
SENATE BILL 5988

State of Washington

53rd Legislature

1993 Regular Session

By Senators Prentice, West and Vognild

Read first time 04/22/93. Referred to Committee on Health & Human Services.

1 AN ACT Relating to clinical laboratory science practitioners;
2 adding a new chapter to Title 18 RCW; creating a new section;
3 prescribing penalties; providing effective dates; and declaring an
4 emergency.

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

6 NEW SECTION. **Sec. 1.** INTENT--CONSTRUCTION. The legislature finds
7 that it is necessary to regulate the practice of clinical laboratory
8 science in order to protect the public health, safety, and welfare. It
9 is the intent of the legislature that this chapter shall provide for
10 the better protection of public health and safety by providing minimum
11 qualifications for clinical laboratory science practitioners, thereby
12 ensuring that clinical laboratory tests are performed with an
13 acceptable degree of professional competency by those engaged in
14 providing such services to the citizens of this state.

15 NEW SECTION. **Sec. 2.** DEFINITIONS. Unless the context clearly
16 requires otherwise, the definitions in this section apply throughout
17 this chapter.

1 (1) "Accredited clinical laboratory program" means a program
2 providing a predetermined amount of instruction and experience in
3 clinical laboratory science that has been accredited by one of the
4 accrediting agencies recognized by the United States department of
5 education or 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 a facility, office,
9 or site where clinical laboratory tests are performed.

10 (4) "Clinical laboratory scientist" or "medical technologist" means
11 a person who performs tests pursuant to established and approved
12 protocols requiring 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 including all phases
18 of test performance from procurement of specimens, such as phlebotomy,
19 to reporting of results.

20 (6) "Clinical laboratory science practitioner" means a health care
21 professional who performs clinical laboratory tests and related
22 activities or is engaged in management, education, consulting, or
23 research in clinical laboratory science, and may include laboratory
24 directors, supervisors, clinical laboratory scientists, medical
25 technologists, specialists, technicians, and assistants working in a
26 laboratory or testing site. Such practitioners shall be considered
27 licensed providers under chapter 18.135 RCW and may perform, and train
28 and authorize others to perform, phlebotomy. Persons employed by a
29 clinical laboratory to perform supportive functions not related to
30 direct performance of laboratory tests and clinical laboratory trainees
31 are not included.

32 (7) "Clinical laboratory technician" or "medical laboratory
33 technician" means a person who performs laboratory tests and related
34 activities pursuant to established and approved protocols which require
35 limited exercise of independent judgment and which are performed under
36 the supervision of a clinical laboratory scientist, supervisor, or
37 director. Such practitioners shall be considered licensed providers
38 under chapter 18.135 RCW and may perform, and train and authorize
39 others to perform, phlebotomy.

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

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

14 (10) "Department" means the department of health.

15 (11) "Director" means the person responsible for the technical and
16 administrative functions of laboratory testing.

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

21 (13) "Level I practitioner" means a person certified to perform
22 tests utilizing test methodologies and instruments such as described
23 for the limited function laboratory.

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

31 (15) "Specialist" means a masters or doctorate level laboratory
32 science practitioner or related health care professional who is
33 qualified to practice and who is specialized in an area of the clinical
34 laboratory sciences such as cytology, chemistry, hematology,
35 immunology, immunohematology, or microbiology.

36 (16) "Specialty laboratory" means any site which only performs
37 tests within one specialty or subspecialty. A person performing tests
38 at such sites may be granted a limited license or certificate to

1 perform such testing providing the person meets appropriate
2 qualifications set by the board.

3 (17) "Supervisor" means the person responsible for the supervision
4 of the testing personnel, performance, or both, of tests and related
5 activities.

6 NEW SECTION. **Sec. 3.** EXEMPTIONS. This chapter does not apply to:

7 (1) Any person licensed in this state who, under any other
8 licensing authority, engages in the practice for which he or she is
9 licensed.

