

“(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Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance published under subsection (a) not later than 1 year after the comment period for such draft guidance closes.”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-7<sup>1</sup> 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-7<sup>1</sup> 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 organizations 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 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:

<sup>1</sup> See References in Text note below.