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HOUSE BILL 2081

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State of Washington                      52nd Legislature                      1991 Regular Session

By Representatives Day, Forner, Prentice and Casada.

Read first time February 21, 1991. Referred to Committee on Health Care.

1            AN ACT Relating to clinical laboratory science practitioners;  
2 adding a new chapter to Title 18 RCW; and providing effective dates.

3 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

4            NEW SECTION.    **Sec. 1.**            The legislature finds that the  
5 profession of clinical laboratory science practitioners satisfies the  
6 criteria of RCW 18.120.010, and that the applicants for regulation of  
7 this profession have satisfied the factors described in RCW 18.120.030.  
8 Therefore, the legislature declares that it is necessary to protect the  
9 public health, safety, and welfare to prescribe minimum qualifications  
10 for clinical laboratory science practitioners.

11           NEW SECTION.    **Sec. 2.**            Unless the context clearly requires  
12 otherwise, the definitions in this section apply throughout this  
13 chapter.

1 (1) "Accredited clinical laboratory program" means a program that  
2 provides a predetermined amount of instruction and experience in  
3 clinical laboratory science and is accredited by one of the accrediting  
4 agencies recognized by the United States department of education or  
5 department of health and human services.

6 (2) "Board" means the clinical laboratory board appointed by the  
7 governor.

8 (3) "Clinical laboratory" or "laboratory" means any facility,  
9 office, or site where clinical laboratory tests are performed.

10 (4) "Clinical laboratory scientist" or "medical technologist" means  
11 a person who performs tests according to established and approved  
12 protocols that require the exercise of independent judgment and  
13 responsibility, maintains equipment and records, performs quality  
14 assurance activities related to test performance, and may supervise and  
15 teach within a clinical laboratory setting.

16 (5) "Clinical laboratory science practice" means the performance of  
17 clinical laboratory tests and related activities.

18 (6) "Clinical laboratory science practitioner" means a health care  
19 professional who performs clinical laboratory tests or is engaged in  
20 management, education, consulting, or research in clinical laboratory  
21 science, and may include laboratory directors, supervisors, clinical  
22 laboratory scientists, specialists, technicians, and assistants working  
23 in a laboratory or testing site. Persons employed by a clinical  
24 laboratory to perform supportive functions not related to direct  
25 performance of laboratory tests and clinical laboratory trainees are  
26 not included.

27 (7) "Clinical laboratory technician" or "medical laboratory  
28 technician" means a person who performs laboratory tests pursuant to  
29 established and approved protocols that require limited exercise of

1 independent judgment and that are performed under the supervision of a  
2 clinical laboratory scientist, supervisor, or director.

3 (8) "Clinical laboratory test" or "laboratory test" means a  
4 microbiological, serological, chemical, hematological, radiobioassay,  
5 cytological, biophysical, immunological, or other pathological  
6 examination that is performed on material derived from the human body,  
7 or any other such test or procedure conducted that provides information  
8 for the diagnosis, prevention, or treatment of a disease or assessment  
9 of a medical condition, including screening.

10 (9) "Clinical laboratory trainee" means any person in a structured  
11 program, approved by the board, providing instruction and experience in  
12 the clinical laboratory sciences including, but not limited to,  
13 accredited programs. Trainees must be under the direct supervision of  
14 a person qualified to perform the work being performed.

15 (10) "Department" has the meaning given in RCW 18.122.020.

16 (11) "Secretary" has the meaning given in RCW 18.122.020.

17 (12) "Laboratory assistant" means a person who performs tests in a  
18 limited function laboratory or who performs a limited scope of testing  
19 under the direct supervision of a person qualified to perform or  
20 supervise such testing.

21 (13) "Limited function laboratory" means a testing site that uses  
22 test methodologies performed on instruments requiring little technical  
23 skill and no independent judgment due to the instruments' internal  
24 self-calibrated standards, and manual or automated test methodologies  
25 requiring little technical skill and no problem-solving or interpretive  
26 ability, or a testing site that only performs a limited scope of tests  
27 within one specialty or subspecialty.

28 (14) "Specialist" means a laboratory science practitioner or  
29 related health care professional who is qualified to practice and who  
30 is specialized in an area of the clinical laboratory sciences such as

1 cytology, chemistry, hematology, immunology, immunochemistry, or  
2 microbiology.

3 (15) "Specialty laboratory" means any site that only performs tests  
4 within one specialty or subspecialty.

5 (16) "Supervisor" means the person responsible for the supervision  
6 of the testing personnel and/or performance of tests.