10 (2) Clinical laboratory science practitioners employed by the
11 United States government or any bureau, division, or agency of the
12 United States while in the discharge of the employee's official duties.

13 (3) Clinical laboratory science practitioners engaged in teaching
14 or research, provided that the results of an examination performed are
15 not used in health maintenance, diagnosis or treatment of disease, or
16 screening.

17 (4) Students or trainees enrolled in a clinical laboratory science
18 education program, provided that these activities constitute a part of
19 a planned course in the program, that the persons are designated by
20 title such as intern, trainee, or student, and the persons work
21 directly under an individual licensed by this state to practice
22 clinical laboratory science, or an instructor exempt under subsection
23 (3) of this section.

24 (5) Physicians licensed in this state who are certified by the
25 American board of pathology or the American board of osteopathic
26 pathology.

27 (6) Business managers of laboratories provided they have no direct
28 or indirect involvement with test performance.

29 (7) A person performing tests that are waived from regulatory
30 requirements under P.L. 100-578 (CLIA 88).

31 NEW SECTION. **Sec. 4.** LICENSE REQUIRED. (1) No person may
32 practice clinical laboratory science or hold himself or herself out as
33 a clinical laboratory science practitioner in this state unless
34 licensed under this chapter.

35 (2) All persons engaged in the practice of clinical laboratory
36 science on the effective date of this act, and who have applied to the
37 board on or before the effective date of this act and have complied

1 with all necessary requirements for such application may continue to
2 direct, supervise, or perform clinical laboratory tests until (a) the
3 expiration of twelve months after the filing of the application, (b)
4 the denial of the application by the board, or (c) the withdrawal of
5 the application, whichever occurs first.

6 (3) The board may issue an initial license to an applicant who is
7 an existing or prospective practitioner, who applies within twenty-four
8 months of the effective date of this act without requiring such
9 applicant to successfully complete an examination or obtain
10 certification upon proof that the applicant holds the title and has
11 been practicing at the level of the license requested.

12 (4) Effective twenty-four months after the effective date of this
13 act, no initial license shall be issued until an applicant meets all of
14 the requirements under this chapter and successfully meets
15 certification or equivalent qualifications approved by the board.

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

23 (2) The board shall be composed of:

24 (a) One physician certified by the American board of pathology or
25 American board of osteopathic pathology;

26 (b) Four clinical laboratory science practitioners, at least one of
27 whom is a nonphysician laboratory director or manager, one of whom is
28 a clinical laboratory scientist or medical technologist and one of whom
29 is a clinical laboratory technician or medical laboratory technician,
30 and who, except for the initial appointments, hold active and valid
31 licenses as clinical laboratory science practitioners in this state;
32 and

33 (c) Two public members, neither of whom is a member of any other
34 licensing board, or holder of a health occupation license, or an
35 employee of any health facility, or who has any fiduciary obligation to
36 a health facility or agency, or who has a material financial interest
37 in the rendering of health services.

1 (3) Board members shall serve for terms of three years and until
2 their successors are appointed and qualified, except that the initial
3 appointments, which shall be made within ninety days after the
4 effective date of this act, shall be as follows:

5 (a) A pathologist, a nonphysician laboratory director or manager,
6 and a clinical laboratory technician shall be appointed to serve for
7 three years;

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

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

11 (4) Whenever a vacancy occurs on the board by reason other than the
12 expiration of a term of office, the governor shall appoint a successor
13 of like qualifications for the remainder of the unexpired term. No
14 person may be appointed to serve more than two successive full terms.

15 (5) The board shall hold a regular annual meeting at which it shall
16 select from its members a chair and vice-chair. Other meetings shall
17 be held at such times as the rules of the board may provide. Special
18 meetings may be held at such times as may be deemed necessary or
19 advisable by a majority of the members. Reasonable notice of all
20 meetings shall be given in a manner prescribed by the rules of the
21 board. A quorum of the board shall consist of a majority of its
22 members. The secretary of the board shall be appointed by the board
23 and shall serve at the pleasure of the board. The secretary may or may
24 not be a member of the board. The board shall work with and through
25 the department of health.

