

after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that the owner or operator or any employee of the laboratory—

(1) has been guilty of misrepresentation in obtaining the certification,

(2) has failed to comply with any standards under section 263a-2 of this title applicable to the certification, or

(3) has refused a request of the State or accreditation organization for permission to inspect the laboratory, its operations, and records.

(b) Effect

If the certification of an embryo laboratory is revoked or suspended, the certification of the laboratory shall continue in effect for 60 days after the laboratory receives notice of the revocation or suspension. If the certification of an embryo laboratory is revoked or suspended, the laboratory may apply for recertification after one year after the date of the revocation or suspension.

(Pub. L. 102-493, § 5, Oct. 24, 1992, 106 Stat. 3150.)

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102-493, set out as a note under section 263a-1 of this title.

§ 263a-5. Publication

The Secretary, through the Centers for Disease Control, shall not later than 3 years after October 24, 1992, and annually thereafter publish and distribute to the States and the public—

(1)(A)¹ pregnancy success rates reported to the Secretary under section 263a-1(a)(1) of this title and, in the case of an assisted reproductive technology program which failed to report one or more success rates as required under such section, the name of each such program and each pregnancy success rate which the program failed to report, and

(B) from information reported under section 263a-1(a)(2) of this title—

(i) the identity of each embryo laboratory in a State which has adopted the certification program under such program and whether such laboratory is certified under section 263a-2 of this title,

(ii) the identity of each embryo laboratory in a State which has not adopted such certification program and which has been certified by an accreditation organization approved by the Secretary under section 263a-3 of this title, and

(iii) in the case of an embryo laboratory which is not certified under section 263a-2 of this title or certified by an accreditation organization approved by the Secretary under section 263a-3 of this title, whether the laboratory applied for certification.

¹ So in original. No par. (2) has been enacted.

(Pub. L. 102-493, § 6, Oct. 24, 1992, 106 Stat. 3151.)

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102-531, title III, § 312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102-493, set out as a note under section 263a-1 of this title.

§ 263a-6. Fees

The Secretary may require the payment of fees for the purpose of, and in an amount sufficient to cover the cost of, administering sections 263a-1 to 263a-7 of this title. A State operating a program under section 263a-2 of this title may require the payment of fees for the purpose of, and in an amount sufficient to cover the costs of, administering its program.

(Pub. L. 102-493, § 7, Oct. 24, 1992, 106 Stat. 3151.)

REFERENCES IN TEXT

Sections 263a-1 to 263a-7 of this title, referred to in text, was in the original “this Act”, meaning Pub. L. 102-493, Oct. 24, 1992, 106 Stat. 3146, known as the Fertility Clinic Success Rate and Certification Act of 1992, which enacted sections 263a-1 to 263a-7 of this title and provisions set out as notes under sections 201 and 263a-1 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102-493, set out as a note under section 263a-1 of this title.

§ 263a-7. Definitions

For purposes of sections 263a-1 to 263a-7 of this title:

(1) Assisted reproductive technology

The term “assisted reproductive technology” means all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies as the Secretary may include in this definition, after making public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency).

(2) Embryo laboratory

The term “embryo laboratory” means a facility in which human oocytes are subject to assisted reproductive technology treatment or procedures based on manipulation of oocytes or embryos which are subject to implantation.

(3) Secretary

The term “Secretary” means the Secretary of Health and Human Services.

(Pub. L. 102-493, § 8, Oct. 24, 1992, 106 Stat. 3151.)

REFERENCES IN TEXT

Sections 263a-1 to 263a-7 of this title, referred to in text, was in the original “this Act”, meaning Pub. L. 102-493, Oct. 24, 1992, 106 Stat. 3146, known as the Fertility Clinic Success Rate and Certification Act of 1992, which enacted sections 263a-1 to 263a-7 of this title and provisions set out as notes under sections 201 and 263a-1 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102-493, set out as a note under section 263a-1 of this title.

SUBPART 3—MAMMOGRAPHY FACILITIES

PRIOR PROVISIONS

A prior subpart 3 of part F of title III of the Public Health Service Act, comprising this subpart, was renumbered subchapter C of chapter V of the Federal Food, Drug, and Cosmetic Act, by Pub. L. 101-629, § 19(a)(4), Nov. 28, 1990, 104 Stat. 4530, as amended by Pub. L. 103-80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779, and is classified to part C (§ 360hh et seq.) of subchapter V of chapter 9 of Title 21, Food and Drugs.

§ 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 paragraphs¹ (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—

¹ So in original. Probably should be “paragraph”.