

SENATE BILL NO. 295

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-FIFTH LEGISLATURE - SECOND SESSION

BY THE SENATE HEALTH, EDUCATION AND SOCIAL SERVICES COMMITTEE

Introduced: 2/27/08

Referred: Labor and Commerce, Finance

A BILL

FOR AN ACT ENTITLED

1 **"An Act relating to the licensing of clinical laboratory science professionals; and**
2 **providing for an effective date."**

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

4 *** Section 1.** AS 08 is amended by adding a new chapter to read:

5 **Chapter 30. Clinical Laboratory Science Professionals.**

6 **Article 1. Volunteer Advisory Board of Clinical Laboratory Science Professionals.**

7 **Sec. 08.30.010. Board creation; membership.** (a) There is created in the
8 Department of Commerce, Community, and Economic Development the Volunteer
9 Advisory Board of Clinical Laboratory Science Professionals consisting of five
10 members appointed by the governor.

11 (b) Board members must be residents of the state, and the membership of the
12 board must reflect the rural and urban demographics of the state. Not more than two
13 members may be residents of the same house district.

14 (c) The membership of the board shall consist of

1 (1) four licensed clinical laboratory science professionals, with not
 2 more than one member from each licensed category of clinical laboratory science
 3 professional; and

4 (2) one public member who does not have a financial or personal
 5 association with clinical laboratory science.

6 (d) Members of the board do not receive compensation for service on the
 7 board, and are not eligible for transportation expenses or per diem under
 8 AS 39.20.180.

9 **Sec. 08.30.020. Board member terms; vacancies.** Notwithstanding
 10 AS 08.01.035, each member of the board shall serve a term of three years and until a
 11 successor is appointed and qualifies. If a vacancy occurs, the governor shall appoint a
 12 successor of like qualification for the remainder of an unexpired term. A person may
 13 not be appointed to serve more than two successive terms.

14 **Sec. 08.30.030. Duties of the board.** The board shall advise the department on

15 (1) credentialing agencies or organizations; and

16 (2) what laboratory tests should be defined as waived tests.

17 **Article 2. Examination and Licensing.**

18 **Sec. 08.30.050. License required.** Except as provided in AS 08.30.100, a
 19 person may not perform clinical laboratory tests, use the title "clinical laboratory
 20 scientist," "medical technologist," "clinical laboratory technician," "medical laboratory
 21 technician," or a title listed under AS 08.30.060, or offer or attempt to practice, or
 22 advertise or announce as being prepared or qualified to perform, clinical laboratory
 23 tests without a license issued under this chapter.

24 **Sec. 08.30.060. Licensing of clinical laboratory science professionals.** The
 25 department shall issue a license to an applicant for licensure as a clinical laboratory
 26 scientist, clinical laboratory technician, clinical laboratory assistant, phlebotomy
 27 technician, cytotechnologist, histotechnologist, or histotechnician if the applicant
 28 submits an application on the form approved by the department, pays the required fee,
 29 and provides evidence satisfactory to the department that the applicant is certified by a
 30 nationally recognized credentialing agency or organization approved by the
 31 department.

1 **Sec. 08.30.070. Scope of practice.** A person licensed under this chapter may
2 perform clinical laboratory testing as follows:

3 (1) a clinical laboratory scientist may perform any clinical laboratory
4 test or research function and direct, supervise, consult, or educate other clinical
5 laboratory professionals;

6 (2) a clinical laboratory technician shall follow established protocols
7 that require a limited exercise of independent judgment and act under the supervision
8 of a licensed clinical laboratory scientist; a clinical laboratory technician may perform
9 waived and moderately complex tests;

10 (3) a clinical laboratory assistant shall follow established protocols that
11 require a limited knowledge of general laboratory procedure and act under the
12 supervision of a licensed clinical laboratory scientist; a clinical laboratory assistant
13 may perform waived and moderately complex tests as determined by the department
14 in regulation;