26 NEW SECTION. **Sec. 6.** DUTIES AND POWERS OF THE CLINICAL LABORATORY
27 BOARD. The clinical laboratory board shall:

28 (1) Prescribe, publish, adopt, amend, and repeal rules for the
29 implementation of this chapter including but not limited to rules that
30 delineate qualifications for licensure of clinical laboratory science
31 practitioners; specify requirements for the renewal of licensure or
32 certification; and establish standards of professional conduct. The
33 rules shall govern and control the professional conduct of every person
34 who holds a license or certificate to perform clinical laboratory tests
35 or otherwise engages in the profession of clinical laboratory science
36 medical technology;

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

4 (3) Adopt rules governing qualifications for licensure of
5 specialists in such clinical laboratory science specialties as the
6 board may determine in accordance with section 8 of this act;

7 (4) Adopt rules governing personnel performing tests in limited
8 function laboratories, and personnel performing limited scopes of
9 testing;

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

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

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

19 (8) Adopt rules necessary to implement and further the purpose of
20 this chapter.

21 NEW SECTION. **Sec. 7. FEES--ACCOUNT.** (1) The department shall
22 establish a schedule of fees for license and certificate applications
23 and renewals. In fixing the fees, the department shall set the fees at
24 a sufficient level to defray the cost of administering the program. In
25 determining the fee schedule, the department shall consider the
26 following: (a) The level of license or certificate; (b) general costs
27 of the program established under this chapter; and (c) the advice of
28 the board.

29 (2) The clinical laboratory licensure account is created in the
30 state treasury. All receipts from license and certificate fees shall
31 be deposited into the account. Moneys in the account may be spent only
32 after appropriation. Expenditures from the account may be used only
33 for the purposes of this chapter.

34 NEW SECTION. **Sec. 8. STANDARDS FOR LICENSURE.** (1) Clinical
35 laboratory scientist or medical technologists. The board shall issue
36 a clinical laboratory scientist's license to an individual who is
37 certified, or who holds equivalent credentials, in the clinical

1 laboratory sciences by an agency acceptable to the board, and who meets
2 such other qualifications as adopted by the board, including at least
3 one of the following qualifications. Where experience requirements are
4 not met in the four major disciplines, the board shall issue a
5 categorical or specialist license for those disciplines in which the
6 person is qualified:

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

10 (b) A baccalaureate degree in biological, chemical, or physical
11 science from an accredited college or university, and at least twelve
12 months of appropriate clinical education in an accredited clinical
13 laboratory science program;

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

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

32 (e) An associate degree or sixty semester or equivalent hours of
33 college course work including thirty-six semester or equivalent hours
34 in the biological and physical sciences plus five years of acceptable
35 full-time laboratory work experience within the last ten years that has
36 included a minimum of six months in each of the four disciplines of
37 laboratory practice, chemistry, hematology, immunology or
38 immunohematology, or microbiology. At least two years of the

1 laboratory work experience must be under the supervision of an
2 appropriately qualified clinical laboratory scientist;

3 (f) A valid license, certificate, or equivalent issued in another
4 state, city, or country, provided that the requirements under which the
5 license, certificate, or equivalent was issued are equivalent to or
6 exceed the standards required by this subsection (1).

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

15 (a) An associate degree or completion of sixty semester or
16 equivalent hours from a clinical laboratory technician or medical
17 laboratory technician program, or equivalent, accredited by an agency
18 recognized by the United States department of education that included
19 a structured curriculum in clinical laboratory techniques;

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

26 (c) Four years of full-time laboratory work experience that has
27 encompassed the four major disciplines of laboratory practice, clinical
28 chemistry, hematology, immunohematology and microbiology, plus eight
29 continuing education units in clinical laboratory science within the
30 last seven years. At least two years of the laboratory work experience
31 must be under the supervision of an appropriately qualified clinical
32 laboratory scientist, consultant, or technician;

33 (d) A valid license, certificate, or equivalent issued in another
34 state, city, or country, provided that the requirements under which the
35 license, certificate, or equivalent was issued are equivalent to or
36 exceed the standards required by this subsection (2).