7 NEW SECTION. **Sec. 3.** (1) No person may practice clinical  
8 laboratory science, or appear to be a practitioner of clinical  
9 laboratory science, unless licensed by the department under this  
10 chapter.

11 (2) All clinical laboratory science practitioners who applied to  
12 the department before January 1, 1993, and who complied with all  
13 necessary requirements for applying, may continue to direct, supervise,  
14 or perform clinical laboratory tests until either: (a) The end of  
15 twelve months from the filing date of their application; (b) the  
16 department denies the application; or (c) the applicant withdraws.

17 (3) For twenty-four months after January 1, 1993, and only during  
18 that time, the department may issue a license to a currently practicing  
19 practitioner, or a prospective practitioner, without requiring the  
20 practitioner to successfully complete an examination or obtain  
21 certification. The practitioner shall supply evidence that he or she  
22 holds the title for which the license is to be issued and has practiced  
23 at the level required by the license for sixty days before applying for  
24 the license.

25 NEW SECTION. **Sec. 4.** This chapter does not apply to:

26 (1) Any person licensed by this state who engages in the practice  
27 for which he or she is licensed, as long as such person is not engaged  
28 in any activity for which a license is required under this chapter;

1 (2) Clinical laboratory science practitioners employed by the  
2 federal government or any of its bureaus, divisions, or agencies while  
3 in the discharge of the employee's official duties;

4 (3) Clinical laboratory science practitioners engaged in teaching  
5 or research if the results of any examination performed are not used in  
6 health maintenance, diagnosis, treatment of disease, or screening;

7 (4) Students or trainees enrolled in a clinical laboratory science  
8 education program if these activities constitute a part of a planned  
9 course in the program, the persons are designated by title such as  
10 intern, trainee, or student, and the persons work directly under an  
11 individual licensed by this state to practice clinical laboratory  
12 science, or an instructor exempt under subsection (3) of this section;

13 (5) Physicians licensed in this state who are certified by the  
14 American board of pathology or the American board of osteopathic  
15 pathology;

16 (6) Business managers of laboratories if they have no direct or  
17 indirect involvement with test performance;

18 (7) Any person performing tests which are not regulated under  
19 chapter 70.42 RCW.

20 NEW SECTION. **Sec. 5.** (1) The clinical laboratory board is  
21 created within the department of health which shall consist of seven  
22 persons who are United States citizens and are residents of this state,  
23 and, except for the members of the public, who are actively engaged in  
24 their areas of practice. The governor shall make appointments to the  
25 board, and those appointments shall be confirmed by the senate.

26 (2) After the initial appointments are made, the board shall be  
27 composed of:

28 (a) One physician certified by the American board of pathology or  
29 the American board of osteopathic pathology;

1 (b) Four clinical laboratory science practitioners, at least one of  
2 whom is a nonphysician laboratory director or manager, one of whom is  
3 a clinical laboratory scientist (medical technologist), and one of whom  
4 is a clinical laboratory technician (medical laboratory technician),  
5 and who hold active and valid licenses as clinical laboratory science  
6 practitioners in this state; and

7 (c) Two members of the public, neither of whom is a member of any  
8 other licensing board, or holder of a health occupation license, or an  
9 employee of any health facility, or who has any fiduciary obligation to  
10 a health facility or agency, or who has a material financial interest  
11 in the rendering of health services.

12 (3) Board members shall serve for a term of three years and until  
13 their successors are appointed and qualified, except that the initial  
14 appointments, which shall be made within ninety days after the  
15 effective date of this act, shall be as follows:

16 (a) A pathologist, a nonphysician laboratory director or manager,  
17 and a clinical laboratory technician shall be appointed to serve for  
18 three years;

19 (b) The public representatives shall be appointed to serve for two  
20 years; and

21 (c) The remaining members shall be appointed to serve for one year.

22 (4) Whenever a vacancy shall occur on the board by reason other  
23 than the expiration of a term of office, the governor shall appoint a  
24 successor of like qualifications for the remainder of the unexpired  
25 term. No person shall be appointed to serve more than two successive  
26 full terms.

27 (5) The board shall hold a regular annual meeting at which it shall  
28 select from its members a chairman and vice-chairman. Other meetings  
29 shall be held at such times as the rules of the board may provide.  
30 Special meetings may be held at such times as may be deemed necessary

1 or advisable by a majority of its members. Reasonable notice of all  
2 meetings shall be given in a manner prescribed by the rules of the  
3 board. A quorum of the board shall consist of a majority of its  
4 members. The secretary of the board shall be appointed by the board  
5 and shall serve at the pleasure of the board. The secretary may or  
6 may not be a member of the board. The board shall work with and  
7 through the department of health.

