

HOUSE BILL NO. 241

INTRODUCED BY STRIZICH, FRANKLIN, J. RICE, VOGEL, S. RICE,
RYAN, WISEMAN, CHRISTIAENS, HARPER, HANSEN, KADAS, WILSON,
MCCULLOCH, DRISCOLL, HARRINGTON, DOWELL, SMITH, ECK,
D. BROWN, COCCHIARELLA, TOOLE, SQUIRES, BARNHART, SIMPKINS,
MENAHAH, DOHERTY, WYATT, HARP, TUSS, KLAMPE, RANEY, BIRD,
RYE, SIMON, BOHLINGER, PAVLOVICH

IN THE HOUSE

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| JANUARY 19, 1993 | INTRODUCED AND REFERRED TO COMMITTEE ON HUMAN SERVICES & AGING. |
| | FIRST READING. |
| JANUARY 21, 1993 | ON MOTION, ADDITIONAL SPONSORS ADDED. |
| FEBRUARY 1, 1993 | COMMITTEE RECOMMEND BILL DO PASS AS AMENDED. REPORT ADOPTED. |
| FEBRUARY 2, 1993 | PRINTING REPORT. |
| FEBRUARY 3, 1993 | SECOND READING, DO PASS AS AMENDED. |
| FEBRUARY 4, 1993 | ENGROSSING REPORT. |
| FEBRUARY 5, 1993 | THIRD READING, PASSED. AYES, 88; NOES, 10. |
| | TRANSMITTED TO SENATE. |

IN THE SENATE

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| FEBRUARY 8, 1993 | INTRODUCED AND REFERRED TO COMMITTEE ON PUBLIC HEALTH, WELFARE, & SAFETY. |
| | FIRST READING. |
| MARCH 12, 1993 | COMMITTEE RECOMMEND BILL BE CONCURRED IN AS AMENDED. REPORT ADOPTED. |
| MARCH 13, 1993 | SECOND READING, CONCURRED IN. |
| MARCH 15, 1993 | THIRD READING, CONCURRED IN. AYES, 45; NOES, 4. |
| | RETURNED TO HOUSE WITH AMENDMENTS. |

IN THE HOUSE

APRIL 1, 1993

SECOND READING, AMENDMENTS
CONCURRED IN.

APRIL 2, 1993

THIRD READING, AMENDMENTS
CONCURRED IN.

SENT TO ENROLLING.

REPORTED CORRECTLY ENROLLED.

1 *Bellevue* House BILL NO. *241* *M. Ryan*
 2 INTRODUCED BY *Franklin Kane Vogel*

3 *Harry Williams*
 4 A BILL FOR AN ACT ENTITLED: "AN ACT PROVIDING FOR THE
 5 LICENSURE OF CLINICAL LABORATORY SCIENCE PRACTITIONERS; AND
 6 PROVIDING AN IMMEDIATE EFFECTIVE DATE." *Klampe*
 7 *Simpkins Menahan Dwyer W. G. P. C. L. M.*
 8 *Bray Bick*

STATEMENT OF INTENT

9 A statement of intent is needed for this bill because it
 10 establishes a board of clinical laboratory science
 11 practitioners and gives the board rulemaking authority. The
 12 board is required to adopt rules to establish licensing and
 13 certification procedures, educational requirements for
 14 licensure, and continuing education requirements. The board
 15 is also required to establish rules for the renewal,
 16 suspension, and revocation of licenses. The board shall
 17 establish an investigation and hearing procedure for
 18 handling complaints and shall set fees for administration of
 19 the board's duties. The fees must be commensurate with the
 20 costs of administration.

21
 22 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

23 NEW SECTION. Section 1. Short title. [Sections 1
 24 through 5 and 7 through 13] may be cited as the "Clinical
 25 Laboratory Science Practice Act".

1 NEW SECTION. Section 2. Declaration of policy and
 2 purpose. The legislature finds and declares that because the
 3 practice of clinical laboratory science affects the public
 4 health, safety, and welfare of Montana citizens, it is the
 5 purpose of [sections 1 through 5 and 7 through 13] to
 6 provide for the common good by regulating and ensuring the
 7 qualified and professional practice of clinical laboratory
 8 science. The legislature further declares that because
 9 clinical laboratory science practitioners provide essential
 10 services to other health care providers by furnishing vital
 11 information that may be used in the assessment of human
 12 health and in the diagnosis, prevention, and treatment of
 13 disease or impairment, clinical laboratory tests must be
 14 performed by individuals who meet specific standards of
 15 competency.

16 NEW SECTION. Section 3. Definitions. As used in
 17 [sections 1 through 5 and 7 through 13], the following
 18 definitions apply:

19 (1) "Board" means the board of clinical laboratory
 20 science practitioners established in [section 6].

21 (2) "Clinical laboratory" or "laboratory" means any
 22 facility or office in which clinical laboratory tests are
 23 performed.

24 (3) (a) "Clinical laboratory science practitioner"
 25 means a health care professional who performs clinical

1 laboratory tests or who is engaged in management, education,
2 consulting, or research in clinical laboratory science.

3 (b) The term includes laboratory directors, managers,
4 supervisors, clinical laboratory scientists, clinical
5 laboratory specialists, and clinical laboratory technicians
6 who work in a laboratory.

7 (c) The term does not include:

8 (i) persons employed by a clinical laboratory to
9 perform supportive functions not related to direct
10 performance of laboratory tests; or

11 (ii) clinical laboratory trainees.

12 (4) "Clinical laboratory scientist" means a person who:

13 (a) performs clinical laboratory tests pursuant to
14 established and approved protocols requiring the exercise of
15 independent judgment and responsibility;

16 (b) maintains equipment and records;

17 (c) performs quality assurance activities related to
18 test performance; and

19 (d) may supervise and teach within a clinical
20 laboratory setting.

21 (5) "Clinical laboratory specialist" means a person
22 who:

23 (a) performs laboratory testing in a specialized
24 testing area, such as microbiology, chemistry, immunology,
25 or hematology, according to approved protocols requiring the

1 exercise of independent judgment and responsibility;

2 (b) maintains equipment and records;

3 (c) performs quality assurance activities related to
4 test performance; and

5 (d) may supervise and teach within the specific area of
6 the clinical laboratory.

7 (6) "Clinical laboratory technician" means a person who
8 performs laboratory tests pursuant to established and
9 approved protocols that require limited exercise of
10 independent judgment and that are performed under the
11 personal and direct supervision of a clinical laboratory
12 scientist, laboratory supervisor, or laboratory director.

13 (7) "Clinical laboratory test" or "laboratory test"
14 means:

15 (a) a microbiological, serological, chemical,
16 hematological, radiobioassay, cytological, biophysical,
17 immunological, cytogenetical, or other examination that is
18 performed on material derived from the human body; or

19 (b) any other test or procedure conducted by a
20 laboratory or facility that provides information for the
21 assessment of a medical condition or for the diagnosis,
22 prevention, or treatment of a disease.

23 (8) "Department" means the department of commerce
24 provided for in 2-15-1801.

25 (9) "License" means the clinical laboratory science

1 license issued under [sections 1 through 5 and 7 through
2 13].

3 (10) "Practice of clinical laboratory science" means the
4 performance and interpretation of microbiological,
5 serological, chemical, hematological, radiobioassay,
6 cytological, biophysical, immunological, cytogenetical, or
7 other examination on material that is derived from the human
8 body and that provides information for the assessment of a
9 medical condition or for the diagnosis, prevention, or
10 treatment of a disease.

11 NEW SECTION. Section 4. License required. A person may
12 not practice clinical laboratory science or hold out to the
13 public that the person is a clinical laboratory science
14 practitioner in this state unless the person is licensed
15 pursuant to [sections 1 through 5 and 7 through 13].

16 NEW SECTION. Section 5. Exemptions. (1) [Sections 1
17 through 5 and 7 through 13] do not limit or regulate the
18 practice of licensed physicians, including but not limited
19 to pathologists.

20 (2) [Sections 1 through 5 and 7 through 13] do not
21 apply to:

22 (a) any other profession licensed under Title 37 to the
23 extent that the applicable scope of that practice authorizes
24 the performance of a clinical laboratory test;

25 (b) clinical laboratory science practitioners employed

1 by the United States or by any bureau, division, or agency
2 of the United States, while in the discharge of the
3 employee's official duties;

4 (c) clinical laboratory science practitioners engaged
5 in teaching or research, provided that the results of any
6 examination performed are not used in health maintenance,
7 diagnosis, or treatment of disease;

8 (d) students or trainees enrolled in a clinical
9 laboratory science education or training program, provided
10 that:

11 (i) these activities constitute a planned course in the
12 program;

13 (ii) the persons are designated by a title, such as
14 intern, trainee, or student; and

15 (iii) the persons work directly under an individual
16 licensed by this state to practice clinical laboratory
17 science; or

18 (e) any person performing only waived tests as provided
19 for in the federal clinical laboratory regulations set forth
20 in 42 CFR part 493.

21 NEW SECTION. Section 6. Board -- composition --
22 allocation -- quasi-judicial -- compensation. (1) There is a
23 board of clinical laboratory science practitioners.

