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38 39 Second Regular Session - 2016

IN THE HOUSE OF REPRESENTATIVES

HOUSE BILL NO. 453

BY HEALTH AND WELFARE COMMITTEE

AN ACT 1 RELATING TO LICENSURE OF MEDICAL LABORATORY SCIENCE PRACTITIONERS; AMEND-2 ING TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW CHAPTER 58, TITLE 54, 3 IDAHO CODE, TO PROVIDE A SHORT TITLE, TO PROVIDE LEGISLATIVE INTENT, 4 5 TO DEFINE TERMS, TO REQUIRE LICENSURE, TO PROVIDE QUALIFICATIONS FOR LICENSURE OF A MEDICAL LABORATORY SCIENTIST OR TECHNOLOGIST, TO PRO-6 VIDE QUALIFICATIONS FOR LICENSURE OF A MEDICAL LABORATORY TECHNICIAN, 7 TO PROVIDE QUALIFICATIONS FOR LICENSURE OF A CATEGORICAL MEDICAL LAB-8 ORATORY SCIENTIST, TO PROVIDE EXEMPTIONS, TO PROVIDE AUTHORITY FOR 9 10 ENDORSEMENT LICENSURE, TO PROVIDE FOR RENEWAL OF LICENSURE, TO ESTAB-LISH FEES, TO PROVIDE FOR SUSPENSION AND REVOCATION OF LICENSURE AND 11 REFUSAL TO RENEW, TO PROVIDE APPLICATION OF DUE PROCESS PROCEDURES, TO 12 ESTABLISH THE MEDICAL LABORATORY BOARD AND TO PROVIDE FOR APPOINTMENT, 13 TO PROVIDE POWERS AND DUTIES OF THE BOARD, TO PROVIDE FOR EXPENSES AND 14 15 DISPOSITION OF RECEIPTS, TO AUTHORIZE ADOPTION OF RULES, TO SPECIFY APPLICATION PROCEDURES AND TO PROHIBIT MISREPRESENTATION. 16

Be It Enacted by the Legislature of the State of Idaho:

SECTION 1. That Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a <u>NEW CHAPTER</u>, to be known and designated as Chapter 58, Title 54, Idaho Code, and to read as follows:

CHAPTER 58 MEDICAL LABORATORY SCIENCE PRACTICE ACT

54-5801. SHORT TITLE. The provisions of this chapter shall be known and may be cited as the "Medical Laboratory Science Practice Act."

54-5802. LEGISLATIVE INTENT. It is hereby declared to be a policy of this state that the practice of medical laboratory science by health care professionals affects the public health, safety and welfare and is subject to control and regulation in the public interest. It is further declared that medical laboratories and medical laboratory science practitioners provide essential services by furnishing vital information that may be used in the diagnosis, prevention and treatment of disease or impairment, and the assessment of the health of humans. The purpose of this chapter is to provide for the better protection of public health by providing minimum qualifications for medical laboratory science professionals and by ensuring that medical laboratory tests are performed with the highest degree of professional competency by those engaged in providing such services in this state. It is the purpose of the provisions of this chapter to provide for the licensure and regulation of persons performing medical laboratory procedures for the public.

54-5803. DEFINITIONS. As used in this chapter:

