

(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*

(2) REQUIREMENTS FOR CERTIFICATES OF WAIVER.—

(A) IN GENERAL.—A laboratory which only performs laboratory examinations and procedures described in para-

laboratory for analysis as prohibited under subsection (i)(4).

tinued compliance with the Secretary's standards under subsection (f),

(E) has refused a reasonable request of the Secretary, or any Federal officer or employee duly designated by the Secretary, for permission to inspect the laboratory and its operations and pertinent records during the hours the laboratory is in operation,

(F) has violated or aided and abetted in the violation of any provisions of this section or of any regulation promulgated thereunder, or

(G) has not complied with an intermediate sanction imposed under subsection (h).

(2) ACTION BEFORE A HEARING.—If the Secretary determines that—

(A) the failure of a laboratory to comply with the standards of the Secretary under subsection (f) presents an imminent and serious risk to human health, or

(B) a laboratory has engaged in an action described in subparagraph (D) or (E) of paragraph (1),

the Secretary may suspend or limit the certificate of the laboratory before holding a hearing under paragraph (1) regarding such failure or refusal. The opportunity for a hearing shall be provided no later than 60 days from the effective date of the suspension or limitation. A suspension or limitation under this paragraph shall stay in effect until the decision of the Secretary made after the hearing under paragraph (1).

(3) INELIGIBILITY TO OWN OR OPERATE LABORATORIES AFTER REVOCATION.—No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section. The certificate of a laboratory which has been excluded from participation under the medicare program under title XVIII of the Social Security Act because of actions relating to the quality of the laboratory shall be suspended for the period the laboratory is so excluded.

(4) IMPROPER REFERRALS.—Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis ~~shall~~ ^{may} have its certificate revoked for at least one year and shall be subject to appropriate fines and penalties as provided for in subsection (h).

(j) INJUNCTIONS.—Whenever the Secretary has reason to believe that continuation of any activity by a laboratory would constitute a significant hazard to the public health the Secretary may bring suit in the district court of the United States for the district in which such laboratory is situated to enjoin continuation of such activity. Upon proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order under this subsection shall be granted without bond by such court.

(k) JUDICIAL REVIEW.—

(1) PETITION.—Any laboratory which has had an intermediate sanction imposed under subsection (h) or has had its certificate suspended, revoked, or limited under subsection (i)

except that pursuant to revocations under paragraph (4) of this subsection, the Secretary may substitute intermediate sanctions under subsection (h) in lieu of the two year ban under this paragraph.