24 (2) The board is composed of five members who have been
25 residents of this state for at least 2 years prior to

1 appointment and who are actively engaged in their respective
2 practices.

3 (3) Members are appointed by the governor, with consent
4 of the senate. The members are:

5 (a) one physician who is qualified to direct a high
6 complexity laboratory as provided for in the federal
7 clinical laboratory regulations set forth in 42 CFR part
8 493;

9 (b) three clinical laboratory science practitioners
10 who, except for the initial appointments, hold active
11 licenses as clinical laboratory science practitioners in
12 Montana; and

13 (c) one public member who is not associated with or
14 financially interested in the practice of clinical
15 laboratory science.

16 (4) Following the initial appointments of members to
17 the board, all members shall serve 4-year terms. The terms
18 of the initial appointments must be staggered, with three
19 members serving a 4-year term and two members serving a
20 2-year term. A member may not serve more than two
21 consecutive terms.

22 (5) Whenever a vacancy occurs on the board during a
23 term of office, the governor shall appoint a successor with
24 similar qualifications for the remainder of the unexpired
25 term.

1 (6) The board is allocated to the department for
2 administrative purposes only, as provided in 2-15-121.

3 (7) The board is designated a quasi-judicial board for
4 the purposes of 2-15-124, except that a member of the board
5 need not be an attorney licensed to practice law in this
6 state.

7 (8) Members of the board are entitled to compensation
8 and travel expenses as provided by law.

9 **NEW SECTION. Section 7. Powers and duties of the board**
10 **-- rulemaking authority.** (1) The board shall:

11 (a) meet at least once annually, and at other times as
12 agreed upon, to elect officers and to perform the duties
13 described in this section; and

14 (b) administer oaths, take affidavits, summon
15 witnesses, and take testimony as to matters within the scope
16 of the board's duties.

17 (2) The board has the authority to administer and
18 enforce all the powers and duties granted statutorily or
19 adopted administratively.

20 (3) The board shall adopt rules to administer [sections
21 1 through 5 and 7 through 13]. The rules must include but
22 are not limited to:

23 (a) the development of a license application procedure
24 and acceptable certifications for each category of license;

25 (b) the establishment of license fees commensurate with

1 actual costs;

2 (c) the establishment of criteria for educational
3 requirements that, at a minimum, meet the standards set
4 forth in [section 8];

5 (d) the development of procedures for the issuance,
6 renewal, suspension, revocation, and reciprocity of
7 licenses;

8 (e) the adoption of disciplinary standards for
9 licensees;

10 (f) the establishment of investigatory and hearing
11 procedures for processing complaints received by the board;
12 and

13 (g) the establishment of continuing education
14 requirements of at least 14 hours annually for license
15 renewal for clinical laboratory practitioners.

16 **NEW SECTION. Section 8. Standards for licensure.** (1)

17 The board shall issue a clinical laboratory scientist
18 license to an individual who meets the qualifications as
19 promulgated by rules of the board. At a minimum, a licensee
20 must be a person who:

21 (a) has graduated with a baccalaureate degree,
22 including a minimum number of hours in areas or disciplines
23 established by rule by the board; and

24 (b) has passed a certifying examination approved by the
25 board.

1 (2) The board shall issue a clinical laboratory
2 specialist license to an individual who has graduated with a
3 baccalaureate degree as described in subsection (1) and has
4 passed a certifying examination covering those fields in
5 which the applicant is eligible and approved by the board.
6 The license must be issued as a clinical laboratory
7 specialist license and must state the designation of the
8 area of specialty.

9 (3) The board shall issue a clinical laboratory
10 technician license to an individual who meets the
11 qualifications promulgated by the board, including the
12 following minimum qualifications:

13 (a) completion of an associate degree or 60 semester
14 hours in a science-related discipline;

15 (b) completion of other equivalent formal education as
16 approved by the board; and

17 (c) passing a certifying examination approved by the
18 board.

19 **NEW SECTION. Section 9. Waiver of requirements --**
20 **temporary license -- reciprocity.** (1) Upon payment of a
21 license fee, the board may issue a license to a person
22 practicing clinical laboratory science on [the effective
23 date of this act] if the applicant can provide
24 documentation, verified by oath, of at least 1 year of
25 full-time experience in clinical laboratory science in

Montana within the last 3 years. Application for licensure under this provision must be completed within 1 year of [the effective date of this act].

(2) (a) Upon payment of a license fee, the board may issue a temporary license to a person who practiced clinical laboratory science in another state if that person can provide documentation, verified by oath, of at least 1 year of full-time experience in clinical laboratory science within the last 3 years. A temporary license may not be valid for more than 15 months.

(b) A temporary licensee shall pass a board-approved certification examination within 15 months of receiving a temporary license.

(3) Upon payment of the license fee, the board may issue a license to practice clinical laboratory science to an applicant who is currently licensed to practice clinical laboratory science in another state, territory, or country if the qualifications for the other license are considered by the board to be equal to or exceed the requirements of [sections 1 through 5 and 7 through 13] and if the other state, territory, or country extends similar privileges to clinical laboratory science practitioners licensed under [sections 1 through 5 and 7 through 13].

NEW SECTION. Section 10. Licensure application procedures. (1) An applicant shall submit an application for

a license to the board upon the forms prescribed and furnished by the board and shall pay an application fee set by the board.

(2) Upon receipt of the application and fee, the board shall issue a license for a clinical laboratory scientist, a clinical laboratory specialist, or a clinical laboratory technician to any person who meets the qualifications specified by the board as set forth in rules adopted by the board pursuant to [sections 7 and 8].

(3) A license issued under [sections 1 through 5 and 7 through 13] must be renewed by May 1 of each year.

(4) Except for the assessment provided in 37-1-101(6), money paid for application, license, and license renewal fees must be deposited in the state special revenue fund for use by the board.

NEW SECTION. Section 11. Disciplinary measures -- grounds -- fine. (1) The board, after notice and hearing, may reprimand a licensee or deny, suspend, revoke, or refuse to renew the license of a licensee who:

(a) uses alcohol or other drugs to the extent that job performance is impaired;

(b) is guilty of immoral or unprofessional conduct as defined by board rule;

(c) is guilty of gross negligence in the practice of clinical laboratory science;

(d) has obtained or attempted to obtain a license by fraud or material misrepresentation;

(e) is guilty of conduct detrimental to the best interests of the public; or

(f) has violated a provision of [sections 1 through 5 and 7 through 13] or a rule adopted by the board.

(2) The board may impose an administrative fine of not more than \$500 per incident for any violation that could result in the suspension or revocation of a license. A fine collected under this subsection must be deposited in the state special revenue fund for use by the board.

NEW SECTION. Section 12. Violation -- penalties -- injunction -- manner of charging violation. (1) A person who violates a provision of [sections 1 through 5 and 7 through 13] or a rule adopted pursuant to [sections 1 through 5 and 7 through 13] is guilty of a misdemeanor and is punishable by a fine not to exceed \$500, by imprisonment in the county jail for a term of not more than 6 months, or both.

(2) Except as provided in [section 5], the board may maintain an action to enjoin a person from engaging in the practice of clinical laboratory science until a license to practice is obtained. A person who has been enjoined and who violates the injunction is punishable for contempt of court. The injunction does not relieve the person practicing clinical laboratory science without a license from criminal

prosecution. The remedy by injunction is in addition to remedies provided for criminal prosecution of the offender.

(3) When charging a person in a complaint for injunction or in an affidavit, information, or indictment with a violation of law by practicing clinical laboratory science without a license, it is sufficient to charge that the person did, on a certain day and in a certain county, engage in the practice of clinical laboratory science while not having a license to do so, without specifying particular facts concerning the violation.

NEW SECTION. Section 13. Due process procedures -- hearing -- temporary suspension. (1) The proceedings for the revocation, suspension, or limiting of a license may be initiated by the board or by any person, corporation, association, or public officer by filing written charges with the board.

(2) A license may not be revoked, suspended, or limited without a hearing before the board after charges are filed. If the board finds that there is a significant threat to the public health, the board, upon notice to the licensee, may temporarily suspend the license without a hearing for a period not to exceed 30 days.

NEW SECTION. Section 14. Severability. If a part of [this act] is invalid, all valid parts that are severable from the invalid part remain in effect. If a part of [this

1 act] is invalid in one or more of its applications, the part
2 remains in effect in all valid applications that are
3 severable from the invalid applications.

4 NEW SECTION. **Section 15.** Codification instruction. (1)
5 [Section 6] is intended to be codified as an integral part
6 of Title 2, chapter 15, part 18, and the provisions of Title
7 2, chapter 15, part 18, apply to [section 6].

8 (2) [Sections 1 through 5 and 7 through 13] are
9 intended to be codified as an integral part of Title 37, and
10 the provisions of Title 37 apply to [sections 1 through 5
11 and 7 through 13].

12 NEW SECTION. **Section 16.** Effective date. [This act] is
13 effective on passage and approval.

-End-

STATE OF MONTANA - FISCAL NOTE

Form BD-15

In compliance with a written request, there is hereby submitted a Fiscal Note for HB0241, as introduced.