- (1) "Accredited medical laboratory program" means a program, as provided in rule, that provides appropriate instruction and experience in medical laboratory science that has been accredited by one (1) of the accrediting agencies recognized by the United States department of education.
- (2) "Board" means the medical laboratory board created in section 54-5814, Idaho Code.
- (3) "Categorical medical laboratory scientist" means an individual eligible under the provisions of this chapter who is qualified to perform medical laboratory tests only in a specialized testing field, such as microbiology, chemistry, immunology, hematology, immunohematology or future categories according to approved protocols, including those that require the exercise of independent judgment.
- (4) "Inactive license" means a license issued pursuant to section 54-5810, Idaho Code, for a person who does not engage in any practice defined by this chapter.
- (5) "Medical laboratory" or "laboratory" means any facility in which medical laboratory tests are performed.
- (6) "Medical laboratory science" means the practice by an individual who manages, supervises, educates, consults, researches or performs medical laboratory testing or technical procedures in a medical laboratory. "Medical laboratory science" does not include an activity that constitutes the practice of medicine.
- (7) "Medical laboratory scientist or technologist" means an individual eligible under the provisions of this chapter to perform any medical laboratory test including those that require the exercise of independent judgment. In addition, the individual may be responsible for the establishment and implementation of protocols, quality assessment, method development and selection, equipment selection and maintenance, and all activities related to the pre-analytic, analytic and post-analytic phases of testing. The medical laboratory scientist or technologist may also direct, supervise, consult, educate or perform research functions.
- (8) "Medical laboratory technician" means an individual eligible under the provisions of this chapter who is qualified to perform medical laboratory tests pursuant to established and approved protocols that require limited exercise of independent judgment and that are performed with oversight from a medical laboratory scientist or technologist, laboratory supervisor or laboratory director.
- (9) "Medical laboratory test" or "laboratory test" means a microbiological, serological, chemical, biological, hematological, immunological, immunohematological, radiobioassay, biophysical or any other test or procedure performed on material derived from or existing in a human body that provides information for the diagnosis, prevention or monitoring of a disease or impairment or assessment of a medical condition. Medical laboratory test encompasses the pre-analytic, analytic and post-analytic phases of testing.
- (10) "Point-of-care testing" means those analytical patient testing activities provided within an institution but performed outside the physical facilities of the central medical laboratory. The primary criterion of point-of-care testing is that it does not require permanent dedicated space. Examples include analytical instruments that are temporarily brought to a

patient care location. Point-of-care testing must be under the direction, authority, jurisdiction and responsibility of a person licensed under this chapter.

- (11) "Temporary license" means a license issued to an applicant eligible to sit for and registered to take the certification examination within six (6) months of issuance of the temporary license or who has taken the examination and is awaiting the results or who meets the educational requirements for the license and is seeking to qualify for the certification examination by completing the medical laboratory experience required.
- (12) "Trainee" or "student" means an individual who has not fulfilled the educational requirements to take an approved, nationally recognized certification examination or who needs to obtain full-time comprehensive experience under supervision.
- (13) "Waived test" means a simple laboratory examination or procedure that, under a federal interpretation of the clinical laboratory improvement amendments of 1988, employs a simple and accurate methodology that renders the likelihood of erroneous results negligible or poses no reasonable risk of harm to the patient if performed incorrectly.
- 54-5804. LICENSE REQUIRED. (1) On and after July 1, 2017, a license shall be required to engage in the practice of medical laboratory science. No person shall perform medical laboratory tests, or hold himself out as or use in connection with his name or place of business the title of medical laboratory scientist or technologist, medical laboratory technician or categorical medical laboratory scientist in this state unless the person possesses a valid license issued under the provisions of this chapter or is exempt from the requirements of this chapter.
- (2) Until July 1, 2018, the board may issue a license to a person engaged in the practice of medical laboratory science on the effective date of this chapter if the applicant can provide documentation, verified by oath, of the equivalent of at least three (3) years of full-time experience in medical laboratory science in Idaho within the last five (5) years. The applicant's level of practice on the effective date of this chapter determines the type of license issued. Application for licensure under this provision must be submitted within one (1) year of the effective date of this chapter.
- 54-5805. QUALIFICATIONS FOR LICENSURE -- MEDICAL LABORATORY SCIENTIST OR TECHNOLOGIST. (1) A person performing laboratory procedures as a medical laboratory scientist or technologist and who meets the requirements for licensure under the provisions of this section and who is not licensed pursuant to section 54-5804, Idaho Code, or exempt under section 54-5808, Idaho Code, shall apply to the board for the issuance of a license. The application shall be on a form provided by the board.
- (2) The board may issue a license to the applicant without restriction to any area of practice specialty if the applicant successfully passes a nationally recognized certification examination as provided in rule and authorized by the board and provides proof to the board that he meets at least one (1) of the following criteria:
 - (a) The applicant has earned a baccalaureate degree from an accredited college or university including, or in addition to, successful comple-

tion of a medical laboratory scientist or technologist program accredited by an agency recognized by the United States department of education and certification by a board-approved, nationally recognized certifying agency as provided in rule;

