

through (d) and subsection (i) through (l) of such section 353 as in effect on December 31, 1988, shall continue to apply to clinical laboratories. The remaining subsections of such section 353, as so amended, shall take effect January 1, 1990, except that subsections (f)(1)(C) and (g)(2) shall take effect July 1, 1991, with respect to laboratories which were not subject to the requirements of such section 353 as in effect on December 31, 1988.”

EFFECTIVE DATE

Pub. L. 90-174, § 5(b), Dec. 5, 1967, 81 Stat. 539, provided that: “The amendment made by subsection (a) [enacting this section] shall become effective on the first day of the thirteenth month after the month [December 1967] in which it is enacted, except that the Secretary of Health, Education, and Welfare may postpone such effective date for such additional period as he finds necessary, but not beyond the first day of the 19th month after such month [December 1967] in which the amendment is enacted.”

CLIA WAIVER IMPROVEMENTS

Pub. L. 114-255, div. A, title III, § 3057, Dec. 13, 2016, 130 Stat. 1128, provided that:

“(a) DRAFT REVISED GUIDANCE.—Not later than 1 year after the date of the enactment of this Act [Dec. 13, 2016], the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance that—

“(1) revises ‘Section V. Demonstrating Insignificant Risk of an Erroneous Result – Accuracy’ of the guidance entitled ‘Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices’ and dated January 30, 2008; and

“(2) includes the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.

“(b) FINAL REVISED GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance published under subsection (a) not later than 1 year after the comment period for such draft guidance closes.”

STUDIES

Pub. L. 100-578, § 4, Oct. 31, 1988, 102 Stat. 2914, directed Secretary to conduct studies and submit report to Congress, not later than May 1, 1990, relating to the reliability and quality control procedures of clinical laboratory testing programs and the effect of errors in the testing procedures and results on the diagnosis and treatment of patients.

§ 263a-1. Assisted reproductive technology programs

(a) In general

Effective 2 years after October 24, 1992, each assisted reproductive technology (as defined in section 263a-7¹ of this title) program shall annually report to the Secretary through the Centers for Disease Control—

(1) pregnancy success rates achieved by such program through each assisted reproductive technology, and

(2) the identity of each embryo laboratory (as defined in section 263a-7¹ of this title) used by such program and whether the laboratory is certified under section 263a-2 of this title or has applied for such certification.

(b) Pregnancy success rates

(1) In general

For purposes of subsection (a)(1), the Secretary shall, in consultation with the organi-

zations referenced in subsection (c), define pregnancy success rates and shall make public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency) during its development.

(2) Definition

In developing the definition of pregnancy success rates, the Secretary shall take into account the effect on success rates of age, diagnosis, and other significant factors and shall include in such rates—

(A) the basic live birth rate calculated for each assisted reproductive technology performed by an assisted reproductive technology program by dividing the number of pregnancies which result in live births by the number of ovarian stimulation procedures attempted by such program, and

(B) the live birth rate per successful oocyte retrieval procedure calculated for each assisted reproductive technology performed by an assisted reproductive technology program by dividing the number of pregnancies which result in live births by the number of successful oocyte retrieval procedures performed by such program.

(c) Consultation

In developing the definition under subsection (b), the Secretary shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with assisted reproductive technologies.

(Pub. L. 102-493, § 2, Oct. 24, 1992, 106 Stat. 3146.)

Editorial Notes

REFERENCES IN TEXT

Section 263a-7 of this title, referred to in subsec. (a), was in the original “section 7” meaning section 7 of Pub. L. 102-493, which was translated as reading section 8 to reflect the probable intent of Congress, because definitions are contained in section 8 instead of section 7.

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

Pub. L. 102-493, § 9, Oct. 24, 1992, 106 Stat. 3152, provided that: “This Act [enacting this section, sections 263a-2 to 263a-7 of this title, and provisions set out as a note under section 201 of this title] shall take effect upon the expiration of 2 years after the date of the enactment of this Act [Oct. 24, 1992].”

§ 263a-2. Certification of embryo laboratories

(a) In general

(1) Development

Not later than 2 years after October 24, 1992, the Secretary, through the Centers for Disease

¹ See References in Text note below.

Control, shall develop a model program for the certification of embryo laboratories (referred to in this section as a “certification program”) to be carried out by the States.

(2) Consultation

In developing the certification program under paragraph (1), the Secretary shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with the assisted reproductive technology programs.

(b) Distribution

The Secretary shall distribute a description of the certification program to—

- (1) the Governor of each State,
- (2) the presiding officers of each State legislature,
- (3) the public health official of each State, and
- (4) the official responsible in each State for the operation of the State’s contract with the Secretary under section 1395aa of this title,

and shall encourage such officials to assist in the State adopting such program.