DESCRIPTION OF PROPOSED LEGISLATION:

The bill provides for the licensure of clinical laboratory science practitioners.

ASSUMPTIONS:

1. There will need to be 3 meetings per year for the first 2 years, lasting 2 days per meeting.
2. 900 new licenses the first year and 10 the second year.
3. Fees will be: Applications \$35, Licenses \$10, Temporary Permit \$100, Renewal \$30, Late Penalty \$30.
4. At the end of the legislative session the Department of Commerce will have to determine if any additional staffing is needed to cover all of the bills that passed during the session.

FISCAL IMPACT:

| | <u>FY '94</u> | | | <u>FY '95</u> | | |
|----------------------|--------------------|---------------------|-------------------|--------------------|---------------------|-------------------|
| | <u>Current Law</u> | <u>Proposed Law</u> | <u>Difference</u> | <u>Current Law</u> | <u>Proposed Law</u> | <u>Difference</u> |
| <u>Expenditures:</u> | | | | | | |
| Personal Services | 0 | 2,500 | 2,500 | 0 | 2,500 | 2,500 |
| Operating Expenses | <u>0</u> | <u>25,500</u> | <u>25,500</u> | <u>0</u> | <u>23,500</u> | <u>23,500</u> |
| Total | 0 | 28,000 | 28,000 | 0 | 26,000 | 26,000 |
| <u>Revenues:</u> | | | | | | |
| Fees (02) | 0 | 41,500 | 41,500 | 0 | 29,950 | 29,950 |
| <u>Net Impact:</u> | 0 | 13,500 | 13,500 | 0 | 3,950 | 3,950 |

David Lewis 1-25-93

DAVID LEWIS, BUDGET DIRECTOR DATE
Office of Budget and Program Planning

WILLIAM S. STRIZICH, PRIMARY SPONSOR DATE

Fiscal Note for HB0241, as introduced

HB 241

APPROVED BY COMM. ON
HUMAN SERVICES AND AGING

HOUSE BILL NO. 241

INTRODUCED BY STRIZICH, FRANKLIN, J. RICE, VOGEL, S. RICE,
RYAN, WISEMAN, CHRISTIAENS, HARPER, HANSEN, KADAS, WILSON,
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A BILL FOR AN ACT ENTITLED: "AN ACT PROVIDING FOR THE
LICENSURE OF CLINICAL LABORATORY SCIENCE PRACTITIONERS; AND
PROVIDING AN-IMMEDIATE EFFECTIVE DATE DATES."

STATEMENT OF INTENT

A statement of intent is needed for this bill because it
establishes a board of clinical laboratory science
practitioners and gives the board rulemaking authority. The
board is required to adopt rules to establish licensing and
certification procedures, educational requirements for
licensure, and continuing education requirements. The board
is also required to establish rules for the renewal,
suspension, and revocation of licenses. The board shall
establish an investigation and hearing procedure for
handling complaints and shall set fees for administration of
the board's duties. The fees must be commensurate with the
costs of administration. THE BOARD SHALL ALSO ADOPT RULES

IMPLEMENTING THE REQUIREMENT THAT A SUPERVISOR OF A CLINICAL
LABORATORY TECHNICIAN MUST BE ACCESSIBLE AT ALL TIMES THAT
TESTING IS BEING PERFORMED IN ORDER TO PROVIDE ONSITE,
TELEPHONIC, OR ELECTRONIC CONSULTATION.

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

NEW SECTION. Section 1. Short title. [Sections 1
through 5 and 7 through 13] may be cited as the "Clinical
Laboratory Science Practice Act".

NEW SECTION. Section 2. Declaration of policy and
purpose. The legislature finds and declares that because the
practice of clinical laboratory science affects the public
health, safety, and welfare of Montana citizens, it is the
purpose of [sections 1 through 5 and 7 through 13] to
provide for the common good by regulating and ensuring the
qualified and professional practice of clinical laboratory
science. The legislature further declares that because
clinical laboratory science practitioners provide essential
services to other health care providers by furnishing vital
information that may be used in the assessment of human
health and in the diagnosis, prevention, and treatment of
disease or impairment, clinical laboratory tests must be
performed by individuals who meet specific standards of
competency.

NEW SECTION. Section 3. Definitions. As used in

[sections 1 through 5 and 7 through 13], the following definitions apply:

(1) "Board" means the board of clinical laboratory science practitioners established in [section 6].

(2) "Clinical laboratory" or "laboratory" means any facility or office in which clinical laboratory tests are performed.

(3) (a) "Clinical laboratory science practitioner" means a health care professional who performs clinical laboratory tests or who is engaged in management, education, consulting, or research in clinical laboratory science.

(b) The term includes laboratory directors, managers, supervisors, clinical laboratory scientists, clinical laboratory specialists, and clinical laboratory technicians who work in a laboratory.

(c) The term does not include:

(i) persons employed by a clinical laboratory to perform supportive functions not related to direct performance of laboratory tests; or

(ii) clinical laboratory trainees.

(4) "Clinical laboratory scientist" means a person who:

(a) performs clinical laboratory tests pursuant to established and approved protocols requiring the exercise of independent judgment and responsibility;

(b) maintains equipment and records;

(c) performs quality assurance activities related to test performance; and

(d) may supervise and teach within a clinical laboratory setting.

(5) "Clinical laboratory specialist" means a person who:

(a) performs laboratory testing in a specialized testing area, such as microbiology, chemistry, immunology, or hematology, according to approved protocols requiring the exercise of independent judgment and responsibility;

(b) maintains equipment and records;

(c) performs LOW AND MEDIUM COMPLEXITY quality assurance activities related to test performance; and

(d) may supervise and teach within the specific area of the clinical laboratory.

(6) "Clinical laboratory technician" means a person who performs laboratory tests pursuant to established and approved protocols that require limited exercise of independent judgment and that are performed under the ~~person's~~ ~~and-direct~~ supervision of a clinical laboratory scientist, laboratory supervisor, or laboratory director.

(7) "Clinical laboratory test" or "laboratory test" means:

(a) a microbiological, serological, chemical, hematological, radiobioassay, cytological, biophysical,

immunological, cytogenetical, or other examination that is performed on material derived from the human body; or

(b) any other test or procedure conducted by a laboratory or facility that provides information for the assessment of a medical condition or for the diagnosis, prevention, or treatment of a disease.

(8) "Department" means the department of commerce provided for in 2-15-1801.

(9) "License" means the clinical laboratory science license issued under [sections 1 through 5 and 7 through 13].

(10) "Practice of clinical laboratory science" means the performance and interpretation of microbiological, serological, chemical, hematological, radiobioassay, cytological, biophysical, immunological, cytogenetical, or other examination on material that is derived from the human body and that provides information for the assessment of a medical condition or for the diagnosis, prevention, or treatment of a disease.

NEW SECTION. Section 4. License required. A person may not ENGAGE IN THE practice OF clinical laboratory science or hold out to the public that the person is a clinical laboratory science practitioner in this state unless the person is licensed pursuant to [sections 1 through 5 and 7 through 13].

NEW SECTION. Section 5. Exemptions. (1) [Sections 1 through 5 and 7 through 13] do not limit or regulate the practice of licensed physicians, including but not limited to pathologists.

(2) [Sections 1 through 5 and 7 through 13] do not apply to:

(a) any other profession licensed under Title 37 to the extent that the applicable scope of that practice, AS DEFINED BY STATUTE, RULES OF THE BOARD OR AGENCY GOVERNING THE OTHER PROFESSION, OR BOTH THE STATUTE AND RULES, authorizes the performance of a clinical laboratory test;

(b) clinical laboratory science practitioners employed by the United States or by any bureau, division, or agency of the United States, while in the discharge of the employee's official duties;

(c) clinical laboratory science practitioners engaged in teaching or research, provided that the results of any examination performed are not used in health maintenance, diagnosis, or treatment of disease;

(d) students or trainees enrolled in a clinical laboratory science education or training program, provided that:

(i) these activities constitute a planned course in the program;

(ii) the persons are designated by a title, such as

intern, trainee, or student; and

(iii) the persons work directly under an individual licensed by this state to practice clinical laboratory science; or

(e) any person performing only waived tests as provided for in the federal clinical laboratory regulations set forth in 42 CFR part 493.

NEW SECTION. Section 6. Board -- composition -- allocation -- quasi-judicial -- compensation. (1) There is a board of clinical laboratory science practitioners.

(2) The board is composed of five members who have been residents of this state for at least 2 years prior to appointment and who are actively engaged in their respective practices.

(3) Members are appointed by the governor, with consent of the senate. The members are:

(a) one physician who is qualified to direct a high complexity laboratory as provided for in the federal clinical laboratory regulations set forth in 42 CFR part 493;

(b) three clinical laboratory science practitioners who, except for the initial appointments, hold active licenses as clinical laboratory science practitioners in Montana; and

(c) one public member who is not associated with or

financially interested in the practice of clinical laboratory science.

(4) Following the initial appointments of members to the board, all members shall serve 4-year terms. The terms of the initial appointments must be staggered, with three members serving a 4-year term and two members serving a 2-year term. A member may not serve more than two consecutive terms.

