

CHAPTER 97-91

Committee Substitute for Senate Bill No. 270

An act relating to clinical laboratory personnel; amending s. 408.033, F.S.; providing an exemption from certain health care facilities assessments for clinical laboratories operated by practitioners for exclusive use; amending s. 483.035, F.S.; requiring the Agency for Health Care Administration to adopt rules relating to personnel of such laboratories; amending s. 483.061, F.S.; authorizing the agency to perform on-site or off-site inspections; amending s. 483.172, F.S.; providing for expiration of the agency's authority to collect a fee from certain laboratories; amending s. 483.181, F.S.; prohibiting discrimination against certain practitioners in the acceptance of specimens; amending ss. 483.801, 483.813, F.S.; providing for an exemption from regulation for certain practitioners and persons employed by certain laboratories; amending s. 483.803, F.S.; revising the definition of "clinical laboratory personnel"; amending s. 483.811, F.S.; providing application of regulatory provisions to certain clinical laboratories; creating s. 483.824, F.S.; providing qualifications of a clinical laboratory director; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (a) of subsection (3) of section 408.033, Florida Statutes, is amended to read:

408.033 Local and state health planning.—

(3) FUNDING.—

(a) The Legislature intends that the cost of local health councils and the Statewide Health Council be borne by application fees for certificates of need and by assessments on selected health care facilities subject to facility licensure by the Agency for Health Care Administration, including abortion clinics, assisted living facilities, ambulatory surgical centers, birthing centers, clinical laboratories except community nonprofit blood banks and clinical laboratories operated by practitioners for exclusive use regulated under s. 483.035, home health agencies, hospices, hospitals, intermediate care facilities for the developmentally disabled, nursing homes, and multiphasic testing centers and by assessments on organizations subject to certification by the agency pursuant to chapter 641, part III, including health maintenance organizations and prepaid health clinics.

Section 2. Subsection (1) of section 483.035, Florida Statutes, is amended to read:

483.035 Clinical laboratories operated by practitioners for exclusive use; licensure and regulation.—

(1) A clinical laboratory operated by one or more practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, or

chapter 466, exclusively in connection with the diagnosis and treatment of their own patients, must be licensed under this part and must comply with the provisions of this part, except that the agency shall adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing, and for construction standards relating to the licensure and operation of the laboratory based upon and not exceeding the same standards contained in the federal Clinical Laboratory Improvement Amendments of 1988 and the federal regulations adopted thereunder.

Section 3. Subsection (1) of section 483.061, Florida Statutes, is amended to read:

483.061 Inspection of clinical laboratories.—

(1) The agency shall ensure that each clinical laboratory, ~~collection station, and branch office~~ subject to this part is inspected either on-site or off-site when deemed necessary by the agency, but at least every 2 years, for the purpose of evaluating the ~~premises~~, operation, supervision, and procedures of the facility to ensure compliance with this part. Collection stations and branch offices may be inspected either on-site or off-site, when deemed necessary by the agency. The agency may conduct or cause to be conducted the following announced or unannounced inspections at any reasonable time:

(a) An inspection conducted at the direction of the federal Health Care Financing Administration.

(b) A licensure inspection.

(c) A validation inspection.

(d) A complaint investigation, including a full licensure investigation with a review of all licensure standards as outlined in rule. Complaints received by the agency from individuals, organizations, or other sources are subject to review and investigation by the agency. If a complaint has been filed against a laboratory or if a laboratory has a substantial licensure deficiency, the agency may inspect the laboratory annually or as the agency considers necessary.

However, for laboratories operated under s. 483.035, biennial licensure inspections shall be scheduled so as to cause the least disruption to the practitioner's scheduled patients.

Section 4. Subsection (4) of section 483.172, Florida Statutes, is amended to read:

483.172 License fees.—

(4) Upon October 1, 1993, and until the agency is granted state exemption status by the Health Care Financing Administration, laboratories that are licensed under the Clinical Laboratory Improvement Amendments of 1988 may not be assessed the fees specified in subsections (2) and (3) by the agency. During that period, a fee must be assessed to those laboratories to

cover the cost of state activities beyond those required under the Clinical Laboratory Improvement Amendments of 1988. This fee is \$100 biennially. The authority to collect the fee set forth in this subsection expires July 1, 1998.

