
SENATE BILL 6071

State of Washington

54th Legislature

1995 Regular Session

By {S}

Read first time {i}. Referred to Committee on {C}.

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, may supervise and
15 teach within a clinical laboratory setting, and may accredit and
16 certify level I practitioners subject to the authority granted and the
17 rules adopted by the board.

18 (5) "Clinical laboratory science practice" means the performance of
19 clinical laboratory tests and related activities including all phases
20 of test performance from procurement of specimens, such as phlebotomy,
21 to reporting of results.

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

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

1 under chapter 18.135 RCW and may perform, and train and authorize
2 others to perform, phlebotomy.

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. These are the methods,
10 procedures, and tests contained in the federal regulations implementing
11 P.L. 100-578 (CLIA 88).

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

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

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

21 (12) "Laboratory assistant" means a person performing testing in a
22 limited function laboratory or performing a limited scope of testing
23 under the direct supervision of a person qualified to perform or
24 supervise such testing.

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

28 (14) "Limited function laboratory" means a testing site utilizing
29 test methodologies performed on instruments requiring little technical
30 skill and no independent judgment due to the instruments' internal
31 self-calibrated standards, and manual or automated test methodologies
32 requiring little technical skill and no problem-solving or interpretive
33 ability, or a testing site that only performs a limited scope of tests
34 within one specialty or subspecialty, or a point of care testing site
35 operating in or near an acute care setting.

36 (15) "Specialist" means a masters or doctorate level laboratory
37 science practitioner or related health care professional who is
38 qualified to practice and who is specialized in an area of the clinical

1 laboratory sciences such as cytology, chemistry, hematology,
2 immunology, immunohematology, or microbiology.

3 (16) "Specialty laboratory" means any site which only performs
4 tests within one specialty or subspecialty. A person performing tests
5 at such sites may be granted a limited license or certificate to
6 perform such testing providing the person meets appropriate
7 qualifications set by the board.

8 (17) "Supervisor" means the person responsible for the supervision
9 of the testing personnel, performance, or both, of tests and related
10 activities.

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

12 (1) Any person licensed in this state who, under any other
13 licensing authority, engages in the practice for which he or she is
14 licensed;

15 (2) Clinical laboratory science practitioners employed by the
16 United States government or any bureau, division, or agency of the
17 United States while in the discharge of the employee's official duties;

18 (3) Clinical laboratory science practitioners engaged in teaching
19 or research, provided that the results of an examination performed are
20 not used in health maintenance, diagnosis or treatment of disease, or
21 screening;

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

29 (5) Physicians licensed in this state who are certified by the
30 American board of pathology or the American board of osteopathic
31 pathology;

32 (6) Business managers of laboratories provided they have no direct
33 or indirect involvement with test performance;

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

36 (8) Perfusionists performing within their scope of practice related
37 to their function during surgery. Alternatively, certified

1 perfusionists may qualify for a limited license under this chapter and
2 may exercise their option to apply for such a license.

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

7 (2) All persons engaged in the practice of clinical laboratory
8 science on the effective date of this act, and who have applied to the
9 board on or before the effective date of this act and have complied
10 with all necessary requirements for such application may continue to
11 direct, supervise, or perform clinical laboratory tests until (a) the
12 expiration of twelve months after the filing of the application, (b)
13 the denial of the application by the board, or (c) the withdrawal of
14 the application, whichever occurs first.

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

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

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

32 (2) The board shall be composed of:

33 (a) One physician certified by the American board of pathology or
34 American board of osteopathic pathology;

35 (b) Four clinical laboratory science practitioners, at least one of
36 whom is a nonphysician laboratory director or manager, one of whom is
37 a clinical laboratory scientist or medical technologist and one of whom

1 is a clinical laboratory technician or medical laboratory technician,
2 and who, except for the initial appointments, hold active and valid
3 licenses as clinical laboratory science practitioners in this state;
4 and

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

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

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

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

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

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

24 (5) The board shall hold a regular annual meeting at which it shall
25 select from its members a chair and vice-chair. Other meetings shall
26 be held at such times as the rules of the board may provide. Special
27 meetings may be held at such times as may be deemed necessary or
28 advisable by a majority of the members. Reasonable notice of all
29 meetings shall be given in a manner prescribed by the rules of the
30 board. A quorum of the board shall consist of a majority of its
31 members. The secretary of the board shall be appointed by the board
32 and shall serve at the pleasure of the board. The secretary may or may
33 not be a member of the board. The board shall work with and through
34 the department of health.

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

37 (1) Prescribe, publish, adopt, amend, and repeal rules for the
38 implementation of this chapter including but not limited to rules that

1 delineate qualifications for licensure of clinical laboratory science
2 practitioners relative to the complexity and risk of harm of the tests
3 allowed by the license; specify requirements for the renewal of
4 licensure or certification; and establish standards of professional
5 conduct. The rules shall govern and control the professional conduct
6 of every person who holds a license or certificate to perform clinical
7 laboratory tests or otherwise engages in the profession of clinical
8 laboratory science medical technology;

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

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

15 (4) Adopt rules governing personnel performing tests in limited
16 function laboratories, and personnel performing limited scopes of
17 testing;

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

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

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

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

29 NEW SECTION. **Sec. 7. FEES--ACCOUNT.** (1) The department shall
30 establish a schedule of fees for license and certificate applications
31 and renewals. In fixing the fees, the department shall set the fees at
32 a sufficient level to defray the cost of administering the program. In
33 determining the fee schedule, the department shall consider the
34 following: (a) The level of license or certificate; (b) general costs
35 of the program established under this chapter; and (c) the advice of
36 the board.