(5) Whenever a vacancy occurs on the board during a term of office, the governor shall appoint a successor with similar qualifications for the remainder of the unexpired term.

(6) The board is allocated to the department for administrative purposes only, as provided in 2-15-121.

(7) The board is designated a quasi-judicial board for the purposes of 2-15-124, except that a member of the board need not be an attorney licensed to practice law in this state.

(8) Members of the board are entitled to compensation and travel expenses as provided by law.

NEW SECTION. Section 7. Powers and duties of the board -- rulemaking authority. (1) The board shall:

(a) meet at least once annually, and at other times as agreed upon, to elect officers and to perform the duties described in this section; and

(b) administer oaths, take affidavits, summon witnesses, and take testimony as to matters within the scope of the board's duties.

(2) The board has the authority to administer and enforce all the powers and duties granted statutorily or adopted administratively.

(3) The board shall adopt rules to administer [sections 1 through 5 and 7 through 13]. The rules must include but are not limited to:

(a) the development of a license application procedure and acceptable certifications for each category of license;

(b) the establishment of license fees commensurate with actual costs;

(c) the establishment of criteria for educational requirements that, at a minimum, meet the standards set forth in [section 8];

(d) the development of procedures for the issuance, renewal, suspension, revocation, and reciprocity of licenses;

(e) the adoption of disciplinary standards for licensees;

(f) the establishment of investigatory and hearing procedures for processing complaints received by the board; and

(g) the establishment of continuing education

requirements of at least 14 hours annually for license renewal for clinical laboratory practitioners; AND

(H) A REQUIREMENT THAT THE SUPERVISOR OF A CLINICAL LABORATORY TECHNICIAN BE ACCESSIBLE AT ALL TIMES THAT TESTING IS BEING PERFORMED BY THE TECHNICIAN IN ORDER TO PROVIDE ONSITE, TELEPHONIC, OR ELECTRONIC CONSULTATION.

NEW SECTION. Section 8. Standards for licensure. (1)

The board shall issue a clinical laboratory scientist license to an individual who meets the qualifications as promulgated by rules of the board. At a minimum, a licensee must be a person who:

(a) has graduated with a baccalaureate degree, including a minimum number of hours in areas or disciplines established by rule by the board; and

(b) has passed a certifying examination approved by the board.

(2) The board shall issue a clinical laboratory specialist license to an individual who has graduated with a baccalaureate degree as described in subsection (1) and has passed a certifying examination covering those fields in which the applicant is eligible and approved by the board. The license must be issued as a clinical laboratory specialist license and must state the designation of the area of specialty.

(3) The board shall issue a clinical laboratory

1 technician license to an individual who meets the
2 qualifications promulgated by the board, including the
3 following minimum qualifications:

4 (a) completion of an associate degree or 60 semester
5 hours in a science-related discipline;

6 (b) completion of other equivalent formal education as
7 approved by the board; and

8 (c) passing a certifying examination approved by the
9 board.

10 NEW SECTION. Section 9. Waiver of requirements --
11 temporary license -- reciprocity. (1) Upon payment of a
12 license fee, the board may issue a license to a person
13 practicing ENGAGED IN THE PRACTICE OF clinical laboratory
14 science on [the effective date of this act] if the applicant
15 can provide documentation, verified by oath, of at least 1
16 year of full-time experience in clinical laboratory science
17 in Montana within the last 3 years. Application for
18 licensure under this provision must be completed within 1
19 year of [the effective date of this act].

20 (2) (a) Upon payment of a license fee, the board may
21 issue a temporary license to a person who practiced ENGAGED
22 IN THE PRACTICE OF clinical laboratory science in another
23 state if that person can provide documentation, verified by
24 oath, of at least 1 year of full-time experience in clinical
25 laboratory science within the last 3 years. A temporary

1 license may not be valid for more than 15 months.

2 (b) A temporary licensee shall pass a board-approved
3 certification examination within 15 months of receiving a
4 temporary license.

5 (3) Upon payment of the license fee, the board may
6 issue a license to practice clinical laboratory science to
7 an applicant who is currently licensed to practice clinical
8 laboratory science in another state, territory, or country
9 if the qualifications for the other license are considered
10 by the board to be equal to or exceed the requirements of
11 [sections 1 through 5 and 7 through 13] and if the other
12 state, territory, or country extends similar privileges to
13 clinical laboratory science practitioners licensed under
14 [sections 1 through 5 and 7 through 13].

15 NEW SECTION. Section 10. Licensure application
16 procedures. (1) An applicant shall submit an application for
17 a license to the board upon the forms prescribed and
18 furnished by the board and shall pay an application fee set
19 by the board.

20 (2) Upon receipt of the application and fee, the board
21 shall issue a license for a clinical laboratory scientist, a
22 clinical laboratory specialist, or a clinical laboratory
23 technician to any person who meets the qualifications
24 specified by the board as set forth in rules adopted by the
25 board pursuant to [sections 7 and 8].

(3) A license issued under [sections 1 through 5 and 7 through 13] must be renewed by May 1 of each year.

(4) Except for the assessment provided in 37-1-101(6), money paid for application, license, and license renewal fees must be deposited in the state special revenue fund for use by the board.

NEW SECTION. Section 11. Disciplinary measures -- grounds -- fine. (1) The board, after notice and hearing, may reprimand a licensee or deny, suspend, revoke, or refuse to renew the license of a licensee who:

(a) uses alcohol or other drugs to the extent that job performance is impaired;

(b) is guilty of immoral or unprofessional conduct as defined by board rule;

(c) is guilty of gross negligence in the practice of clinical laboratory science;

(d) has obtained or attempted to obtain a license by fraud or material misrepresentation;

(e) is guilty of conduct detrimental to the best interests of the public; or

(f) has violated a provision of [sections 1 through 5 and 7 through 13] or a rule adopted by the board.

(2) The board may impose an administrative fine of not more than \$500 per incident for any violation that could result in the suspension or revocation of a license. A fine

collected under this subsection must be deposited in the state special revenue fund for use by the board.

NEW SECTION. Section 12. Violation -- penalties -- injunction -- manner of charging violation. (1) A person who violates a provision of [sections 1 through 5 and 7 through 13] or a rule adopted pursuant to [sections 1 through 5 and 7 through 13] is guilty of a misdemeanor and is punishable by a fine not to exceed \$500, by imprisonment in the county jail for a term of not more than 6 months, or both.

(2) Except as provided in [section 5], the board may maintain an action to enjoin a person from engaging in the practice of clinical laboratory science until a license to practice is obtained. A person who has been enjoined and who violates the injunction is punishable for contempt of court. The injunction does not relieve the person practicing clinical laboratory science without a license from criminal prosecution. The remedy by injunction is in addition to remedies provided for criminal prosecution of the offender.

(3) When charging a person in a complaint for injunction or in an affidavit, information, or indictment with a violation of law by practicing clinical laboratory science without a license, it is sufficient to charge that the person did, on a certain day and in a certain county, engage in the practice of clinical laboratory science while not having a license to do so, without specifying particular

1 facts concerning the violation.

2 NEW SECTION. Section 13. Due process procedures --
 3 hearing -- temporary suspension. (1) The proceedings for the
 4 revocation, suspension, or limiting of a license may be
 5 initiated by the board or by any person, corporation,
 6 association, or public officer by filing written charges
 7 with the board. THE BOARD MAY IN ALL CASES CONDUCT AN
 8 INVESTIGATION OF THE ALLEGATIONS IN THE WRITTEN CHARGES AND
 9 DISMISS THOSE THAT IT DETERMINES ARE FRIVOLOUS OR WITHOUT
 10 SUFFICIENT FACTUAL FOUNDATION.

11 (2) A license may not be revoked, suspended, or limited
 12 without a hearing before the board after charges are filed.
 13 If the board finds that there is a significant threat to the
 14 public health, the board, upon notice to the licensee, may
 15 temporarily suspend the license without a hearing for a
 16 period not to exceed 30 days.

17 NEW SECTION. Section 14. Severability. If a part of
 18 [this act] is invalid, all valid parts that are severable
 19 from the invalid part remain in effect. If a part of [this
 20 act] is invalid in one or more of its applications, the part
 21 remains in effect in all valid applications that are
 22 severable from the invalid applications.

23 NEW SECTION. Section 15. Codification instruction. (1)
 24 [Section 6] is intended to be codified as an integral part
 25 of Title 2, chapter 15, part 18, and the provisions of Title

1 2, chapter 15, part 18, apply to [section 6].

2 (2) [Sections 1 through 5 and 7 through 13] are
 3 intended to be codified as an integral part of Title 37, and
 4 the provisions of Title 37 apply to [sections 1 through 5
 5 and 7 through 13].

6 NEW SECTION. Section 16. Effective date. ~~[This act]~~ is
 7 [SECTIONS 6, 7, 14, 15, AND THIS SECTION] ARE effective on
 8 passage and approval.

