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IN THE SENATE
BY THE RULES COMMITTEE
BY REQUEST OF THE GOVERNOR

SENATE BILL NO. 155

IN THE LEGISLATURE OF THE STATE OF ALASKA
FIRST LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to clinical laboratories in Alaska; providing for the regulation of clinical laboratories; providing for licensing and prescribing fees thereof; providing for the examination and licensing of clinical laboratory bioanalysts and clinical laboratory technologists and for the registration of clinical laboratory technologist trainees, and prescribing fees thereof; providing penalties for violations; and providing for an effective date."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

ARTICLE I

DEFINITIONS

Section 1. Every provision of this Act shall be liberally construed to protect the interests of all persons affected. As used in this Act:

- (1) "person" includes firm, association, and corporation;
- (2) "division" means the state division of health and "department" means the Department of Health and Welfare;
- (3) "clinical laboratory bioanalyst" means any person licensed under this Act to engage in the work and direction of a clinical laboratory;

1 (4) "clinical laboratory technologist" means any person
2 other than a licensed clinical laboratory bioanalyst or registered
3 clinical laboratory technologist trainee who is licensed or
4 registered under this Act to perform the technical procedures
5 called for in a clinical laboratory under the direction of a
6 clinical laboratory bioanalyst or physician and surgeon;

7 (5) "clinical laboratory technologist trainee" means
8 any person registered under this Act for the purpose of receiving
9 comprehensive practical experience and instruction in clinical
10 laboratory procedures under the direct and responsible super-
11 vision of a duly licensed physician and surgeon, clinical labora-
12 tory bioanalyst, or clinical laboratory technologist in a clini-
13 cal laboratory certified for this purpose by the department under
14 this Act;

15 (6) "clinical laboratory" means any place, establish-
16 ment, or institution organized and operated for the practical
17 application of one or more of the fundamental sciences by the use
18 of specialized apparatus, equipment, and methods for the purpose
19 of obtaining scientific data which may be used as an aid to
20 ascertain the presence, progress, and source of disease in human
21 beings.

22 ARTICLE II

23 ADMINISTRATION AND REGULATION

24 Sec. 2. The department shall by regulation require that
25 all clinical laboratories be conducted, maintained, and operated
26 without injury to the public health.

27 Sec. 3. The division may employ special examiners, and the
28 department may make regulations for the conduct of examinations
29 under this Act.

1 Sec. 4. The division may approve schools providing instruc-
2 tion in clinical laboratory technic which in the judgment of the
3 division will provide instruction adequate to prepare individuals
4 to meet the requirements for licensure under this Act.

5 Sec. 5. The division may approve clinical laboratories
6 desiring to employ clinical laboratory technologist trainees for
7 training purposes upon satisfactory evidence that said labora-
8 tories possess qualified personnel and are equipped to carry out
9 all of the laboratory procedures commonly required in the fol-
10 lowing fields: bacteriology, serology, parasitology, hematology,
11 and biochemistry; and that the scope of activities of said
12 laboratories offer sufficient training in said laboratory pro-
13 cedures.

14 Sec. 6. The division may employ inspectors, special agents,
15 and investigators, and any such clerical and technical assistance
16 as it may deem necessary to administer the provisions of this Act
17 and may incur such other expenses as it may deem necessary.

18 Sec. 7. The department shall make such regulations as may
19 be necessary for the enforcement of this Act.

20 Sec. 8. Agents of the division may inspect and inquire into
21 the methods and equipment used by clinical laboratories operating
22 under this Act. The division may cooperate with or assist per-
23 sons licensed under this Act, or other qualified persons, in
24 evaluating laboratory procedures and technics and in recommending
25 the preferred procedures and technics for use in clinical labora-
26 tories.

27 Sec. 9. Each biennium the department may compile and may
28 thereafter publish and sell a directory of persons within the
29 state licensed under the provisions of this Act who hold

1 unforfeited and unrevoked certificates. This directory is to be
2 distributed without charge to licentiates of this Act. The
3 directory may also contain a copy of the provisions of this Act
4 and regulations relating thereto and such other information as the
5 department may determine advisable. Every person licensed or
6 registered under this Act shall file his address with the depart-
7 ment and shall report within 15 days any change of address,
8 giving both the old and the new address.

9 ARTICLE III

10 APPLICATION

11 Sec. 10. This Act does not authorize any person to practice
12 medicine and surgery or to furnish the services of physicians for
13 the practice of medicine and surgery. This Act does not repeal
14 or in any manner affect any provision of the laws relating to the
15 practice of medicine.