- (b) The applicant has earned a baccalaureate degree from an accredited college or university, including a minimum of sixteen (16) semester hours or twenty-four (24) quarter hours of biology coursework acceptable toward a major in biological science and pertinent to the medical laboratory sciences, sixteen (16) semester hours or twenty-four (24) quarter hours of chemistry coursework acceptable toward a major in chemistry and one (1) course in college-level mathematics, certification by a board-approved, nationally recognized certification agency, plus two (2) years of full-time medical laboratory experience within the past four (4) years that has included a minimum of four (4) months in each of the four (4) major disciplines of laboratory practice, which are medical chemistry, hematology, immunohematology and microbiology; and
 - (i) Holds certification as a medical laboratory technician; or
 - (ii) Has successfully completed a medical laboratory technician program accredited by an agency recognized by the United States department of education; or
- (c) The applicant has earned a baccalaureate degree from an accredited college or university, including a minimum of sixteen (16) semester hours or twenty-four (24) quarter hours of biology coursework acceptable toward a major in biological science and pertinent to the medical laboratory sciences, sixteen (16) semester hours or twenty-four (24) quarter hours of chemistry coursework acceptable toward a major in chemistry and one (1) course in college-level mathematics, certification by a board-approved, nationally recognized certification agency, plus five (5) years of full-time medical laboratory experience within the past ten (10) years that has included a minimum of four (4) months in each of the four (4) major disciplines of laboratory practice, which are medical chemistry, hematology, immunohematology and microbiology.
- 54-5806. QUALIFICATIONS FOR LICENSURE -- MEDICAL LABORATORY TECHNICIAN. (1) A person performing laboratory procedures as a medical laboratory technician and who meets the requirements for licensure under the provisions of this section and who is not licensed pursuant to section 54-5804, Idaho Code, or exempt under section 54-5808, Idaho Code, shall apply to the board for the issuance of a license. The application shall be on a form provided by the board.
- (2) The board may issue a license to the applicant without restriction to any area of practice specialty if the applicant successfully passes a nationally recognized certification examination authorized by the board and provides proof to the board that he meets at least one (1) of the following criteria:
 - (a) The applicant has earned an associate degree from an accredited college or university, including successful completion of a medical laboratory science technician program accredited by an agency approved by the United States department of education, and certification by a board-approved, nationally recognized certifying agency;

- (b) The applicant has earned an associate degree or successfully completed at least sixty (60) semester hours or ninety (90) quarter hours from an accredited college or university, including a minimum of six (6) semester hours or nine (9) quarter hours of biology coursework acceptable toward a major in biological science and pertinent to the medical laboratory sciences, six (6) semester hours or nine (9) quarter hours of chemistry coursework acceptable toward a major in chemistry and one (1) course of college-level mathematics, plus successful completion of a medical laboratory science technician program accredited by an organization recognized by the United States department of education, including successful completion of an advanced military laboratory specialist program, and certification by a board-approved, nationally recognized certifying agency; or
- (c) The applicant has earned an associate degree or successfully completed at least sixty (60) semester hours or ninety (90) quarter hours from an accredited college or university, including a minimum of six (6) semester hours or nine (9) quarter hours of biology coursework acceptable toward a major in biological sciences and pertinent to the medical laboratory sciences, six (6) semester hours or nine (9) quarter hours of chemistry coursework acceptable toward a major in chemistry and one (1) course of college-level mathematics, certification by a board-approved, nationally recognized certifying agency, plus three (3) years of full-time medical laboratory experience within the past six (6) years that has included a minimum of four (4) months in each of the four (4) major disciplines of laboratory practice, which are medical chemistry, hematology, immunohematology and microbiology.
- 54-5807. QUALIFICATIONS FOR LICENSURE -- CATEGORICAL MEDICAL LABORATORY SCIENTIST. (1) A person practicing or performing laboratory procedures as a categorical medical laboratory scientist and who meets the requirements for licensure under the provisions of this section and who is not licensed pursuant to section 54-5804, Idaho Code, or exempt under section 54-5808, Idaho Code, shall apply to the board for the issuance of a license. The application shall be on a form provided by the board.
- (2) The board may issue a license to the applicant with restriction to a specified category of practice specialty, if the applicant successfully passes a nationally recognized certification examination authorized by the board and has earned a baccalaureate degree in the appropriate medical laboratory specialty from an accredited college or university, certification by a board-approved, nationally recognized certifying organization issuing certification in that category of expertise, plus one (1) year of experience in the last five (5) years in the appropriate specialty.
- 54-5808. EXEMPTIONS. Nothing in this chapter shall be construed as preventing or restricting the practice or performance of medical laboratory science requiring licensure pursuant to this chapter:
- (1) Of any person licensed in this state under any other chapter who, as part of the person's licensed professional practice and within the scope and discipline of the person's profession, is permitted to practice medical laboratory science;

