

(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.

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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) of this section to accredit mammography facilities.

(2) Certificate

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

(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) of this section.

(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) of this section.

(8) Review physician

The term “review physician” means a physician as prescribed by the Secretary under sub-