15 (4) a phlebotomy technician may, under the supervision of a licensed
16 clinical laboratory scientist, licensed physician, or medical laboratory director, obtain
17 blood samples for testing by means of venipuncture, capillary sticks, or access by
18 venous devices and may perform waived and point of care testing;

19 (5) a cytotechnologist may

20 (A) process and interpret cellular material derived from the
21 human body to delineate data regarding human cytopathological disease;

22 (B) review and interpret gynecological cytology preparations;
23 and

24 (C) screen other cytology preparations if reviewed and
25 interpreted by a person licensed to practice medicine under AS 08.64;

26 (6) a histotechnologist may

27 (A) process cellular and tissue components through methods of
28 selected gross dissection and description fixation, dehydration, embedding,
29 microtomy, frozen sectioning, staining, and other related procedures and
30 techniques employed in the preparation of smears, slides, and tissues; and

31 (B) perform methods for antigen detection and other molecular

1 hybridization testing methods if the purpose of the testing is to analyze or
 2 quantify cellular tissue components for interpretation by a person licensed to
 3 practice medicine under AS 08.64;

4 (7) a histotechnician may, under the supervision of a medical
 5 laboratory director, licensed histotechnologist, or licensed clinical laboratory scientist,

6 (A) process cellular and tissue components through methods of
 7 selected gross dissection and description fixation, dehydration, embedding,
 8 microtomy, frozen sectioning, staining, and other related procedures and
 9 techniques employed in the preparation of smears, slides, and tissues; and

10 (B) perform methods for antigen detection and other molecular
 11 hybridization testing methods if the purpose of the testing is to analyze or
 12 quantify cellular tissue components for interpretation by a person licensed to
 13 practice medicine under AS 08.64.

14 **Sec. 08.30.080. Renewal of license.** (a) A license, other than a temporary
 15 license, issued by the department is valid for three years or until the license is
 16 relinquished, suspended, or revoked.

17 (b) The department may renew a license under this section if the applicant
 18 submits

19 (1) a completed application on a form approved by the department;

20 (2) the fee established by the department; and

21 (3) satisfactory proof of

22 (A) continuing certification by a nationally recognized
 23 credentialing agency or organization approved by the department; and

24 (B) other measures of competency as required by the
 25 department.

26 **Article 3. General Provisions.**

27 **Sec. 08.30.090. Grounds for denial of license or for disciplinary sanctions.**

28 The department may deny a license, refuse to renew a license, or impose a disciplinary
 29 sanction under AS 08.01.075 on a person licensed under this chapter when the
 30 department finds that the person

31 (1) made a material misstatement of fact in information presented to

1 the department;

2 (2) violated a provision of this chapter or a regulation implementing
3 this chapter;

4 (3) was convicted of a crime that is a felony or that is a misdemeanor
5 that involves dishonesty or the practice of clinical laboratory science in any state or
6 federal jurisdiction;

7 (4) was issued a license based on a misrepresentation of fact;

8 (5) engaged in unprofessional conduct described in regulations adopted
9 by the department;

10 (6) engaged in dishonorable or unethical conduct of a type likely to
11 deceive, defraud, or harm the public;

12 (7) provided professional services while mentally incompetent or
13 under the influence of alcohol or of a controlled substance that was used in excess of a
14 therapeutic amount or without valid medical indications; or

15 (8) performed or agreed to perform clinical tests directly or indirectly
16 in a manner that offers or implies a rebate, fee-splitting inducements or arrangements,
17 or other benefit other than the person's salary.