37 (2) The clinical laboratory licensure account is created in the
38 state treasury. All receipts from license and certificate fees shall

1 be deposited into the account. Moneys in the account may be spent only
2 after appropriation. Expenditures from the account may be used only
3 for the purposes of this chapter.

4 NEW SECTION. **Sec. 8.** STANDARDS FOR LICENSURE. (1) Clinical
5 laboratory scientist or medical technologists. The board shall issue
6 a clinical laboratory scientist's license to an individual who is
7 certified, or who holds equivalent credentials, in the clinical
8 laboratory sciences by an agency acceptable to the board, and who meets
9 such other qualifications as adopted by the board, including at least
10 one of the following qualifications. Where experience requirements are
11 not met in the four major disciplines, the board shall issue a
12 categorical or specialist license for those disciplines in which the
13 person is qualified:

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

17 (b) A baccalaureate degree in biological, chemical, or physical
18 science from an accredited college or university, and at least twelve
19 months of appropriate clinical education in an accredited clinical
20 laboratory science program;

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

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

1 (e) An associate degree or sixty semester or equivalent hours of
2 college course work including thirty-six semester or equivalent hours
3 in the biological and physical sciences plus five years of acceptable
4 full-time laboratory work experience within the last ten years that has
5 included a minimum of six months in each of the four disciplines of
6 laboratory practice, chemistry, hematology, immunology or
7 immunochemistry, or microbiology. At least two years of the
8 laboratory work experience must be under the supervision of an
9 appropriately qualified clinical laboratory scientist;

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

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

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

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

33 (c) Four years of full-time laboratory work experience that has
34 encompassed the four major disciplines of laboratory practice, clinical
35 chemistry, hematology, immunochemistry, and microbiology, plus eight
36 continuing education units in clinical laboratory science within the
37 last seven years. At least two years of the laboratory work experience
38 must be under the supervision of an appropriately qualified clinical
39 laboratory scientist, consultant, or technician;

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

5 (3) The board may establish standards for such other clinical
6 laboratory science practitioners specializing in areas such as
7 biophysics, chemistry, cytology, hematology, histology,
8 immunohematology, microbiology, serology, nuclear medical technology,
9 or similar recognized academic and scientific disciplines.

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

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

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

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

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

25 (2) Upon receipt of application and payment of a fee, the board
26 shall issue a license for a clinical laboratory scientist or
27 technologist, a clinical laboratory technician or an appropriate
28 specialty or categorical license, or limited function certificate to
29 any person who meets the qualifications specified in this chapter and
30 the rules adopted under this chapter.

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

35 NEW SECTION. **Sec. 10.** LICENSURE RENEWAL. (1) Licenses issued
36 under this chapter shall expire after a time specified by the board,
37 but not less than one year or more than four years. The renewal

1 process shall contain a grace period of not less than thirty days or
2 more than ninety days from expiration of the license.

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

5 (a) Submission of an application for renewal on a form prescribed
6 by the board and payment of an appropriate fee determined by the
7 department; and

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

15 (3) The board may require other such evidence of competency as it
16 shall deem reasonably appropriate as a prerequisite to the renewal of
17 a license or certificate provided for in this chapter, so long as the
18 requirements are uniform as to application, are reasonably related to
19 the measurement of qualification, performance, or competence, and are
20 desirable and necessary for the protection of the public health and
21 safety.

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

29 NEW SECTION. **Sec. 11.** DISCIPLINARY REQUIREMENTS. The board may
30 refuse to issue, renew, or revoke a license, or may suspend, place on
31 probation, censure, or reprimand a licensee, or may take such other
32 disciplinary action as the board may deem appropriate, including the
33 imposition of a civil penalty not to exceed that allowed under chapter
34 18.130 RCW for conduct that may result from, but not necessarily be
35 limited to:

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

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

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

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

7 (5) Violation of a standard of professional conduct adopted by the
8 board;

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

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

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

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

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

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

1 chapter. It is a misdemeanor to do laboratory testing without a
2 license.

3 NEW SECTION. **Sec. 14.** PETITION OF SUPERIOR COURT FOR REVIEW OF
4 DISCIPLINARY ACTION. A person who has had a denial, condition,
5 suspension, or revocation of his or her license, or a civil monetary
6 penalty upheld after administrative review under chapter 34.05 RCW,
7 may, within sixty days of the administrative determination, petition
8 the superior court for review of the decision.

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

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

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

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

25 NEW SECTION. **Sec. 19.** LEGISLATIVE DIRECTIVE. Sections 1 through
26 18 of this act constitute a new chapter in Title 18 RCW.

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

29 NEW SECTION. **Sec. 21.** EFFECTIVE DATES. (1) Sections 5 through 7
30 of this act are necessary for the immediate preservation of the public

1 peace, health, or safety, or support of the state government and its
2 existing public institutions, and shall take effect July 1, 1995.
3 (2) Sections 1 through 4, and 8 through 18 of this act shall take
4 effect January 1, 1996.

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