
42 U.S. Code § 263a

Certification of laboratories

(a) “Laboratory” or “clinical laboratory” defined

As used in this section, the term “laboratory” or “clinical laboratory” means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(b) Certificate requirement

No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.

(c) Issuance and renewal of certificates

(1) In general

The Secretary may issue or renew a certificate for a laboratory only if the laboratory meets the requirements of subsection (d).

(2) Term

A certificate issued under this section shall be valid for a period of 2 years or such shorter period as the Secretary may establish.

(d) Requirements for certificates

(1) In general

A laboratory may be issued a certificate or have its certificate renewed if—

(A) the laboratory submits (or if the laboratory is accredited under subsection (e), the accreditation body which accredited the laboratory submits), an application—

- (i) in such form and manner as the Secretary shall prescribe,
- (ii) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory including—
 - (I) the number and types of laboratory examinations and other procedures performed,
 - (II) the methodologies for laboratory examinations and other procedures employed, and
 - (III) the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures, and
- (iii) that contains such other information as the Secretary may require to determine compliance with this section, and

the laboratory agrees to provide to the Secretary (or if the laboratory is accredited, to the accreditation

body which accredited it) a description of any change in the information submitted under clause (ii) not later than 6 months after the change was put into effect,

(B) the laboratory provides the Secretary—

(i) with satisfactory assurances that the laboratory will be operated in accordance with standards issued by the Secretary under subsection (f), or

(ii) with proof of accreditation under subsection (e),

(C) the laboratory agrees to permit inspections by the Secretary under subsection (g),

(D) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may reasonably require, and

(E) the laboratory agrees to treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business, except that no proficiency testing sample shall be referred to another laboratory for analysis as prohibited under subsection (i)(4).

(2) Requirements for certificates of waiver

(A) In general

A laboratory which only performs laboratory examinations and procedures described in paragraph (3) shall be issued a certificate of waiver or have its certificate of waiver renewed if—

(i) the laboratory submits an application—

(I) in such form and manner as the Secretary shall prescribe,

(II) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory, including the number and types of laboratory examinations and other procedures performed, the methodologies for laboratory examinations and other procedures employed, and the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures, and

(III) that contains such other information as the Secretary may reasonably require to determine compliance with this section, and

(ii) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may require.

(B) Changes

If a laboratory makes changes in the examinations and other procedures performed by it only with respect to examinations and procedures which are described in paragraph (3), the laboratory shall report such changes to the Secretary not later than 6 months after the change has been put into effect. If a laboratory proposes to make changes in the examinations and procedures performed by it such that the laboratory will perform an examination or procedure not described in paragraph (3), the laboratory shall report such change to the Secretary before the change takes effect.

(C) Effect

Subsections (f) and (g) shall not apply to a laboratory to which has been issued a certificate of waiver.

(3) Examinations and procedures

The examinations and procedures identified in paragraph (2) are laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that—

- (A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or
- (B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly.

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