18 **Sec. 08.30.100. Exemption from license requirement.** The license
19 requirements under this chapter do not apply to a

20 (1) person licensed in the state to perform activities for which the
21 license was issued;

22 (2) clinical laboratory science professional employed or contracted by
23 the United States government while performing official duties;

24 (3) clinical laboratory science professional while engaged exclusively
25 in research that does not involve health maintenance, diagnosis, or treatment of a
26 person;

27 (4) student or trainee who is enrolled in a clinical laboratory science
28 program while performing duties under the program and under the direct supervision
29 of a licensee;

30 (5) person performing waived testing;

31 (6) person performing point of care testing in an acute care facility if

1 the facility

2 (A) employs a licensed clinical laboratory science professional
3 to manage testing by

4 (i) designing and supervising a training program for
5 point of care testing personnel;

6 (ii) supervising and monitoring quality assurance and
7 control over activities occurring at the testing site;

8 (iii) assisting in the selection of technology used for the
9 testing;

10 (iv) reviewing the results of proficiency testing and
11 recommending corrective action when necessary;

12 (v) monitoring the continued competency of testing
13 personnel; and

14 (B) adopts and employs procedures approved by the
15 department that include adequate documentation by and monitoring of testing
16 personnel.

17 **Sec. 08.30.500. Definitions.** In this chapter,

18 (1) "board" means the Voluntary Advisory Board of Clinical
19 Laboratory Science Professionals established under AS 08.30.010;

20 (2) "clinical laboratory testing," "clinical laboratory test," or
21 "laboratory test" means a microbiological, serological, chemical, biological,
22 hematological, immunological, immunohematological, genetic, radiobiassay,
23 cytological, biophysical, or any other procedure performed on material derived from
24 or existing in a human body that provides information for the diagnosis, prevention, or
25 monitoring of a disease, impairment, or clinical condition; clinical laboratory tests
26 encompass the pre-analytic, analytic, and post-analytic phases of testing;

27 (3) "department" means the Department of Commerce, Community,
28 and Economic Development;

29 (4) "medical laboratory director" means a licensed physician who is
30 responsible for the administrative, scientific, and technical operation of a medical
31 laboratory and who provides evidence satisfactory to the department that the person is

1 certified in clinical pathology by a nationally recognized credentialing agency,
2 organization, or school approved by the department;

3 (5) "moderately complex test" means a clinical laboratory procedure
4 that is more technologically demanding than is a waived test and requires some degree
5 of independent judgment and interpretation as further defined by the department;

6 (6) "point of care testing" means a procedure that involves analysis, is
7 performed at the site of patient care, and does not require independent laboratory or
8 technological support;

9 (7) "supervision" means the provision of direction and evaluation of
10 the tasks assigned;

11 (8) "waived testing" or "waived test" means a simple laboratory
12 procedure, as further defined by the department, that employs methodologies that are
13 so simple and accurate as to render the likelihood of an erroneous result negligible
14 and, even if performed incorrectly, that does not pose a significant risk of harm;
15 "waived tests" include those approved by the United States Food and Drug
16 Administration for home use.

17 * **Sec. 2.** The uncodified law of the State of Alaska is amended by adding a new section to
18 read:

19 **APPLICABILITY.** AS 08.30.050 - 08.30.500, added by sec. 1 of this Act, apply
20 immediately to persons who have not been employed in the state in the field of clinical
21 laboratory science, as described in this Act, before the effective date of this Act. For persons
22 who have been employed in the state within the past five years in a specified field of clinical
23 laboratory science and have been certified by any national certifying agency or organization
24 approved by the department, the provisions of sec. 1 of this Act apply two years after the
25 effective date of this Act.

26 * **Sec. 3.** The uncodified law of the State of Alaska is amended by adding a new section to
27 read:

28 **VOLUNTEER ADVISORY BOARD OF CLINICAL LABORATORY SCIENCE**
29 **PROFESSIONALS; TRANSITION; STAGGERED TERMS.** Notwithstanding AS 08.30.010,
30 added by sec. 1 of this Act, the members appointed to the Voluntary Advisory Board of
31 Clinical Laboratory Science Professionals

1 (1) may be unlicensed for the first year of the member's initial appointment or
2 until 30 days after the department has begun issuing licenses, whichever first occurs; and

3 (2) shall be appointed to staggered terms in the first year as follows:

4 (A) two members shall be appointed to serve three years;

5 (B) two members shall be appointed to serve two years; and

6 (C) one member shall be appointed to serve one year.

7 * **Sec. 4.** This Act takes effect October 1, 2008.