37 (3) The board may establish standards for such other clinical
38 laboratory science practitioners specializing in areas such as
39 biophysics, chemistry, cytology, hematology, histology,

1 immunoematology, microbiology, serology, nuclear medical technology,
2 or similar recognized academic and scientific disciplines.

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

6 (a) Completion of an appropriate training program that is
7 accredited by an agency recognized by the United States department of
8 education or department of health and human services;

9 (b) Completion of a formal education program in medical assisting
10 that is accredited by an agency recognized by the United States
11 department of education or department of health and human services;

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

14 NEW SECTION. **Sec. 9.** LICENSURE APPLICATION PROCEDURES. (1)
15 Licensure applicants shall submit their application for licensure to
16 the department upon the forms prescribed and furnished by the board and
17 the department, and shall pay the designated application fee.

18 (2) Upon receipt of application and payment of a fee, the board
19 shall issue a license for a clinical laboratory scientist or
20 technologist, a clinical laboratory technician or an appropriate
21 specialty or categorical license, or limited function certificate to
22 any person who meets the qualifications specified in this chapter and
23 the rules adopted under this chapter.

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

28 NEW SECTION. **Sec. 10.** LICENSURE RENEWAL. (1) Licenses issued
29 under this chapter shall expire after a time specified by the board,
30 but not less than one year or more than four years. The renewal
31 process shall contain a grace period of not less than thirty days or
32 more than ninety days from expiration of the license.

33 (2) Every person licensed or certified under this chapter shall be
34 issued a renewal license or certificate upon:

35 (a) Submission of an application for renewal on a form prescribed
36 by the board and payment of an appropriate fee determined by the
37 department; and

1 (b) Proof of completion, in the period since the license or
2 certificate was first issued or last renewed, of at least ten hours per
3 year of continuing education courses, clinics, lectures, training
4 programs, seminars, or other programs pertinent to clinical laboratory
5 practice that are approved or accepted by the board; or proof of
6 recertification by a board-approved national accrediting organization
7 that mandates equivalent requirements.

8 (3) The board may require other such evidence of competency as it
9 shall deem reasonably appropriate as a prerequisite to the renewal of
10 a license or certificate provided for in this chapter, so long as the
11 requirements are uniform as to application, are reasonably related to
12 the measurement of qualification, performance, or competence, and are
13 desirable and necessary for the protection of the public health and
14 safety.

15 (4) The board shall develop procedures and criteria for the renewal
16 of licenses which have expired. The board shall review such
17 applications on a case-by-case basis to determine if the applicant's
18 circumstances and qualifications meet the intent of this chapter. In
19 the event such an application is denied, the board shall notify the
20 applicant of the specific reasons for such denial, and may advise the
21 applicant how to qualify for license renewal.

22 NEW SECTION. **Sec. 11.** DISCIPLINARY REQUIREMENTS. The board may
23 refuse to issue, renew, or revoke a license, or may suspend, place on
24 probation, censure, or reprimand a licensee, or may take such other
25 disciplinary action as the board may deem appropriate, including the
26 imposition of a civil penalty not to exceed that allowed under chapter
27 18.130 RCW for conduct that may result from, but not necessarily be
28 limited to:

29 (1) A material misstatement in furnishing information to the board;

30 (2) A violation or negligent or intentional disregard of this
31 chapter, or of the rules adopted under this chapter;

32 (3) A conviction of a crime under the laws of the United States or
33 a state or territory the United States that is a felony or a
34 misdemeanor, an essential element of which is dishonesty, or of a crime
35 that is directly related to the practice of the profession;

36 (4) Making a misrepresentation for the purpose of obtaining
37 licensure or certification or violating any provision of this chapter;

