

HOUSE BILL NO. 28

IN THE LEGISLATURE OF THE STATE OF ALASKA
TWENTY-SIXTH LEGISLATURE - FIRST SESSION

BY REPRESENTATIVES CRAWFORD, Kerttula

Introduced: 1/20/09

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 08.01.010 is amended by adding a new paragraph to read:

5 (39) regulation of clinical laboratory science professionals under
6 AS 08.30.

7 *** Sec. 2.** AS 08 is amended by adding a new chapter to read:

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

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

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

14 (b) Board members must be residents of the state, and the membership of the

1 board must reflect the rural and urban demographics of the state. Not more than two
2 members may be residents of the same house district.

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

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

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

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

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

17 **Sec. 08.30.030. Duties of the board.** The board shall advise the department on
18 credentialing agencies or organizations.

19 **Article 2. Examination and Licensing.**

20 **Sec. 08.30.100. License required.** Except as provided in AS 08.30.210, a
21 person may not perform clinical laboratory tests, use a title listed under AS 08.30.110,
22 or offer or attempt to practice, or advertise or announce as being prepared or qualified
23 to perform, clinical laboratory tests without a license issued under this chapter.

24 **Sec. 08.30.110. 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 competent,
30 as evidenced by the applicant's certification by a credentialing agency or organization
31 approved by the department in consultation with the board.

1 **Sec. 08.30.120. 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 licensed physician;

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 licensed physician;

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

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

9 (B) perform methods for antigen detection and other molecular
10 hybridization testing methods if the purpose of the testing is to analyze or
11 quantify cellular tissue components for interpretation by a licensed physician.

12 **Sec. 08.30.130. Duration of license; license renewal.** (a) A license, other than
13 a temporary license, issued by the department is valid for three years or until the
14 license is relinquished, suspended, or revoked.

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

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

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

19 (3) satisfactory proof of

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

22 (B) other measures of competency as required by the
23 department.

24 **Article 3. General Provisions.**

25 **Sec. 08.30.200. Grounds for denial of license or for disciplinary sanctions.**

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

29 (1) made a material misstatement of fact in information presented to
30 the department;

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

1 this chapter;

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

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

6 (5) engaged in unprofessional conduct described in regulations adopted
7 by the department;

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

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

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

16 **Sec. 08.30.210. Exemption from license requirement.** The license
17 requirements under this chapter do not apply to a

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

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

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

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

28 (5) person performing waived testing;

29 (6) person performing point of care testing in an acute care facility if
30 the facility

31 (A) employs a licensed clinical laboratory science professional

1 to manage testing by

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

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

6 (iii) assisting in the selection of technology used for the
7 testing;

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

10 (v) monitoring the continued competency of testing
11 personnel; and

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

15 **Sec. 08.30.220. Department regulations.** The department shall adopt
16 regulations, subject to AS 44.62 (Administrative Procedure Act), to carry out the
17 purposes of this chapter and the duties assigned to the department under this chapter.

18 **Sec. 08.30.299. Definitions.** In this chapter,

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

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

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

30 (4) "medical laboratory director" means a licensed physician who is
31 responsible for the administrative, scientific, and technical operation of a medical

1 laboratory and who provides evidence satisfactory to the department that the person is
 2 certified in clinical pathology by a nationally recognized credentialing agency,
 3 organization, or school approved by the department;

4 (5) "moderately complex test" means a clinical laboratory procedure as
 5 defined by the United States Food and Drug Administration under 42 C.F.R.
 6 493.17(a), as amended, and listed in the Federal Register under 42 C.F.R. 493.17(c),
 7 as amended;

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

11 (7) "supervision" means the provision of direction and evaluation of
 12 the tasks assigned;

13 (8) "waived testing" or "waived test"

14 (A) means a simple laboratory procedure, as defined by the
 15 United States Food and Drug Administration under 42 C.F.R. 493.15(b), as
 16 amended, and listed under 42 C.F.R. 493.15(c), as amended; and

17 (B) includes those tests described in (A) of this paragraph
 18 approved by the United States Food and Drug Administration for home use.

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

21 **APPLICABILITY.** AS 08.30.100 - 08.30.299, added by sec. 2 of the Act, apply

22 (1) immediately to persons who have not been employed in the state in the
 23 field of clinical laboratory science, as described in this Act, before the effective date of this
 24 Act; and

25 (2) two years after the effective date of this Act as to persons who have been
 26 employed in the state within the five years immediately preceding the effective date of this
 27 Act in a specified field of clinical laboratory science and have been certified by a national
 28 credentialing agency or organization approved by the Department of Commerce, Community,
 29 and Economic Development under AS 08.30.110 and 08.30.220, added by sec. 2 of this Act.

30 * **Sec. 4.** The uncodified law of the State of Alaska is amended by adding a new section to
 31 read:

1 VOLUNTEER ADVISORY BOARD OF CLINICAL LABORATORY SCIENCE
2 PROFESSIONALS; TRANSITION; STAGGERED TERMS. Notwithstanding AS 08.30.010,
3 added by sec. 2 of this Act, the members appointed to the Voluntary Advisory Board of
4 Clinical Laboratory Science Professionals

5 (1) may be unlicensed for the first year of each member's initial appointment
6 or until 30 days after the Department of Commerce, Community, and Economic Development
7 has begun issuing licenses, whichever first occurs for each member; and

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

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

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

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

12 * **Sec. 5.** This Act takes effect October 1, 2009.