-End-

1 HOUSE BILL NO. 241

2 INTRODUCED BY STRIZICH, FRANKLIN, J. RICE, VOGEL, S. RICE,
3 RYAN, WISEMAN, CHRISTIAENS, HARPER, HANSEN, KADAS, WILSON,
4 MCCULLOCH, DRISCOLL, HARRINGTON, DOWELL, SMITH, ECK,
5 D. BROWN, COCCHIARELLA, TOOLE, SQUIRES, BARNHART, SIMPKINS,
6 MENAHAN, DOHERTY, WYATT, HARP, TUSS, KLAMPE, RANEY, BIRD,
7 RYE, SIMON, BOHLINGER, PAVLOVICH

8
9 A BILL FOR AN ACT ENTITLED: "AN ACT PROVIDING FOR THE
10 LICENSURE OF CLINICAL LABORATORY SCIENCE PRACTITIONERS; AND
11 PROVIDING AN-IMMEDIATE EFFECTIVE DATE DATES."
12

13 STATEMENT OF INTENT

14 A statement of intent is needed for this bill because it
15 establishes a board of clinical laboratory science
16 practitioners and gives the board rulemaking authority. The
17 board is required to adopt rules to establish licensing and
18 certification procedures, educational requirements for
19 licensure, and continuing education requirements. The board
20 is also required to establish rules for the renewal,
21 suspension, and revocation of licenses. The board shall
22 establish an investigation and hearing procedure for
23 handling complaints and shall set fees for administration of
24 the board's duties. The fees must be commensurate with the
25 costs of administration. THE BOARD SHALL ALSO ADOPT RULES

1 IMPLEMENTING THE REQUIREMENT THAT A SUPERVISOR OF A CLINICAL
2 LABORATORY TECHNICIAN MUST BE ACCESSIBLE AT ALL TIMES THAT
3 TESTING IS BEING PERFORMED IN ORDER TO PROVIDE ONSITE,
4 TELEPHONIC, OR ELECTRONIC CONSULTATION.
5

6 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

7 NEW SECTION. Section 1. Short title. [Sections 1
8 through 5 and 7 through 13] may be cited as the "Clinical
9 Laboratory Science Practice Act".

10 NEW SECTION. Section 2. Declaration of policy and
11 purpose. The legislature finds and declares that because the
12 practice of clinical laboratory science affects the public
13 health, safety, and welfare of Montana citizens, it is the
14 purpose of [sections 1 through 5 and 7 through 13] to
15 provide for the common good by regulating and ensuring the
16 qualified and professional practice of clinical laboratory
17 science. The legislature further declares that because
18 clinical laboratory science practitioners provide essential
19 services to other health care providers by furnishing vital
20 information that may be used in the assessment of human
21 health and in the diagnosis, prevention, and treatment of
22 disease or impairment, clinical laboratory tests must be
23 performed by individuals who meet specific standards of
24 competency.

25 NEW SECTION. Section 3. Definitions. As used in

1 [sections 1 through 5 and 7 through 13], the following
2 definitions apply:

3 (1) "Board" means the board of clinical laboratory
4 science practitioners established in [section 6].

5 (2) "Clinical laboratory" or "laboratory" means any
6 facility or office in which clinical laboratory tests are
7 performed.

8 (3) (a) "Clinical laboratory science practitioner"
9 means a health care professional who performs clinical
10 laboratory tests or who is engaged in management, education,
11 consulting, or research in clinical laboratory science.

12 (b) The term includes laboratory directors, managers,
13 supervisors, clinical laboratory scientists, clinical
14 laboratory specialists, and clinical laboratory technicians
15 who work in a laboratory.

16 (c) The term does not include:

17 (i) persons employed by a clinical laboratory to
18 perform supportive functions not related to direct
19 performance of laboratory tests; or

20 (ii) clinical laboratory trainees.

21 (4) "Clinical laboratory scientist" means a person who:

22 (a) performs clinical laboratory tests pursuant to
23 established and approved protocols requiring the exercise of
24 independent judgment and responsibility;

25 (b) maintains equipment and records;

1 (c) performs quality assurance activities related to
2 test performance; and

3 (d) may supervise and teach within a clinical
4 laboratory setting.

5 (5) "Clinical laboratory specialist" means a person
6 who:

7 (a) performs laboratory testing in a specialized
8 testing area, such as microbiology, chemistry, immunology,
9 or hematology, according to approved protocols requiring the
10 exercise of independent judgment and responsibility;

11 (b) maintains equipment and records;

12 (c) performs ~~LOW---AND---MEDIUM---COMPLEXITY~~ quality
13 assurance activities related to test performance; and

14 (d) may supervise and teach within the specific area of
15 the clinical laboratory.

16 (6) "Clinical laboratory technician" means a person who
17 performs LOW AND MEDIUM COMPLEXITY laboratory tests pursuant
18 to established and approved protocols that require limited
19 exercise of independent judgment and that are performed
20 under the ~~personal-and-direct~~ supervision of a clinical
21 laboratory scientist, laboratory supervisor, or laboratory
22 director.

23 (7) "Clinical laboratory test" or "laboratory test"
24 means:

25 (a) a microbiological, serological, chemical,

hematological, radiobioassay, cytological, biophysical, immunological, cytogenetical, or other examination that is performed on material derived from the human body; or

(b) any other test or procedure conducted by a laboratory or facility that provides information for the assessment of a medical condition or for the diagnosis, prevention, or treatment of a disease.

(8) "Department" means the department of commerce provided for in 2-15-1801.

(9) "License" means the clinical laboratory science license issued under [sections 1 through 5 and 7 through 13].

(10) "Practice of clinical laboratory science" means the performance and interpretation of microbiological, serological, chemical, hematological, radiobioassay, cytological, biophysical, immunological, cytogenetical, or other examination on material that is derived from the human body and that provides information for the assessment of a medical condition or for the diagnosis, prevention, or treatment of a disease.

NEW SECTION. Section 4. License required. A person may not ENGAGE IN THE practice OF clinical laboratory science or hold out to the public that the person is a clinical laboratory science practitioner in this state unless the person is licensed pursuant to [sections 1 through 5 and 7

through 13].

NEW SECTION. Section 5. Exemptions. (1) [Sections 1 through 5 and 7 through 13] do not limit or regulate the practice of licensed physicians, including but not limited to pathologists.

(2) [Sections 1 through 5 and 7 through 13] do not apply to:

(a) any other profession licensed under Title 37 to the extent that the applicable scope of that practice, AS DEFINED BY STATUTE, RULES OF THE BOARD OR AGENCY GOVERNING THE OTHER PROFESSION, OR BOTH THE STATUTE AND RULES, authorizes the performance of a clinical laboratory test;

(b) clinical laboratory science practitioners employed by the United States or by any bureau, division, or agency of the United States, while in the discharge of the employee's official duties;

(c) clinical laboratory science practitioners engaged in teaching or research, provided that the results of any examination performed are not used in health maintenance, diagnosis, or treatment of disease;

(d) students or trainees enrolled in a clinical laboratory science education or training program, provided that:

(i) these activities constitute a planned course in the program;

(ii) the persons are designated by a title, such as intern, trainee, or student; and

(iii) the persons work directly under an individual licensed by this state to practice clinical laboratory science; or

(e) any person performing only waived tests as provided for in the federal clinical laboratory regulations set forth in 42 CFR part 493.

NEW SECTION. Section 6. Board -- composition -- allocation -- quasi-judicial -- compensation. (1) There is a board of clinical laboratory science practitioners.

(2) The board is composed of five members who have been residents of this state for at least 2 years prior to appointment and who are actively engaged in their respective practices.

(3) Members are appointed by the governor, with consent of the senate. The members are:

(a) one physician who is qualified to direct a high complexity laboratory as provided for in the federal clinical laboratory regulations set forth in 42 CFR part 493;

(b) three clinical laboratory science practitioners who, except for the initial appointments, hold active licenses as clinical laboratory science practitioners in Montana; and

(c) one public member who is not associated with or financially interested in the practice of clinical laboratory science.

(4) Following the initial appointments of members to the board, all members shall serve 4-year terms. The terms of the initial appointments must be staggered, with three members serving a 4-year term and two members serving a 2-year term. A member may not serve more than two consecutive terms.

(5) Whenever a vacancy occurs on the board during a term of office, the governor shall appoint a successor with similar qualifications for the remainder of the unexpired term.

(6) The board is allocated to the department for administrative purposes only, as provided in 2-15-121.

(7) The board is designated a quasi-judicial board for the purposes of 2-15-124, except that a member of the board need not be an attorney licensed to practice law in this state.

(8) Members of the board are entitled to compensation and travel expenses as provided by law.

NEW SECTION. Section 7. Powers and duties of the board -- rulemaking authority. (1) The board shall:

(a) meet at least once annually, and at other times as agreed upon, to elect officers and to perform the duties

1 described in this section; and

2 (b) administer oaths, take affidavits, summon
3 witnesses, and take testimony as to matters within the scope
4 of the board's duties.

5 (2) The board has the authority to administer and
6 enforce all the powers and duties granted statutorily or
7 adopted administratively.

