

(D) if the Secretary determines—

- (i) that such State in carrying out the certification program has not met the requirements applicable to such program, or
- (ii) the accreditation organization which certified such laboratory has not met the requirements of section 263a-3 of this title,

the Secretary may revoke the approval of the State certification program or revoke the approval of such accreditation organization.

(i) Limitation

(1) Secretary

In developing the certification program, the Secretary may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs.

(2) State

In adopting the certification program, a State may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs.

(j) Term

The term of a certification issued by a State or an accreditation organization in a State shall be prescribed by the Secretary in the certification program and shall be valid for a period of time to be defined by the Secretary through the public comment process described in subsection (h)(2).⁴ The Secretary shall provide an application for recertification to be submitted at the time of changes in the ownership of a certified laboratory or changes in the administration of such a laboratory.

(Pub. L. 102-493, § 3, Oct. 24, 1992, 106 Stat. 3146.)

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-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.)

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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.

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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

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)”.

⁴ So in original. Probably should be subsection “(g)(2)”.