(c) Requirements

The certification program shall include the following requirements:

(1) Administration

The certification program shall be administered by the State and shall provide for the inspection and certification of embryo laboratories in the State by the State or by approved accreditation organizations.

(2) Application requirements

The certification program shall provide for the submission of an application to a State by an embryo laboratory for certification, in such form as may be specified by the State. Such an application shall include—

- (A) assurances satisfactory to the State that the embryo laboratory will be operated in accordance with the standards under subsection (d),
- (B) a report to the State identifying the assisted reproductive technology programs with which the laboratory is associated, and
- (C) such other information as the State finds necessary.

An embryo laboratory which meets the requirements of section 263a of this title shall, for the purposes of subparagraph (A) be considered in compliance with the standards referred to in such subparagraph which are the same as the standards in effect under section 263a of this title.

(d) Standards

The certification program shall include the following standards developed by the Secretary:

- (1) A standard to assure consistent performance of procedures by each embryo laboratory certified under the certification program or by an approved accreditation organization in a State which has not adopted the certification program.
- (2) A standard for a quality assurance and a quality control program to assure valid, reli-

able, and reproduceable¹ procedures in the laboratory.

(3) A standard for the maintenance of records (on a program by program basis) on laboratory tests and procedures performed, including the scientific basis of, and the methodology used for, the tests, procedures, and preparation of any standards or controls, criteria for acceptable and unacceptable outcomes, criteria for sample rejection, and procedures for safe sample disposal.

(4) A standard for the maintenance of written records on personnel and facilities necessary for proper and effective operation of the laboratory, schedules of preventive maintenance, function verification for equipment, and the release of such records to the State upon demand.

(5) A standard for the use of such personnel who meet such qualifications as the Secretary may develop.

(e) Certification under State programs

A State may qualify to adopt the certification program if the State has submitted an application to the Secretary to adopt such program and the Secretary has approved the application. Such an application shall include—

- (1) assurances by the State satisfactory to the Secretary that the certification program within the State meets the requirements of this section,
- (2) an agreement to make such reports as the Secretary may require, and
- (3) information about any proposed use of accreditation organizations under subsection (g).²

(f) Use of accreditation organizations

A State which has adopted the certification program may use accreditation organizations approved under section 263a-3 of this title to inspect and certify embryo laboratories.

(g) Inspections

(1) In general

A State which qualifies to adopt the certification program within the State shall conduct inspections in accordance with paragraph (2) to determine if laboratories in the State meet the requirements of such program. Such inspections shall be carried out by the State or by accreditation organizations used by the State under subsection (g).²

(2) Requirements

Inspections carried out under paragraph (1) shall—

- (A) be periodic and unannounced, or
- (B) be announced in such circumstances as the Secretary determines will not diminish the likelihood of discovering deficiencies in the operations of a laboratory.

Before making a determination under subparagraph (B), the Secretary shall make public, in such manner as to facilitate comment from any person (including any Federal or other public agency), a proposal indicating the circumstances under which announced inspections would be permitted.

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

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

(3) Results

The specific findings, including deficiencies, identified in an inspection carried out under paragraph (1) and any subsequent corrections to those deficiencies shall be announced and made available to the public upon request beginning no later than 60 days after the date of the inspection.

(h) Validation inspections**(1) In general**

The Secretary may enter and inspect, during regular hours of operation, embryo laboratories—

(A) which have been certified by a State under the certification program, or

(B) which have been certified by an accreditation organization approved by the Secretary under section 263a-3 of this title,

for the purpose of determining whether the laboratory is being operated in accordance with the standards in subsection (d).

(2) Access to facilities and records

In conducting an inspection of an embryo laboratory under paragraph (1), the Secretary shall have access to all facilities, equipment, materials, records, and information which the Secretary determines is necessary to determine if such laboratory is being operated in accordance with the standards in subsection (d). As part of such an inspection, the Secretary may copy any material, record, or information inspected or require it to be submitted to the Secretary. Such an inspection may be made only upon the presentation of identification to the owner, operator, or agent in charge of the laboratory being inspected.

(3) Failure to comply

If the Secretary determines as a result of an inspection under paragraph (1) that the embryo laboratory is not in compliance with the standards in subsection (d), the Secretary shall—

(A) notify the State in which the laboratory is located and, if appropriate, the accreditation organization which certified the laboratory,

(B) make available to the public the results of the inspection,

(C) conduct additional inspections of other embryo laboratories under paragraph (1) to determine if—

(i) such State in carrying out the certification program is reliably identifying the deficiencies of such laboratory, or

(ii) the accreditation organization which certified such laboratories is reliably identifying such deficiencies,³ and

(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.)

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-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.

³ So in original. Probably should be “deficiencies.”

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