8 (3) The board shall adopt rules to administer [sections
9 1 through 5 and 7 through 13]. The rules must include but
10 are not limited to:

11 (a) the development of a license application procedure
12 and acceptable certifications for each category of license;

13 (b) the establishment of license fees commensurate with
14 actual costs;

15 (c) the establishment of criteria for educational
16 requirements that, at a minimum, meet the standards set
17 forth in [section 8];

18 (d) the development of procedures for the issuance,
19 renewal, suspension, revocation, and reciprocity of
20 licenses;

21 (e) the adoption of disciplinary standards for
22 licensees;

23 (f) the establishment of investigatory and hearing
24 procedures for processing complaints received by the board;
25 and

1 (g) the establishment of continuing education
2 requirements of at least 14 hours annually for license
3 renewal for clinical laboratory practitioners; AND

4 (H) A REQUIREMENT THAT THE SUPERVISOR OF A CLINICAL
5 LABORATORY TECHNICIAN BE ACCESSIBLE AT ALL TIMES THAT
6 TESTING IS BEING PERFORMED BY THE TECHNICIAN IN ORDER TO
7 PROVIDE ONSITE, TELEPHONIC, OR ELECTRONIC CONSULTATION.

8 NEW SECTION. Section 8. Standards for licensure. (1)
9 The board shall issue a clinical laboratory scientist
10 license to an individual who meets the qualifications as
11 promulgated by rules of the board. At a minimum, a licensee
12 must be a person who:

13 (a) has graduated with a baccalaureate degree,
14 including a minimum number of hours in areas or disciplines
15 established by rule by the board; and

16 (b) has passed a certifying examination approved by the
17 board.

18 (2) The board shall issue a clinical laboratory
19 specialist license to an individual who has graduated with a
20 baccalaureate degree as described in subsection (1) and has
21 passed a certifying examination covering those fields in
22 which the applicant is eligible and approved by the board.
23 The license must be issued as a clinical laboratory
24 specialist license and must state the designation of the
25 area of specialty.

(3) The board shall issue a clinical laboratory technician license to an individual who meets the qualifications promulgated by the board, including the following minimum qualifications:

(a) completion of an associate degree or 60 semester hours in a science-related discipline;

(b) completion of other equivalent formal education as approved by the board; and

(c) passing a certifying examination approved by the board.

NEW SECTION. Section 9. Waiver of requirements -- temporary license -- reciprocity. (1) Upon payment of a license fee, the board may issue a license to a person practicing ENGAGED IN THE PRACTICE OF clinical laboratory science on [the effective date of this act] if the applicant can provide documentation, verified by oath, of at least 1 year of full-time experience in clinical laboratory science in Montana within the last 3 years. Application for licensure under this provision must be completed within 1 year of [the effective date of this act].

(2) (a) Upon payment of a license fee, the board may issue a temporary license to a person who practiced ENGAGED IN THE PRACTICE OF clinical laboratory science in another state if that person can provide documentation, verified by oath, of at least 1 year of full-time experience in clinical

laboratory science within the last 3 years. A temporary license may not be valid for more than 15 months.

(b) A temporary licensee shall pass a board-approved certification examination within 15 months of receiving a temporary license.

(3) Upon payment of the license fee, the board may issue a license to practice clinical laboratory science to an applicant who is currently licensed to practice clinical laboratory science in another state, territory, or country if the qualifications for the other license are considered by the board to be equal to or exceed the requirements of [sections 1 through 5 and 7 through 13] and if the other state, territory, or country extends similar privileges to clinical laboratory science practitioners licensed under [sections 1 through 5 and 7 through 13].

NEW SECTION. Section 10. Licensure application procedures. (1) An applicant shall submit an application for a license to the board upon the forms prescribed and furnished by the board and shall pay an application fee set by the board.

(2) Upon receipt of the application and fee, the board shall issue a license for a clinical laboratory scientist, a clinical laboratory specialist, or a clinical laboratory technician to any person who meets the qualifications specified by the board as set forth in rules adopted by the

1 board pursuant to [sections 7 and 8].

2 (3) A license issued under [sections 1 through 5 and 7
3 through 13] must be renewed by May 1 of each year.

4 (4) Except for the assessment provided in 37-1-101(6),
5 money paid for application, license, and license renewal
6 fees must be deposited in the state special revenue fund for
7 use by the board.

8 NEW SECTION. Section 11. Disciplinary measures --
9 grounds -- fine. (1) The board, after notice and hearing,
10 may reprimand a licensee or deny, suspend, revoke, or refuse
11 to renew the license of a licensee who:

12 (a) uses alcohol or other drugs to the extent that job
13 performance is impaired;

14 (b) is guilty of immoral or unprofessional conduct as
15 defined by board rule;

16 (c) is guilty of gross negligence in the practice of
17 clinical laboratory science;

18 (d) has obtained or attempted to obtain a license by
19 fraud or material misrepresentation;

20 (e) is guilty of conduct detrimental to the best
21 interests of the public; or

22 (f) has violated a provision of [sections 1 through 5
23 and 7 through 13] or a rule adopted by the board.

24 (2) The board may impose an administrative fine of not
25 more than \$500 per incident for any violation that could

1 result in the suspension or revocation of a license. A fine
2 collected under this subsection must be deposited in the
3 state special revenue fund for use by the board.

4 NEW SECTION. Section 12. Violation -- penalties --
5 injunction -- manner of charging violation. (1) A person who
6 violates a provision of [sections 1 through 5 and 7 through
7 13] or a rule adopted pursuant to [sections 1 through 5 and
8 7 through 13] is guilty of a misdemeanor and is punishable
9 by a fine not to exceed \$500, by imprisonment in the county
10 jail for a term of not more than 6 months, or both.

11 (2) Except as provided in [section 5], the board may
12 maintain an action to enjoin a person from engaging in the
13 practice of clinical laboratory science until a license to
14 practice is obtained. A person who has been enjoined and who
15 violates the injunction is punishable for contempt of court.
16 The injunction does not relieve the person practicing
17 clinical laboratory science without a license from criminal
18 prosecution. The remedy by injunction is in addition to
19 remedies provided for criminal prosecution of the offender.

20 (3) When charging a person in a complaint for
21 injunction or in an affidavit, information, or indictment
22 with a violation of law by practicing clinical laboratory
23 science without a license, it is sufficient to charge that
24 the person did, on a certain day and in a certain county,
25 engage in the practice of clinical laboratory science while

1 not having a license to do so, without specifying particular
2 facts concerning the violation.

3 NEW SECTION. Section 13. Due process procedures --
4 hearing -- temporary suspension. (1) The proceedings for the
5 revocation, suspension, or limiting of a license may be
6 initiated by the board or by any person, corporation,
7 association, or public officer by filing written charges
8 with the board. THE BOARD MAY IN ALL CASES CONDUCT AN
9 INVESTIGATION OF THE ALLEGATIONS IN THE WRITTEN CHARGES AND
10 DISMISS THOSE THAT IT DETERMINES ARE FRIVOLOUS OR WITHOUT
11 SUFFICIENT FACTUAL FOUNDATION.

12 (2) A license may not be revoked, suspended, or limited
13 without a hearing before the board after charges are filed.
14 If the board finds that there is a significant threat to the
15 public health, the board, upon notice to the licensee, may
16 temporarily suspend the license without a hearing for a
17 period not to exceed 30 days.

18 NEW SECTION. Section 14. Severability. If a part of
19 [this act] is invalid, all valid parts that are severable
20 from the invalid part remain in effect. If a part of [this
21 act] is invalid in one or more of its applications, the part
22 remains in effect in all valid applications that are
23 severable from the invalid applications.

24 NEW SECTION. Section 15. Codification instruction. (1)
25 [Section 6] is intended to be codified as an integral part

1 of Title 2, chapter 15, part 18, and the provisions of Title
2 2, chapter 15, part 18, apply to [section 6].

3 (2) [Sections 1 through 5 and 7 through 13] are
4 intended to be codified as an integral part of Title 37, and
5 the provisions of Title 37 apply to [sections 1 through 5
6 and 7 through 13].

7 NEW SECTION. Section 16. Effective date. [This act] is
8 [SECTIONS 6, 7, 14, 15, AND THIS SECTION] ARE effective on
9 passage and approval.

-End-

SENATE STANDING COMMITTEE REPORT

Page 1 of 1
March 11, 1993

MR. PRESIDENT:

We, your committee on Public Health, Welfare, and Safety having had under consideration House Bill No. 241 (first reading copy -- blue), respectfully report that House Bill No. 241 be amended as follows and as so amended be concurred in.

Signed: _____

Dorothy Eck
Senator Dorothy Eck, Chair

That such amendments read:

1. Page 4, line 17.

Following: "performs"

Strike: "LOW AND MEDIUM COMPLEXITY"

2. Page 7, line 5.

Strike: "or"

3. Page 7, line 8.

Following: "493"

Insert: ";

(f) a perfusionist or cardiopulmonary technician who, as part of a surgical team, performs laboratory tests in an operating room during surgery or during the perioperative and immediate postoperative period; or

(g) clinical laboratory science practitioners, employed by certified rural health clinics, who perform only those basic laboratory services required under federal regulations set forth in 42 CFR 491.9(c)(2)"

4. Page 11, lines 15 and 20.

Strike: "act"

Insert: "section"

5. Page 11, line 18.

Following: "years."

Insert: "The applicant's level of practice on [the effective date of this section] determines the type of license issued."