8 NEW SECTION. **Sec. 6.** The clinical laboratory board shall:

9 (1) Prescribe, publish, adopt, and amend rules for the  
10 implementation of this chapter including but not limited to rules that  
11 delineate qualifications for licensure of clinical laboratory science  
12 practitioners; specify requirements for the renewal of licensure or  
13 certification; establish standards of professional conduct; and have  
14 power to amend or repeal the same. Following their adoption, the rules  
15 shall govern and control the professional conduct of every person who  
16 holds a license or certificate to perform clinical laboratory tests or  
17 otherwise engages in the profession of clinical laboratory science  
18 (medical technology);

19 (2) Approve accrediting and certification bodies for purposes of  
20 licensure of clinical laboratory science practitioners as provided for  
21 in section 4 of this act;

22 (3) Adopt rules governing qualifications for licensure of  
23 specialists in such clinical laboratory science specialties as the  
24 board may determine in accordance with the standards of licensure set  
25 forth in this chapter;

26 (4) Adopt rules governing personnel performing tests in limited-  
27 function laboratories, and personnel performing limited scopes of  
28 testing;

1 (5) Advise the department of health in the fixing and publication  
2 of fees for application and renewals;

3 (6) Assist the department of health in the maintenance of a roster  
4 of the names and addresses of persons currently licensed and registered  
5 under the provisions of this chapter, and of all persons whose licenses  
6 have been suspended or revoked within the previous year;

7 (7) Establish criteria and approve programs for the continuing  
8 education of clinical laboratory science practitioners as required for  
9 license renewal; and

10 (8) Adopt other rules necessary to implement and further the  
11 purpose of this chapter.

12 NEW SECTION. **Sec. 7.** (1) The department shall establish a  
13 schedule of fees for license and certificate applications and renewals.  
14 The department shall set the fees at a sufficient level to defray the  
15 cost of administering the program. In determining the fee schedule,  
16 the department shall consider the following: (a) The level of license  
17 or certificate; (b) general costs of the program established under this  
18 chapter; and (c) the advice of the board.

19 (2) The department shall deposit all fees collected under this  
20 section into the clinical laboratory licensure account.

21 NEW SECTION. **Sec. 8.** (1) The board shall issue a clinical  
22 laboratory scientist's license to an individual who is certified, or  
23 who holds equivalent credentials in the clinical laboratory sciences by  
24 an agency acceptable to the board, and who meets such other  
25 qualifications as adopted by the board, including at least one of the  
26 following qualifications. Where experience requirements are not met in

1 the four major disciplines, the board shall issue a categorical license  
2 for those disciplines in which the person is qualified:

3 (a) A baccalaureate degree in clinical laboratory science (medical  
4 technology) from an accredited college or university whose curriculum  
5 included appropriate clinical education;

6 (b) A baccalaureate degree in biological, chemical, or physical  
7 science from an accredited college or university, and at least twelve  
8 months of appropriate clinical education in an accredited clinical  
9 laboratory science program;

10 (c) A baccalaureate degree which includes a minimum of thirty-six  
11 semester or equivalent hours in the biological, chemical, and physical  
12 sciences from an accredited college or university plus two years of  
13 acceptable full-time work experience within the last five years  
14 including a minimum of four months in each of the four major  
15 disciplines of laboratory practice, i.e. clinical chemistry, clinical  
16 microbiology, hematology, and immunology/immunohematology;

17 (d) Approved certification as a clinical laboratory technician or  
18 equivalent and an associate degree or sixty semester or equivalent  
19 hours of college course work including thirty-six semester or  
20 equivalent hours in the biological and physical sciences plus three  
21 years of acceptable full-time laboratory work experience within the  
22 last ten years which has included a minimum of four months in each of  
23 the four major disciplines of laboratory practice, i.e. chemistry,  
24 hematology, immunology/immunohematology, and microbiology. At least  
25 two years of the laboratory work experience must be under the  
26 supervision of an appropriately qualified clinical laboratory  
27 scientist;

28 (e) An associate degree or sixty semester or equivalent hours of  
29 college course work including thirty-six semester or equivalent hours  
30 in the biological and physical sciences plus four years of acceptable

1 full-time laboratory work experience within the last ten years which  
2 has included a minimum of six months in each of the four disciplines of  
3 laboratory practice, i.e. chemistry, hematology,  
4 immunology/immunohematology, microbiology. At least two years of the  
5 laboratory work experience must be under the supervision of an  
6 appropriately qualified clinical laboratory scientist; or

7 (f) A valid license, certificate, or equivalent issued in another  
8 state, city, or country, provided that the requirements under which the  
9 license, certificate, or equivalent was issued are equivalent to or  
10 exceed the standards required by this subsection.