16 Sec. 11. This Act does not apply to a clinical laboratory
17 operated by any of the following:

18 (1) The State of Alaska, or the United States of
19 America, or any department, official, or agency thereof.

20 (2) An individual licentiate of the healing arts for
21 laboratory work performed on his own patients and within the scope
22 of his license privileges; provided, however, that if the labora-
23 tory receives direct or indirect referred work from any other
24 source all provisions of this Act shall apply.

25 Sec. 12. A duly licensed clinical laboratory technologist
26 or clinical laboratory bioanalyst may perform venipuncture or
27 skin puncture for test purposes upon specific authorization from
28 any person in accordance with the authority granted under any
29 provisions of laws relating to the healing arts.

1 division, and whom the department finds by written, oral, and
2 practical examination to be properly qualified. The department
3 shall establish by regulation the required courses to be included
4 in the college or university training. The following may be
5 accepted as equivalent of, and substituted for, experience to a
6 maximum of three years for such experience: (1) a master's degree
7 in fundamental medical sciences, one year; (2) a doctorate in
8 fundamental medical science, two additional years.

9 Sec. 15. The department shall issue a clinical laboratory
10 technologist's license to each person found by it to be properly
11 qualified and it shall hold written, oral, or practical examina-
12 tions to aid it in judging the qualifications of applicants. The
13 examinations for license to work in a clinical laboratory as a
14 technologist shall cover the field of the five subjects of
15 bacteriology, serology, biochemistry, hematology, and parasitology,
16 except that the examination for a special clinical laboratory
17 technologist's license in biochemistry, bacteriology and serology
18 or parasitology, shall be concerned only with the subject or
19 subjects in which the license is to be issued. The prerequisites
20 for entrance into the examination shall be one of the following:

21 (1) Completion of a regular four-year college or
22 university curriculum in medical or clinical laboratory technic
23 with a degree of bachelor of arts or bachelor of science in a
24 college or university approved by the division, the last year
25 of which course shall have been primarily clinical laboratory
26 procedure; provided, however, that if the curriculum did not
27 include practical clinical laboratory work, six months as a
28 clinical laboratory technologist trainee or the equivalent as
29 determined by the division in a clinical laboratory approved by

1 the division shall be required; or

2 (2) Graduation from a college or university maintain-
3 ing standards equivalent, as determined by the division, to those
4 institutions accredited by the Western College Association,
5 Northwest Association of Secondary and Higher Schools or an es-
6 sentially equivalent accrediting agency, as determined by the
7 division, with a degree of bachelor of arts or bachelor of
8 science and a major in bacteriology, biochemistry, or essentially
9 equivalent subject or subjects as may be determined by the divi-
10 sion plus one year as a clinical laboratory technologist trainee
11 or the equivalent as determined by the division in a clinical
12 laboratory approved by the division. One year of practical
13 experience in a public health laboratory may be accepted if such
14 experience or if university or college courses included practical
15 work in clinical biochemistry and hematology; or

16 (3) A minimum of two years of experience as a clinical
17 laboratory technologist trainee or the equivalent, as determined
18 by the department, doing clinical laboratory work embracing the
19 various fields of clinical laboratory activity in a clinical
20 laboratory approved by the division and 60 semester hours or
21 equivalent quarter hours of university or college work in which
22 are included courses, or essential equivalent as may be deter-
23 mined by the department, in fundamental science. Additional
24 college or university work which includes courses in the funda-
25 mental sciences may be substituted for two years of experience
26 in the ratio of 30 semester hours or equivalent quarter hours for
27 each year of experience. Time spent in a school approved by the
28 division in this Act shall count as acceptable experience on a
29 month for month basis.

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1 Sec. 16. No license as a clinical laboratory technologist
2 shall be issued by the department except after examination, pro-
3 vided, that, when delay in meeting these requirements would work
4 a hardship, a temporary clinical laboratory technologist's license
5 may be issued to an individual who by training or experience is
6 apparently qualified; provided, however, that no person shall be
7 issued such temporary license if he has failed a previous examina-
8 tion for said license.