-END-

M- Amd. Coord.
JS Sec. of Senate

Sen. Eve Franklin
Senator Carrying Bill

SENATE

HB 241

551321SC.Sma

HOUSE BILL NO. 241

INTRODUCED BY STRIZICH, FRANKLIN, J. RICE, VOGEL, S. RICE,
RYAN, WISEMAN, CHRISTIAENS, HARPER, HANSEN, KADAS, WILSON,
MCCULLOCH, DRISCOLL, HARRINGTON, DOWELL, SMITH, ECK,
D. BROWN, COCCHIARELLA, TOOLE, SQUIRES, BARNHART, SIMPKINS,
MENAHAH, DOHERTY, WYATT, HARP, TUSS, KLAMPE, RANEY, BIRD,
RYE, SIMON, BOHLINGER, PAVLOVICH

A BILL FOR AN ACT ENTITLED: "AN ACT PROVIDING FOR THE
LICENSURE OF CLINICAL LABORATORY SCIENCE PRACTITIONERS; AND
PROVIDING AN-IMMEDIATE EFFECTIVE DATE DATES."

STATEMENT OF INTENT

A statement of intent is needed for this bill because it
establishes a board of clinical laboratory science
practitioners and gives the board rulemaking authority. The
board is required to adopt rules to establish licensing and
certification procedures, educational requirements for
licensure, and continuing education requirements. The board
is also required to establish rules for the renewal,
suspension, and revocation of licenses. The board shall
establish an investigation and hearing procedure for
handling complaints and shall set fees for administration of
the board's duties. The fees must be commensurate with the
costs of administration. THE BOARD SHALL ALSO ADOPT RULES

IMPLEMENTING THE REQUIREMENT THAT A SUPERVISOR OF A CLINICAL
LABORATORY TECHNICIAN MUST BE ACCESSIBLE AT ALL TIMES THAT
TESTING IS BEING PERFORMED IN ORDER TO PROVIDE ONSITE,
TELEPHONIC, OR ELECTRONIC CONSULTATION.

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

NEW SECTION. Section 1. Short title. [Sections 1
through 5 and 7 through 13] may be cited as the "Clinical
Laboratory Science Practice Act".

NEW SECTION. Section 2. Declaration of policy and
purpose. The legislature finds and declares that because the
practice of clinical laboratory science affects the public
health, safety, and welfare of Montana citizens, it is the
purpose of [sections 1 through 5 and 7 through 13] to
provide for the common good by regulating and ensuring the
qualified and professional practice of clinical laboratory
science. The legislature further declares that because
clinical laboratory science practitioners provide essential
services to other health care providers by furnishing vital
information that may be used in the assessment of human
health and in the diagnosis, prevention, and treatment of
disease or impairment, clinical laboratory tests must be
performed by individuals who meet specific standards of
competency.

NEW SECTION. Section 3. Definitions. As used in



[sections 1 through 5 and 7 through 13], the following definitions apply:

(1) "Board" means the board of clinical laboratory science practitioners established in [section 6].

(2) "Clinical laboratory" or "laboratory" means any facility or office in which clinical laboratory tests are performed.

(3) (a) "Clinical laboratory science practitioner" means a health care professional who performs clinical laboratory tests or who is engaged in management, education, consulting, or research in clinical laboratory science.

(b) The term includes laboratory directors, managers, supervisors, clinical laboratory scientists, clinical laboratory specialists, and clinical laboratory technicians who work in a laboratory.

(c) The term does not include:

(i) persons employed by a clinical laboratory to perform supportive functions not related to direct performance of laboratory tests; or

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(b) maintains equipment and records;

(c) performs quality assurance activities related to test performance; and

(d) may supervise and teach within a clinical laboratory setting.

(5) "Clinical laboratory specialist" means a person who:

(a) performs laboratory testing in a specialized testing area, such as microbiology, chemistry, immunology, or hematology, according to approved protocols requiring the exercise of independent judgment and responsibility;

(b) maintains equipment and records;

(c) performs ~~LOW-AND-MEDIUM-COMPLEXITY~~ quality assurance activities related to test performance; and

(d) may supervise and teach within the specific area of the clinical laboratory.

(6) "Clinical laboratory technician" means a person who performs ~~LOW-AND-MEDIUM-COMPLEXITY~~ laboratory tests pursuant to established and approved protocols that require limited exercise of independent judgment and that are performed under the ~~personal-and-direct~~ supervision of a clinical laboratory scientist, laboratory supervisor, or laboratory director.

(7) "Clinical laboratory test" or "laboratory test" means:

(a) a microbiological, serological, chemical,

1 hematological, radiobioassay, cytological, biophysical,
2 immunological, cytogenetical, or other examination that is
3 performed on material derived from the human body; or

4 (b) any other test or procedure conducted by a
5 laboratory or facility that provides information for the
6 assessment of a medical condition or for the diagnosis,
7 prevention, or treatment of a disease.

8 (8) "Department" means the department of commerce
9 provided for in 2-15-1801.

10 (9) "License" means the clinical laboratory science
11 license issued under [sections 1 through 5 and 7 through
12 13].

13 (10) "Practice of clinical laboratory science" means the
14 performance and interpretation of microbiological,
15 serological, chemical, hematological, radiobioassay,
16 cytological, biophysical, immunological, cytogenetical, or
17 other examination on material that is derived from the human
18 body and that provides information for the assessment of a
19 medical condition or for the diagnosis, prevention, or
20 treatment of a disease.

21 NEW SECTION. Section 4. License required. A person may
22 not ENGAGE IN THE practice OF clinical laboratory science or
23 hold out to the public that the person is a clinical
24 laboratory science practitioner in this state unless the
25 person is licensed pursuant to [sections 1 through 5 and 7

1 through 13].

2 NEW SECTION. Section 5. Exemptions. (1) [Sections 1
3 through 5 and 7 through 13] do not limit or regulate the
4 practice of licensed physicians, including but not limited
5 to pathologists.

6 (2) [Sections 1 through 5 and 7 through 13] do not
7 apply to:

8 (a) any other profession licensed under Title 37 to the
9 extent that the applicable scope of that practice, AS
10 DEFINED BY STATUTE, RULES OF THE BOARD OR AGENCY GOVERNING
11 THE OTHER PROFESSION, OR BOTH THE STATUTE AND RULES,
12 authorizes the performance of a clinical laboratory test;

13 (b) clinical laboratory science practitioners employed
14 by the United States or by any bureau, division, or agency
15 of the United States, while in the discharge of the
16 employee's official duties;

17 (c) clinical laboratory science practitioners engaged
18 in teaching or research, provided that the results of any
19 examination performed are not used in health maintenance,
20 diagnosis, or treatment of disease;

21 (d) students or trainees enrolled in a clinical
22 laboratory science education or training program, provided
23 that:

24 (i) these activities constitute a planned course in the
25 program;

(ii) the persons are designated by a title, such as intern, trainee, or student; and

(iii) the persons work directly under an individual licensed by this state to practice clinical laboratory science; or

(e) any person performing only waived tests as provided for in the federal clinical laboratory regulations set forth in 42 CFR part 493;

(F) A PERFUSIONIST OR CARDIOPULMONARY TECHNICIAN WHO, AS PART OF A SURGICAL TEAM, PERFORMS LABORATORY TESTS IN AN OPERATING ROOM DURING SURGERY OR DURING THE PERIOPERATIVE AND IMMEDIATE POSTOPERATIVE PERIOD; OR

(G) CLINICAL LABORATORY SCIENCE PRACTITIONERS, EMPLOYED BY CERTIFIED RURAL HEALTH CLINICS, WHO PERFORM ONLY THOSE BASIC LABORATORY SERVICES REQUIRED UNDER FEDERAL REGULATIONS SET FORTH IN 42 CFR 491.9(C)(2).

NEW SECTION. Section 6. Board -- composition -- allocation -- quasi-judicial -- compensation. (1) There is a board of clinical laboratory science practitioners.

(2) The board is composed of five members who have been residents of this state for at least 2 years prior to appointment and who are actively engaged in their respective practices.

(3) Members are appointed by the governor, with consent of the senate. The members are:

(a) one physician who is qualified to direct a high complexity laboratory as provided for in the federal clinical laboratory regulations set forth in 42 CFR part 493;

(b) three clinical laboratory science practitioners who, except for the initial appointments, hold active licenses as clinical laboratory science practitioners in Montana; and

(c) one public member who is not associated with or financially interested in the practice of clinical laboratory science.

(4) Following the initial appointments of members to the board, all members shall serve 4-year terms. The terms of the initial appointments must be staggered, with three members serving a 4-year term and two members serving a 2-year term. A member may not serve more than two consecutive terms.

(5) Whenever a vacancy occurs on the board during a term of office, the governor shall appoint a successor with similar qualifications for the remainder of the unexpired term.

(6) The board is allocated to the department for administrative purposes only, as provided in 2-15-121.

(7) The board is designated a quasi-judicial board for the purposes of 2-15-124, except that a member of the board

1 need not be an attorney licensed to practice law in this
2 state.

3 (8) Members of the board are entitled to compensation
4 and travel expenses as provided by law.