Section 5. Subsection (5) is added to section 483.181, Florida Statutes, to read:

483.181 Acceptance, collection, identification, and examination of specimens.—

(5) A clinical laboratory licensed under this part must accept a human specimen submitted for examination by a practitioner licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, or chapter 466, if the specimen and test are the type performed by the clinical laboratory. A clinical laboratory may only refuse a specimen based upon a history of nonpayment for services by the practitioner. A clinical laboratory shall not charge different prices for tests based upon the chapter under which a practitioner submitting a specimen for testing is licensed.

Section 6. Section 483.801, Florida Statutes, is amended to read:

483.801 Exemptions.—This part applies to all clinical laboratories and clinical laboratory personnel within this state, except:

- (1) Clinical laboratories operated by the United States Government.
- (2) Laboratories operated and maintained exclusively for research and teaching purposes, involving no patient or public health service whatsoever.
- (3) Persons engaged in testing performed by laboratories regulated under s. 483.035(1) or exempt from regulation under s. 483.031(2).
- (4) Respiratory therapists and respiratory care practitioners certified or registered under part V of chapter 468.

Section 7. Subsection (3) of section 483.803, Florida Statutes, is amended to read:

483.803 Definitions.—As used in this part, the term:

(3) “Clinical laboratory personnel” includes a clinical laboratory director, supervisor, technologist, blood gas analyst, or technician who performs or is responsible for laboratory test procedures, but the term does not include trainees, persons who perform screening for blood banks or plasmapheresis centers, phlebotomists, or persons employed by a clinical laboratory to perform manual pretesting duties or clerical, personnel, or other administrative responsibilities, or persons engaged in testing performed by laboratories regulated under s. 483.035(1) or exempt from regulation under s. 483.031(2).

Section 8. Subsection (3) of section 483.811, Florida Statutes, is amended to read:

483.811 Approval of laboratory personnel training programs.—

~~(3) A clinical laboratory operated by one or more practitioners who hold the facilities of the laboratory out as available for the performance of diagnostic tests for other practitioners or their patients is subject to the provisions of this part. The board shall adopt rules for the licensure, education, and training of personnel in laboratories operated pursuant to s. 483.035 based upon and not exceeding the standards contained in the federal Clinical Laboratory Improvement Amendments of 1988 and the federal regulations adopted thereunder. This subsection does not apply to a clinical laboratory operated by one or more practitioners who hold the facilities of the laboratory out as available for the performance of diagnostic tests for other practitioners or their patients. If a clinical laboratory receives any referred work, or performs any work for patients referred by another practitioner, all provisions of this part apply.~~

Section 9. Section 483.813, Florida Statutes, is amended to read:

483.813 Clinical laboratory personnel license.—A person may not conduct a clinical laboratory examination or report the results of such examination unless such person is licensed under this part to perform such procedures. However, this provision does not apply to any practitioner of the healing arts authorized to practice in this state or to persons engaged in testing performed by laboratories regulated under s. 483.035(1) or exempt from regulation under s. 483.031(2). The department may grant a temporary license to any candidate it deems properly qualified, for a period not to exceed 6 months.

Section 10. Section 483.824, Florida Statutes, is created to read:

483.824 Qualifications of clinical laboratory director.—A clinical laboratory director must have 4 years of clinical laboratory experience with 2 years of experience in the speciality to be directed or be nationally board certified in the speciality to be directed, and must meet one of the following requirements:

- (1) Be a physician licensed under chapter 458 or chapter 459;
- (2) Hold an earned doctoral degree in a chemical, physical, or biological science from a regionally accredited institution; or
- (3) For the subspecialty of oral pathology, be a physician licensed under chapter 458 or chapter 459 or a dentist licensed under chapter 466.

Section 11. This act shall take effect upon becoming a law.

Became a law without the Governor's approval May 24, 1997.

Filed in Office Secretary of State May 23, 1997.