or local agency on behalf of the Secretary.

(5) Mammogram

The term “mammogram” means a radiographic image produced through mammography.

(6) Mammography

The term “mammography” means radiography of the breast.

(7) Survey

The term “survey” means an onsite physics consultation and evaluation performed by a medical physicist as described in subsection (f)(1)(E).

(8) Review physician

The term “review physician” means a physician as prescribed by the Secretary under subsection (f)(1)(D)

who meets such additional requirements as may be established by an accreditation body under subsection (e) and approved by the Secretary to review clinical images under subsection (e)(1)(B)(i) on behalf of the accreditation body.

(b) Certificate requirement

(1) Certificate

No facility may conduct an examination or procedure described in paragraph (2) involving mammography after October 1, 1994, unless the facility obtains—

(A) a certificate or a temporary renewal certificate—

(i) that is issued, and, if applicable, renewed, by the Secretary in accordance with paragraphs ⁽¹⁾(1) or (2) of subsection (c);

(ii) that is applicable to the examination or procedure to be conducted; and

(iii) that is displayed prominently in such facility; or

(B) a provisional certificate or a limited provisional certificate—

(i) that is issued by the Secretary in accordance with paragraphs (3) and (4) of subsection (c);

(ii) that is applicable to the examination or procedure to be conducted; and

(iii) that is displayed prominently in such facility.

The reference to a certificate in this section includes a temporary renewal certificate, provisional certificate, or a limited provisional certificate.

(2) Examination or procedure

A facility shall obtain a certificate in order to—

(A) operate radiological equipment that is used to image the breast;

(B) provide for the interpretation of a mammogram produced by such equipment at the facility or under arrangements with a qualified individual at a facility different from where the mammography examination is performed; and

(C) provide for the processing of film produced by such equipment at the facility or under arrangements with a qualified individual at a facility different from where the mammography examination is performed.

(c) Issuance and renewal of certificates

(1) In general

The Secretary may issue or renew a certificate for a facility if the person or agent described in subsection (d)(1)(A) meets the applicable requirements of subsection (d)(1) with respect to the facility. The Secretary may issue or renew a certificate under this paragraph for not more than 3 years.

(2) Temporary renewal certificate

The Secretary may issue a temporary renewal certificate, for a period of not to exceed 45 days, to a facility seeking reaccreditation if the accreditation body has issued an accreditation extension, for a period of not to exceed 45 days, for any of the following:

(A) The facility has submitted the required materials to the accreditation body within the established time frames for the submission of such materials but the accreditation body is unable to complete the reaccreditation process before the certification expires.

(B) The facility has acquired additional or replacement equipment, or has had significant personnel changes or other unforeseen situations that have caused the facility to be unable to meet reaccreditation timeframes, but in the opinion of the accreditation body have not compromised the quality of

mammography.

(3) Limited provisional certificate

The Secretary may, upon the request of an accreditation body, issue a limited provisional certificate to an entity to enable the entity to conduct examinations for educational purposes while an onsite visit from an accreditation body is in progress. Such certificate shall be valid only during the time the site visit team from the accreditation body is physically in the facility, and in no case shall be valid for longer than 72 hours. The issuance of a certificate under this paragraph, shall not preclude the entity from qualifying for a provisional certificate under paragraph (4).

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