5 NEW SECTION. Section 7. Powers and duties of the board
6 -- rulemaking authority. (1) The board shall:

7 (a) meet at least once annually, and at other times as
8 agreed upon, to elect officers and to perform the duties
9 described in this section; and

10 (b) administer oaths, take affidavits, summon
11 witnesses, and take testimony as to matters within the scope
12 of the board's duties.

13 (2) The board has the authority to administer and
14 enforce all the powers and duties granted statutorily or
15 adopted administratively.

16 (3) The board shall adopt rules to administer [sections
17 1 through 5 and 7 through 13]. The rules must include but
18 are not limited to:

19 (a) the development of a license application procedure
20 and acceptable certifications for each category of license;

21 (b) the establishment of license fees commensurate with
22 actual costs;

23 (c) the establishment of criteria for educational
24 requirements that, at a minimum, meet the standards set
25 forth in [section 8];

1 (d) the development of procedures for the issuance,
2 renewal, suspension, revocation, and reciprocity of
3 licenses;

4 (e) the adoption of disciplinary standards for
5 licensees;

6 (f) the establishment of investigatory and hearing
7 procedures for processing complaints received by the board;
8 and

9 (g) the establishment of continuing education
10 requirements of at least 14 hours annually for license
11 renewal for clinical laboratory practitioners; AND

12 (H) A REQUIREMENT THAT THE SUPERVISOR OF A CLINICAL
13 LABORATORY TECHNICIAN BE ACCESSIBLE AT ALL TIMES THAT
14 TESTING IS BEING PERFORMED BY THE TECHNICIAN IN ORDER TO
15 PROVIDE ONSITE, TELEPHONIC, OR ELECTRONIC CONSULTATION.

16 NEW SECTION. Section 8. Standards for licensure. (1)
17 The board shall issue a clinical laboratory scientist
18 license to an individual who meets the qualifications as
19 promulgated by rules of the board. At a minimum, a licensee
20 must be a person who:

21 (a) has graduated with a baccalaureate degree,
22 including a minimum number of hours in areas or disciplines
23 established by rule by the board; and

24 (b) has passed a certifying examination approved by the
25 board.

(2) The board shall issue a clinical laboratory specialist license to an individual who has graduated with a baccalaureate degree as described in subsection (1) and has passed a certifying examination covering those fields in which the applicant is eligible and approved by the board. The license must be issued as a clinical laboratory specialist license and must state the designation of the area of specialty.

(3) The board shall issue a clinical laboratory technician license to an individual who meets the qualifications promulgated by the board, including the following minimum qualifications:

(a) completion of an associate degree or 60 semester hours in a science-related discipline;

(b) completion of other equivalent formal education as approved by the board; and

(c) passing a certifying examination approved by the board.

NEW SECTION. **Section 9. Waiver of requirements -- temporary license -- reciprocity.** (1) Upon payment of a license fee, the board may issue a license to a person practicing ENGAGED IN THE PRACTICE OF clinical laboratory science on [the effective date of this act SECTION] if the applicant can provide documentation, verified by oath, of at least 1 year of full-time experience in clinical laboratory

science in Montana within the last 3 years. THE APPLICANT'S LEVEL OF PRACTICE ON [THE EFFECTIVE DATE OF THIS SECTION] DETERMINES THE TYPE OF LICENSE ISSUED. Application for licensure under this provision must be completed within 1 year of [the effective date of this act SECTION].

(2) (a) Upon payment of a license fee, the board may issue a temporary license to a person who practiced ENGAGED IN THE PRACTICE OF clinical laboratory science in another state if that person can provide documentation, verified by oath, of at least 1 year of full-time experience in clinical laboratory science within the last 3 years. A temporary license may not be valid for more than 15 months.

(b) A temporary licensee shall pass a board-approved certification examination within 15 months of receiving a temporary license.

(3) Upon payment of the license fee, the board may issue a license to practice clinical laboratory science to an applicant who is currently licensed to practice clinical laboratory science in another state, territory, or country if the qualifications for the other license are considered by the board to be equal to or exceed the requirements of [sections 1 through 5 and 7 through 13] and if the other state, territory, or country extends similar privileges to clinical laboratory science practitioners licensed under [sections 1 through 5 and 7 through 13].

1 **NEW SECTION. Section 10. Licensure application**
 2 **procedures.** (1) An applicant shall submit an application for
 3 a license to the board upon the forms prescribed and
 4 furnished by the board and shall pay an application fee set
 5 by the board.

6 (2) Upon receipt of the application and fee, the board
 7 shall issue a license for a clinical laboratory scientist, a
 8 clinical laboratory specialist, or a clinical laboratory
 9 technician to any person who meets the qualifications
 10 specified by the board as set forth in rules adopted by the
 11 board pursuant to [sections 7 and 8].

12 (3) A license issued under [sections 1 through 5 and 7
 13 through 13] must be renewed by May 1 of each year.

14 (4) Except for the assessment provided in 37-1-101(6),
 15 money paid for application, license, and license renewal
 16 fees must be deposited in the state special revenue fund for
 17 use by the board.

18 **NEW SECTION. Section 11. Disciplinary measures --**
 19 **grounds -- fine.** (1) The board, after notice and hearing,
 20 may reprimand a licensee or deny, suspend, revoke, or refuse
 21 to renew the license of a licensee who:

22 (a) uses alcohol or other drugs to the extent that job
 23 performance is impaired;

24 (b) is guilty of immoral or unprofessional conduct as
 25 defined by board rule;

1 (c) is guilty of gross negligence in the practice of
 2 clinical laboratory science;

3 (d) has obtained or attempted to obtain a license by
 4 fraud or material misrepresentation;

5 (e) is guilty of conduct detrimental to the best
 6 interests of the public; or

7 (f) has violated a provision of [sections 1 through 5
 8 and 7 through 13] or a rule adopted by the board.

9 (2) The board may impose an administrative fine of not
 10 more than \$500 per incident for any violation that could
 11 result in the suspension or revocation of a license. A fine
 12 collected under this subsection must be deposited in the
 13 state special revenue fund for use by the board.

14 **NEW SECTION. Section 12. Violation -- penalties --**
 15 **injunction -- manner of charging violation.** (1) A person who
 16 violates a provision of [sections 1 through 5 and 7 through
 17 13] or a rule adopted pursuant to [sections 1 through 5 and
 18 7 through 13] is guilty of a misdemeanor and is punishable
 19 by a fine not to exceed \$500, by imprisonment in the county
 20 jail for a term of not more than 6 months, or both.

21 (2) Except as provided in [section 5], the board may
 22 maintain an action to enjoin a person from engaging in the
 23 practice of clinical laboratory science until a license to
 24 practice is obtained. A person who has been enjoined and who
 25 violates the injunction is punishable for contempt of court.

1 The injunction does not relieve the person practicing
2 clinical laboratory science without a license from criminal
3 prosecution. The remedy by injunction is in addition to
4 remedies provided for criminal prosecution of the offender.

5 (3) When charging a person in a complaint for
6 injunction or in an affidavit, information, or indictment
7 with a violation of law by practicing clinical laboratory
8 science without a license, it is sufficient to charge that
9 the person did, on a certain day and in a certain county,
10 engage in the practice of clinical laboratory science while
11 not having a license to do so, without specifying particular
12 facts concerning the violation.

13 NEW SECTION. Section 13. Due process procedures --
14 hearing -- temporary suspension. (1) The proceedings for the
15 revocation, suspension, or limiting of a license may be
16 initiated by the board or by any person, corporation,
17 association, or public officer by filing written charges
18 with the board. THE BOARD MAY IN ALL CASES CONDUCT AN
19 INVESTIGATION OF THE ALLEGATIONS IN THE WRITTEN CHARGES AND
20 DISMISS THOSE THAT IT DETERMINES ARE FRIVOLOUS OR WITHOUT
21 SUFFICIENT FACTUAL FOUNDATION.

22 (2) A license may not be revoked, suspended, or limited
23 without a hearing before the board after charges are filed.
24 If the board finds that there is a significant threat to the
25 public health, the board, upon notice to the licensee, may

1 temporarily suspend the license without a hearing for a
2 period not to exceed 30 days.

3 NEW SECTION. Section 14. Severability. If a part of
4 [this act] is invalid, all valid parts that are severable
5 from the invalid part remain in effect. If a part of [this
6 act] is invalid in one or more of its applications, the part
7 remains in effect in all valid applications that are
8 severable from the invalid applications.

9 NEW SECTION. Section 15. Codification instruction. (1)
10 [Section 6] is intended to be codified as an integral part
11 of Title 2, chapter 15, part 18, and the provisions of Title
12 2, chapter 15, part 18, apply to [section 6].

13 (2) [Sections 1 through 5 and 7 through 13] are
14 intended to be codified as an integral part of Title 37, and
15 the provisions of Title 37 apply to [sections 1 through 5
16 and 7 through 13].

17 NEW SECTION. Section 16. Effective date. ~~[[This act]]~~ is
18 ~~[SECTIONS 6, 7, 14, 15, AND THIS SECTION]~~ ARE effective on
19 passage and approval.

-End-