1 (5) Violation of a standard of professional conduct adopted by the
2 board;

3 (6) Engaging in dishonorable, unethical, or unprofessional conduct
4 of a character likely to deceive, defraud, or harm the public;

5 (7) Providing professional services while mentally incompetent,
6 under the influence of alcohol or narcotic or a dangerous, controlled
7 substance that is in excess of therapeutic amounts or without valid
8 medical indication;

9 (8) Directly or indirectly contracting to perform clinical
10 laboratory tests in a manner that offers or implies an offer of rebate,
11 fee-splitting inducements or arrangements, or other remuneration; or

12 (9) Aiding or assisting another person in violating a provision of
13 this chapter or rule adopted under this chapter.

14 NEW SECTION. **Sec. 12.** DUE PROCESS PROCEDURES. The proceedings
15 for the revocation, suspension, or limiting of a license or certificate
16 may be initiated by a person, corporation, association, or public
17 officer or by the board, by the filing of written charges with the
18 board, but no license may be revoked, suspended, or limited without a
19 hearing before the board within sixty days after the filing of such
20 charges in accordance with the procedures established by the board. A
21 license may be temporarily suspended without a hearing for a period not
22 to exceed thirty days upon notice to the licensee, following a finding
23 by the board that there exists a significant threat to the public
24 health.

25 NEW SECTION. **Sec. 13.** OPERATING WITHOUT A LICENSE--INJUNCTIONS OR
26 OTHER REMEDIES--PENALTY. Notwithstanding the existence or use of any
27 other remedy, the board may, in the manner provided by law and upon the
28 advice of the attorney general, who shall represent the board in the
29 proceedings, maintain an action in the name of the state for an
30 injunction, or other process against a person to restrain or prevent
31 the performance of laboratory testing without a license under this
32 chapter. It is a misdemeanor to do laboratory testing without a
33 license.

34 NEW SECTION. **Sec. 14.** PETITION OF SUPERIOR COURT FOR REVIEW OF
35 DISCIPLINARY ACTION. A person who has had a denial, condition,
36 suspension, or revocation of his or her license, or a civil monetary

1 penalty upheld after administrative review under chapter 34.05 RCW,
2 may, within sixty days of the administrative determination, petition
3 the superior court for review of the decision.

4 NEW SECTION. **Sec. 15.** PERSONS WHO MAY NOT RECEIVE A LICENSE. No
5 person who has had his or her license revoked may be considered for
6 relicensure within two years of the final adjudication of a license
7 revocation.

8 NEW SECTION. **Sec. 16.** CONFIDENTIALITY OF CERTAIN INFORMATION.
9 All information received by the board through filed reports, audits, or
10 on-site reviews, as authorized under this chapter, may not be disclosed
11 publicly in any manner that would identify persons who have specimens
12 of material from their bodies at a test site, absent a written release
13 from the person, or a court order.

14 NEW SECTION. **Sec. 17.** SHORT TITLE. This chapter may be cited as
15 the clinical laboratory sciences practices act.

16 NEW SECTION. **Sec. 18.** SEVERABILITY. If any provision of this act
17 or its application to any person or circumstance is held invalid, the
18 remainder of the act or the application of the provision to other
19 persons or circumstances is not affected.

20 NEW SECTION. **Sec. 19.** LEGISLATIVE DIRECTIVE. Sections 1 through
21 8 of this act constitute a new chapter in Title 18 RCW.

22 NEW SECTION. **Sec. 20.** CAPTIONS. Captions as used in this act
23 constitute no part of the law.

24 NEW SECTION. **Sec. 21.** EFFECTIVE DATES. (1) Sections 5 through 7
25 of this act are necessary for the immediate preservation of the public
26 peace, health, or safety, or support of the state government and its
27 existing public institutions, and shall take effect July 1, 1993.

28 (2) Sections 1 through 4, and 8 through 18 of this act shall take
29 effect January 1, 1994.

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