9 Sec. 17. The division shall register as a clinical laboratory
10 technologist trainee each qualified person, upon application and
11 payment of the fee for such registration, who desires a trainee
12 status in any laboratory or school, other than a college or uni-
13 versity accredited by the Western College Association, Northwest
14 Association of Secondary and Higher Schools or an essential
15 equivalent accrediting agency, as determined by the division, that
16 is approved by the division to give such training. In order to
17 qualify for registration an applicant must have 60 semester hours
18 or equivalent quarter hours of university or college work which
19 includes courses in the fundamental sciences or essential equiva-
20 lent as may be determined by the division; registration certifi-
21 cates shall not be issued for a period in excess of two years
22 after completion of the minimum training period required for the
23 trainee to qualify for the clinical laboratory technologist's
24 examination.

25 Sec. 18. Licenses issued under this Act may cover work in
26 any one basic science, or may cover proficiency in the entire
27 field of clinical laboratory work.

28 Sec. 19. Any clinical laboratory technologist, or clinical
29 laboratory bioanalyst who was regularly employed in such capacity

1 in the State of Alaska on the effective date of this Act, and who
2 had been actively employed in such capacity in Alaska for at
3 least one year immediately preceding the effective date of this
4 Act may be issued a license without examination upon application
5 and payment of the fee herein provided, and upon submission of
6 sufficient and satisfactory evidence of meeting the requirements
7 of training and experience required for such license.

8 Sec. 20. The department shall issue a clinical laboratory
9 permit to any person who has applied for said permit on forms pro-
10 vided by the division and who is found to be in compliance with
11 the provisions of this Act. The application shall include the
12 name or names of the owner or the owners, the name of the director,
13 and the name and location of the laboratory, and such other in-
14 formation as may be required by the department. Application
15 shall be made by the owner of the laboratory and the director
16 prior to its opening. A permit to conduct a clinical laboratory
17 where the owner is not the director shall be issued jointly to
18 the owner and the director and for the premises stated therein,
19 and they shall be severally and jointly responsible to the
20 division for the maintenance and conduct thereof or for any vio-
21 lations of the provisions of this Act and regulations pertaining
22 thereto. The department shall not issue a permit until it is
23 satisfied that the clinical laboratory will be operated within
24 the spirit and intent of this Act, that the owner and director
25 are each of good moral character, and that the granting of such
26 permit will not be in conflict with the interests of public
27 health. A separate permit must be obtained for each location.
28 A permit shall be automatically revoked if there is a change of
29 address, director, or ownership of the laboratory. However, a

1 new permit may be secured for the new location, director, or
2 owner prior to the actual change; provided, that the contemplated
3 change is in compliance with all the provisions of this Act and
4 regulations pertaining thereto. The permit shall be valid for
5 the calendar year for which it is issued unless revoked. Any
6 revocation of a permit under this Act shall be conducted in com-
7 pliance with the laws of Alaska.

8 Sec. 21. Any person maintaining, conducting, or operating a
9 clinical laboratory shall display in a prominent place in the
10 clinical laboratory the license of each person supervising and
11 directing the clinical laboratory, the clinical laboratory permit,
12 and the license or registration certificate of each person per-
13 forming the technical procedures called for in a clinical labora-
14 tory.

15 Sec. 22. A license or permit under this Act may be suspended
16 or revoked by the department for a good cause after hearing on
17 notice in accordance with the laws of Alaska.

18 Sec. 23. Upon filing application therefor, containing such
19 information as the department may require, and the payment of the
20 license or certificate fee, the department shall issue to any
21 person duly licensed under this Act a duplicate license or regis-
22 tration certificate for one previously issued or, where there has
23 been a change of name, another license or registration certificate
24 in lieu of one previously issued.

25 ARTICLE V

26 OFFENSES

27 Sec. 24. It is unlawful

28 (1) for any person to act as a clinical laboratory
29 technologist unless he is licensed in that capacity under this Act;

1 (2) for any person to act as a clinical laboratory
2 bioanalyst unless he is licensed in that capacity under this Act;

3 (3) for any person to own, operate, maintain, direct,
4 or engage in the business of operating a clinical laboratory, as
5 herein defined in this Act, unless he possesses a valid clinical
6 laboratory permit duly issued to him by the department;

7 (4) for any person to make any test or examination in
8 a clinical laboratory unless the person is one of the following:

9 (a) A licensed clinical laboratory technologist
10 in the subject or subjects concerned with the test or
11 examination;

12 (b) A licensed clinical laboratory bioanalyst;

13 (c) A physician and surgeon licensed under the
14 laws on medicine;

15 (d) A registered clinical laboratory technologist
16 trainee under direct and responsible supervision;

