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–3. Accreditation organizations

(a) Approval of accreditation organizations

Not later than 2 years after October 24, 1992, the Secretary, through the Centers for Disease Control, shall promulgate criteria and procedures for the approval of accreditation organizations to inspect and certify embryo laboratories. The procedures shall require an application to the Secretary by an accreditation organization for approval. An accreditation organization which has received such an approval—

(1) may be used by States in the certification program under section 263a–2 of this title to inspect and certify embryo laboratories, or

(2) may certify embryo laboratories in States which have not adopted such a certification program.

(b) Criteria and procedures

The criteria and procedures promulgated under subsection (a) shall include—

(1) requirements for submission of such reports and the maintenance of such records as the Secretary or a State may require, and

(2) requirements for the conduct of inspections under section 263a–2(h)[1] of this title.

(c) Evaluations

The Secretary shall evaluate annually the performance of each accreditation organization approved by the Secretary by—

(1) inspecting under section 263a–2(i)[2] of this title a sufficient number of embryo laboratories accredited by such an organization to allow a reasonable estimate of the performance of such organization, and

(2) such other means as the Secretary determines to be appropriate.

(d) Transition

If the Secretary revokes approval under section 263a–2(i)(3)(D)[3] of this title of an accreditation organization after an evaluation under subsection (c), the certification of any embryo laboratory accredited by the organization shall continue in effect for 60 days after the laboratory is notified by the Secretary of the withdrawal of approval, except that the Secretary may extend the period during which the certification shall remain in effect if the Secretary determines that the laboratory submitted an application to another approved accreditation organization for certification after receipt of such notice in a timely manner.

(Pub. L. 102–493, § 4, Oct. 24, 1992, 106 Stat. 3150.)

Editorial Notes

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.

Statutory Notes and Related Subsidiaries

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–4. Certification revocation and suspension

(a) In general

A certification issued by a State or an accreditation organization for an embryo laboratory shall be revoked or suspended if the State or organization finds, on the basis of inspections and 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.)

Editorial Notes

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.

Statutory Notes and Related Subsidiaries

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 reproduc-

[1] So in original. Probably should be section ''263a–2(g)''.

[2] So in original. Probably should be section ''263a–2(h)''.

[3] So in original. Probably should be section ''263a–2(h)(3)(D)''.

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

tive 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.

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

Editorial Notes

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.

Statutory Notes and Related Subsidiaries

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.)

Editorial Notes

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.

Statutory Notes and Related Subsidiaries

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.)

Editorial Notes

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.

Statutory Notes and Related Subsidiaries

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

Editorial Notes

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,