11 (2) The board shall issue a clinical laboratory technician's  
12 license to an individual who is certified, or who hold equivalent  
13 credentials, in the laboratory sciences by an agency acceptable to the  
14 board, and meets such other qualifications as adopted by the board,  
15 including at least one of the following qualifications. Where  
16 experience requirements are not met in the four major disciplines, the  
17 board shall issue a categorical license for those disciplines in which  
18 the person is qualified:

19 (a) An associate degree or completion of sixty semester or  
20 equivalent hours from a clinical laboratory technician program or  
21 equivalent accredited by an agency recognized by the United States  
22 department of education that included a structured curriculum in  
23 clinical laboratory techniques;

24 (b) A high school diploma or equivalent and (i) completion of  
25 twelve months in a technician training program in an accredited school  
26 approved by the board, or (ii) successful completion of an official  
27 military medical laboratory procedure course of at least fifty weeks'  
28 duration and has held the military enlisted occupational specialty of  
29 medical laboratory specialist (laboratory technician);

1 (c) Four years' full-time laboratory work experience which has  
2 encompassed the four major disciplines of laboratory practice, i.e.  
3 clinical chemistry, hematology, immunohematology, and microbiology plus  
4 eight continuing education units in clinical laboratory science within  
5 the last seven years. At least two years of the laboratory work  
6 experience must be under the supervision of an appropriately qualified  
7 clinical laboratory scientist, consultant, or technician; or

8 (d) A valid license, certificate, or equivalent issued in another  
9 state, city, or country, provided that the requirements under which the  
10 license, certificate, or equivalent was issued are equivalent to or  
11 exceed the standards required by this subsection.

12 (3) The board may establish standards for such other clinical  
13 laboratory science practitioners specializing in areas such as  
14 biophysics, chemistry, cytology, hematology, histology,  
15 immunohematology, microbiology, serology, nuclear medical technology,  
16 or similar recognized academic and scientific disciplines.

17 (4) The board shall issue limited function certificates to  
18 laboratory assistants who meet at least one of the following  
19 qualifications:

20 (a) Completion of an appropriate training program which is  
21 accredited by an agency recognized by the United States department of  
22 education or the department of health and human services;

23 (b) Completion of a formal education program in medical assisting  
24 which is accredited by an agency recognized by the United States  
25 department of education or the department of health and human services;  
26 or

27 (c) Four years' full-time laboratory work experience plus twenty  
28 hours of approved education in clinical laboratory science.

1        NEW SECTION.    **Sec. 9.**        (1) Licensure applicants shall submit  
2 their application for licensure to the department upon the forms  
3 prescribed and furnished by the board and the department, and shall pay  
4 the designated application fee.

5        (2) Upon receipt of application and payment of a fee, the board  
6 shall issue a license for a clinical laboratory scientist  
7 (technologist), a clinical laboratory technician or an appropriate  
8 specialty or categorical license, or limited function certificate to  
9 any person who meets the qualifications specified in this chapter and  
10 the rules adopted in this chapter.

11        (3) The board may establish by rule a procedure for issuance of  
12 temporary permits to individuals otherwise qualified under this chapter  
13 who intend to engage in clinical laboratory science practice in this  
14 state for a limited period of time not to exceed eighteen months.

15        NEW SECTION.    **Sec. 10.**        All licensed clinical laboratory science  
16 practitioners shall be subject to the disciplinary standards and  
17 procedures established in chapter 18.130 RCW.

18        NEW SECTION.    **Sec. 11.**        The department shall not disclose the  
19 identity of persons from whom specimens of material were taken for  
20 testing by a clinical laboratory science practitioner without a written  
21 release from that person or an order from a court with proper  
22 jurisdiction.

23        NEW SECTION.    **Sec. 12.**        (1) Sections 5 through 10 of this act  
24 shall take effect July 1, 1992.

25        (2) Sections 1 through 4 and 11 of this act shall take effect  
26 January 1, 1993.

1        NEW SECTION.    **Sec. 13.**        Sections 1 through 11 of this act shall  
2    constitute a new chapter in Title 18 RCW.