17 (5) for any person to conduct, maintain, or operate a
18 clinical laboratory unless such clinical laboratory is under the
19 direct and responsible supervision and direction of one of the
20 following:

21 (a) A licensed clinical laboratory bioanalyst;

22 (b) A physician and surgeon licensed under the
23 laws on medicine;

24 (6) for a licensed clinical laboratory bioanalyst or
25 physician and surgeon to serve only as the nominal director or
26 supervisor of a clinical laboratory;

27 (7) for any person conducting, ~~maintaining~~, or operat-
28 ing a clinical laboratory to employ any person to perform clini-
29 cal laboratory procedures except a licensed physician and

1 surgeon, a licensed clinical laboratory technologist, a licensed
2 clinical laboratory bioanalyst, or a registered clinical labora-
3 tory technologist trainee;

4 (8) for a registered clinical laboratory technologist
5 trainee to work or to be employed in a clinical laboratory un-
6 less there are on active duty in the laboratory one or more
7 licensed clinical laboratory technologists, one or more licensed
8 clinical laboratory bioanalysts, or one or more licensed
9 physicians and surgeons;

10 (9) for more than two registered clinical laboratory
11 technologist trainees to work or be employed at the same time in
12 the same clinical laboratory unless said laboratory has estab-
13 lished an approved training school as provided in this Act;

14 (10) for any person to operate a school or conduct any
15 course for the purpose of training or preparing persons for a
16 license hereunder or to perform any of the practices or acts
17 herein defined without having first secured the approval of the
18 division as herein provided;

19 (11) for any person to accept clinical laboratory
20 technologist trainees for training without approval of the
21 division.

22 Sec. 25. Any person who violates any provision of this Act
23 is guilty of a misdemeanor, and upon conviction therefor shall be
24 punished according to law.

25 Sec. 26. Any person conducting or operating a clinical
26 laboratory may accept assignments for tests only from and make
27 reports only to persons licensed under the provisions of laws
28 relating to the healing arts. This section does not prohibit the
29 referral of specimens or such assignment from one clinical

1 laboratory to another laboratory providing the report indicates
2 clearly the laboratory performing the test.

3 ARTICLE VI

4 REVENUE

5 Sec. 27. The amount of application and license fee under
6 this Act shall be as follows:

7 (1) The application fee for a clinical laboratory
8 bioanalyst license is \$25.00.

9 (2) The annual renewal fee for a clinical laboratory
10 bioanalyst license shall be fixed by the department at not more
11 than \$15.00 nor less than \$5.00.

12 (3) The application fee for a clinical laboratory
13 technologist license is \$5.00.

14 (4) The annual renewal fee for a clinical laboratory
15 technologist license shall be fixed by the department at not more
16 than \$3.00 nor less than \$1.00.

17 (5) The application fee for a clinical laboratory per-
18 mit is \$10.00; provided, however, that when the applicant is a
19 city, borough, or city and borough, or an official thereof, no
20 fee shall be required.

21 (6) The annual renewal fee for a clinical laboratory
22 permit shall be fixed by the department at not more than \$15.00
23 nor less than \$5.00; provided, however, that when the applicant
24 is a city, borough, or city and borough, or official thereof, no
25 fee shall be required.

26 (7) The application fee for a clinical laboratory
27 technologist trainee's registration certificate is \$1.00.

28 (8) The annual renewal fee for a clinical laboratory
29 technologist trainee's registration certificate is \$1.00.

1 (9) The application fee for a duplicate certificate is
2 \$1.00.

3 Sec. 28. The application fee required by this Act covers
4 the examination, the license fee and the issuance of the license
5 valid for the remainder of the calendar year during which the
6 license is issued.

7 Sec. 29. An application fee is returnable only when the
8 applicant is not admitted to the examination.

9 Sec. 30. The annual renewal fee set under this Act shall be
10 paid on or before the first day of January of each calendar year.
11 Failure to pay the annual fee in advance during the time the
12 license remains in force shall, ipso facto, work a forfeiture of
13 said license after a period of 60 days from the first day of
14 January of each year.

15 Sec. 31. The department shall give written notice to a
16 licensee 30 days in advance of the regular renewal date and shall
17 give written notice by registered mail 90 days in advance of the
18 expiration of the fifth year that a renewal fee has not been paid
19 and if not paid before the expiration of the fifth year of
20 delinquency the licensee may be subject to re-examination.

