(q) Consultations

In carrying out this section, the Secretary shall consult with appropriate private organizations and public agencies.

(July 1, 1944, ch. 373, title III, § 353, as added Pub. L. 90–174, § 5(a), Dec. 5, 1967, 81 Stat. 536; amended Pub. L. 100–578, § 2, Oct. 31, 1988, 102 Stat. 2903; Pub. L. 105–115, title I, § 123(h), Nov. 21, 1997, 111 Stat. 2324; Pub. L. 112–202, § 2, Dec. 4, 2012, 126 Stat. 1483.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (i)(3) and (n)(6), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Titles XVIII and XIX of the Social Security Act are classified generally to subchapters XVIII (§ 1395 et seq.) and XIX (§ 1396 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Subsec. (e)(3) of this section, which required the Secretary to annually prepare and submit to certain committees of Congress a report describing the results of the evaluation conducted under subsec. (e)(2)(D) of this section, terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance. See, also, page 96 of House Document No. 103–7.

AMENDMENTS

2012—Subsec. (d)(1)(E). Pub. L. 112–202, § 2(1), inserted '', except that no proficiency testing sample shall be referred to another laboratory for analysis as prohibited under subsection (i)(4)'' before period at end.

Subsec. (i)(3). Pub. L. 112–202, § 2(2)(A), inserted '', except that if the revocation occurs pursuant to paragraph (4) the Secretary may substitute intermediate sanctions under subsection (h) instead of the 2-year prohibition against ownership or operation which would otherwise apply under this paragraph'' after ''issued under this section''.

Subsec. (i)(4). Pub. L. 112–202, § 2(2)(B), substituted ''may have its certificate revoked'' for ''shall have its certificate revoked''.

1997—Subsec. (d)(3). Pub. L. 105–115 amended heading and text of par. (3) generally. Prior to amendment, text read as follows: ''The examinations and procedures identified in paragraph (2) are simple laboratory examinations and procedures which, as determined by the Secretary, have an insignificant risk of an erroneous result, including those which—

''(A) have been approved by the Food and Drug Administration for home use,

''(B) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or

''(C) the Secretary has determined pose no reasonable risk of harm to the patient if performed incorrectly.''

1988—Pub. L. 100–578 substituted ''Certification of laboratories'' for ''Licensing of laboratories'' in section catchline, and amended text generally, revising and restating as subsecs. (a) to (q) provisions of former subsecs. (a) to (*l*).

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of Title 21, Food and Drugs.

EFFECTIVE DATE OF 1988 AMENDMENT; EXCEPTIONS; CONTINUING APPLICABILITY

Pub. L. 100–578, § 3, Oct. 31, 1988, 102 Stat. 2914, provided that: ''Subsections (g)(1), (h), (i), (j), (k), (*l*), and (m) of section 353 of the Public Health Service Act [42 U.S.C. 263a], as amended by section 101 [probably means section 2 of Pub. L. 100–578], shall take effect January 1, 1989, except that any reference in such subsections to the standards established under subsection (f) shall be considered a reference to the standards established under subsection (d) of such section 353, as in effect on December 31, 1988. During the period beginning January 1, 1989, and ending December 31, 1989, subsections (a) 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–7[1] 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

[1] See References in Text note below.

(2) the identity of each embryo laboratory (as defined in section 263a–7 [1] 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.)

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.

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:

(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: