

By Representatives Saunders, Peaden, Barreiro,  
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1                                   A bill to be entitled  
2           An act relating to clinical laboratory  
3           personnel; amending s. 408.033, F.S.; providing  
4           an exemption from certain health care  
5           facilities assessments for clinical  
6           laboratories operated by practitioners for  
7           exclusive use; amending s. 483.035, F.S.;  
8           requiring the Agency for Health Care  
9           Administration to adopt rules relating to  
10          personnel of such laboratories; amending ss.  
11          483.101, 483.106, F.S.; deleting a requirement  
12          that application for a clinical laboratory  
13          license or certificate of exemption be made  
14          under oath; amending s. 483.172, F.S.;  
15          providing for expiration of the agency's  
16          authority to collect a fee from certain  
17          laboratories; amending ss. 483.801, 483.813,  
18          F.S.; providing for an exemption from  
19          regulation for certain practitioners and  
20          persons employed by certain laboratories;  
21          amending s. 483.803, F.S.; revising the  
22          definition of "clinical laboratory personnel";  
23          amending s. 483.811, F.S.; providing  
24          application of regulatory provisions to certain  
25          clinical laboratories; creating s. 483.824,  
26          F.S.; providing qualifications of a clinical  
27          laboratory director; providing an effective  
28          date.

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30 Be It Enacted by the Legislature of the State of Florida:  
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1           Section 1. Paragraph (a) of subsection (3) of section  
2 408.033, Florida Statutes, is amended to read:

3           408.033 Local and state health planning.--

4           (3) FUNDING.--

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

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

23           483.035 Clinical laboratories operated by  
24 practitioners for exclusive use; licensure and regulation.--

25           (1) A clinical laboratory operated by one or more  
26 practitioners licensed under chapter 458, chapter 459, chapter  
27 460, chapter 461, chapter 462, or chapter 466, exclusively in  
28 connection with the diagnosis and treatment of their own  
29 patients, must be licensed under this part and must comply  
30 with the provisions of this part, except that the agency shall  
31 adopt rules for staffing, for personnel, including education

1 and training of personnel, for proficiency testing, and for  
2 construction standards relating to the licensure and operation  
3 of the laboratory based upon and not exceeding the same  
4 standards contained in the federal Clinical Laboratory  
5 Improvement Amendments of 1988 and the federal regulations  
6 adopted thereunder.

7 Section 3. Section 483.101, Florida Statutes, is  
8 amended to read:

9 483.101 Application for clinical laboratory  
10 license.--An application for a clinical laboratory license  
11 must be made ~~under oath~~ by the owner or operator of the  
12 clinical laboratory or by the public official responsible for  
13 operating a state, municipal, or county clinical laboratory or  
14 institution that contains a clinical laboratory, upon forms  
15 provided by the agency. A license must be issued authorizing  
16 the performance of one or more clinical laboratory procedures  
17 or one or more tests on each specialty or subspecialty. A  
18 separate license is required of all laboratories maintained on  
19 separate premises even if the laboratories are operated under  
20 the same management. Upon receipt of a request for an  
21 application for a clinical laboratory license, the agency  
22 shall provide to the applicant a copy of the rules relating to  
23 licensure and operations applicable to the laboratory for  
24 which licensure is sought.

25 Section 4. Section 483.106, Florida Statutes, is  
26 amended to read:

27 483.106 Application for a certificate of  
28 exemption.--An application for a certificate of exemption must  
29 be made ~~under oath~~ by the owner or operator of a clinical  
30 laboratory that performs only waived tests as defined in s.  
31 483.041. A certificate of exemption authorizes a clinical

1 laboratory to perform waived tests. Laboratories maintained  
2 on separate premises and operated under the same management  
3 may apply for a single certificate of exemption or multiple  
4 certificates of exemption. The agency shall, by rule, specify  
5 the process for biennially issuing certificates of exemption.  
6 Sections 483.011, 483.021, 483.031, 483.041, 483.172, 483.23,  
7 and 483.25 apply to a clinical laboratory that obtains a  
8 certificate of exemption under this section.

9 Section 5. Subsection (4) of section 483.172, Florida  
10 Statutes, is amended to read:

11 483.172 License fees.--

12 (4) Upon October 1, 1993, and until the agency is  
13 granted state exemption status by the Health Care Financing  
14 Administration, laboratories that are licensed under the  
15 Clinical Laboratory Improvement Amendments of 1988 may not be  
16 assessed the fees specified in subsections (2) and (3) by the  
17 agency. During that period, a fee must be assessed to those  
18 laboratories to cover the cost of state activities beyond  
19 those required under the Clinical Laboratory Improvement  
20 Amendments of 1988. This fee is \$100 biennially. The  
21 authority to collect the fee set forth in this subsection  
22 expires July 1, 1997.

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

25 483.801 Exemptions.--This part applies to all clinical  
26 laboratories and clinical laboratory personnel within this  
27 state, except:

28 (1) Clinical laboratories operated by the United  
29 States Government.

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1           (2) Laboratories operated and maintained exclusively  
2 for research and teaching purposes, involving no patient or  
3 public health service whatsoever.

4           (3) Persons engaged in testing performed by  
5 laboratories regulated under s. 483.035(1) or exempt from  
6 regulation under s. 483.031(2).

7           (4) Respiratory therapists and respiratory care  
8 practitioners certified or registered under part V of chapter  
9 468.

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

12           483.803 Definitions.--As used in this part, the term:

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

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

26           483.811 Approval of laboratory personnel training  
27 programs.--

28           (3) A clinical laboratory operated by one or more  
29 practitioners who hold the facilities of the laboratory out as  
30 available for the performance of diagnostic tests for other  
31 practitioners or their patients is subject to the provisions

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

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

15       483.813 Clinical laboratory personnel license.--A  
16 person may not conduct a clinical laboratory examination or  
17 report the results of such examination unless such person is  
18 licensed under this part to perform such procedures. However,  
19 this provision does not apply to any practitioner of the  
20 healing arts authorized to practice in this state or to  
21 persons engaged in testing performed by laboratories regulated  
22 under s. 483.035(1) or exempt from regulation under s.  
23 483.031(2). The department may grant a temporary license to  
24 any candidate it deems properly qualified, for a period not to  
25 exceed 6 months.

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

28       483.824 Qualifications of clinical laboratory  
29 director.--A clinical laboratory director must meet one of the  
30 following requirements:

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