21 Sec. 32. If the renewal fee is not paid for five or more
22 years, the department may require an examination before reinstat-
23 ing the license, except that no examination shall be required as
24 a condition for reinstatement if the original license was issued
25 without an examination. No examination shall be required for
26 reinstatement if the license was forfeited solely by reason of
27 nonpayment of the renewal fee if such nonpayment was for less
28 than five years.

29 Sec. 33. All fees set under this Act shall be collected by

1 and paid to the division. All such moneys shall be deposited by
2 the department in the general fund of the state.

3 ARTICLE VII

4 DENIAL, REVOCATION, AND SUSPENSION

5 OF LICENSES AND PERMITS

6 Sec. 34. Licenses or permits issued by the department may be
7 revoked or suspended for each of the following reasons:

8 (1) Conduct involving moral turpitude or dishonest
9 reporting of tests;

10 (2) Violation of any of the rules and regulations of
11 the department applicable to this Act;

12 (3) Permitting a registered clinical laboratory tech-
13 nician trainee to perform tests, procure specimens, or act for
14 the director in the absence of a duly licensed clinical labora-
15 tory bioanalyst, technologist, or physician and surgeon;

16 (4) Violation of any provision of the laws governing
17 the practice of medicine and surgery;

18 (5) Proof that the holder has made false statements in
19 material regard on his application for licensure or laboratory
20 permit or that he has used any degree or certificate as a means of
21 qualifying for licensure which has been purchased or procured by
22 barter or by any unlawful means or obtained from any institution
23 which at the time said degree or certificate was obtained was not
24 recognized or accredited by the department of education of the
25 state where said institution is or was located to give training in
26 the field of study in which the degree or certificate is claimed;

27 (6) The use of any degree, or certificate, or title
28 in any manner, which has been purchased or procured by barter or
29 by any unlawful means or obtained from any institution which at

1 the time said degree, certificate, or title was obtained was not
2 recognized or accredited by the department of education of the
3 state where said institution is or was located to give training
4 in the field of study in which the degree, certificate, or title
5 is claimed;

6 (7) Violation of any of the provisions of the pre-
7 marital and prenatal laws;

8 (8) The advertising of clinical laboratory procedures
9 to the lay public in magazines, newspapers, directories, circu-
10 lars, signs, etc.;

11 (9) Knowingly accepting an assignment for clinical
12 laboratory tests or specimens from and rendering a report thereon
13 to persons not licensed by law to submit such specimens or
14 assignments;

15 (10) Rendering a report on clinical laboratory work
16 actually performed in another clinical laboratory without desig-
17 nating the laboratory in which the test was performed;

18 (11) Conviction of a felony or of any crime involving
19 moral turpitude under the laws of any state or of the United
20 States arising out of or in connection with the practice of
21 clinical laboratory technology. The record of conviction or a
22 certified copy thereof shall be conclusive evidence of such con-
23 viction.

24 Sec. 35. The adjudication of insanity or mental illness, or
25 the voluntary commitment or admission to a state hospital or
26 other mental hospital of any licensee for a mental illness shall
27 operate as a suspension of the right to practice of any licensee
28 under this Act, such suspension to continue until restoration to
29 or declaration of sanity or mental competence. The record of
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1 adjudication, judgment or order of voluntary commitment is con-
2 clusive evidence of such insanity or mental illness, and upon
3 receipt of a certified copy of any such adjudication, judgment,
4 voluntary commitment or order by the department it shall im-
5 mediately suspend the license of the person adjudicated or com-
6 mitted. The department shall not restore such license to good
7 standing until it shall receive competent evidence of restoration
8 to or declaration of sanity and until it is satisfied that, with
9 due regard for the public interest, said person's right to
10 practice may be safely reinstated. Provided, that in the case of
11 a voluntary commitment to a state hospital or other mental hos-
12 pital, receipt of a certificate of discharge from such hospital
13 and the certificate of the superintendent of said hospital that
14 the licensee is restored to mental competency, shall constitute
15 competent evidence of restoration of sanity. Before reinstating
16 such person, the department may require the person to pass an
17 oral examination to determine his present fitness to resume his
18 practice.

19 Sec. 36. The licenses or permits may be denied for any
20 reason applicable to revocation and suspension of licenses or
21 permits.

22 ARTICLE VIII
23 FORMAL PROVISIONS

24 Sec. 37. This Act shall become effective on January 1,
25 1961.

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