

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.)

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-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.)

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

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.