(2) Of any medical laboratory science practitioners employed by the United States government or any bureau, division or agency thereof, if such person practices or provides medical laboratory services solely under the direction and control of the organization by which such person is employed;

- (3) Of medical laboratory science practitioners engaged in teaching or research, provided that the results of any such examination performed are not used in health maintenance, diagnosis or treatment of disease;
- (4) Of students enrolled in supervised medical laboratory science education courses of study, provided that such activities constitute a part of an accredited, planned course of education, or the equivalent as determined by the board, that the persons are designated by title such as intern, trainee, or student, and the persons work directly under the supervision of an individual licensed by this state to practice medical laboratory science;
- (5) Of any person solely performing waived tests under the clinical laboratory improvement amendments of 1988, P.L. 100-578; or
- (6) Of personnel performing point-of-care testing, provided that the acute care facility complies with the following requirements:
 - (a) Within the point-of-care testing laboratory, a licensed medical laboratory scientist or technologist is responsible for:
 - (i) Designing and providing or supervising the training programs for the point-of-care testing personnel;
 - (ii) Supervising and monitoring the quality assurance and quality control activities of the testing site;
 - (iii) Assisting in the selection of technology;
 - (iv) Reviewing the results of proficiency testing and recommending corrective action, if necessary; and
 - (v) Monitoring the continued competency of the testing personnel; and
 - (b) Processes are in place and are acceptable to the board that ensure and document the continued competency of the point-of-care testing personnel.

Failure to comply with the requirements of this section shall subject the point-of-care testing personnel to loss of the exemption.

54-5809. ENDORSEMENT LICENSURE. An applicant who satisfies the board that he is licensed or registered under the laws of another state, territory or jurisdiction of the United States, which in the opinion of the board imposes substantially equivalent licensing requirements as this chapter, may, upon the payment of the required fee and the approval of the application, be licensed by endorsement pursuant to this chapter.

- 54-5810. RENEWAL AND REINSTATEMENT OF LICENSE -- INACTIVE LICENSE. (1) Licenses issued under this chapter shall be valid for one (1) year.
- (2) All licenses issued under the provisions of this chapter shall be subject to annual renewal. License renewal and reinstatement shall be in accordance with section 67-2614, Idaho Code.
- (3) The board may issue inactive licenses pursuant to rules adopted by the board that may specify the terms and procedures necessary to maintain an

inactive license. The holder of an inactive license shall not engage in any
practice defined by this chapter.

54-5811. FEES. (1) The board shall establish the following fees relating to licensing in amounts sufficient to defray all costs necessary for the administration of this chapter:

- (a) Application fee for a license or a temporary license of twenty-five dollars (\$25.00);
- (b) Initial licensure fee, not to exceed one hundred dollars (\$100);
- (c) Renewal fee, not to exceed one hundred dollars (\$100);

- (d) Reinstatement fees in accordance with section 67-2614, Idaho Code;
- (e) Temporary license fee, not to exceed fifty dollars (\$50.00), which may be applied to the initial licensure fee if the practitioner successfully passes the nationally recognized certification examination; and
- (f) Inactive license fee, not to exceed twenty-five dollars (\$25.00).
- (2) All fees are nonrefundable, except that if a license fee is tendered but the board does not issue a license, the respective license fee shall be returned.
- 54-5812. SUSPENSION AND REVOCATION OF LICENSE -- REFUSAL TO RENEW. The board may refuse to issue or renew, may revoke, or may suspend a license, may place a licensee on probation, and may take such other disciplinary action as the board may deem appropriate, including the imposition of a civil penalty not to exceed one thousand dollars (\$1,000) for conduct that may result from, but not necessarily be limited to:
- (1) Having been convicted of a felony or being convicted of any crime that has a bearing on any practice pursuant to this chapter in the courts of this state or any other state, territory or country. Conviction, as used in this subsection, shall include a finding or verdict of guilt, an admission of guilt or a plea of nolo contendere or its equivalent. The record of conviction, or a certified copy thereof, certified by the clerk of the court or by the judge in whose court the conviction occurred, shall be conclusive evidence of such conviction;
- (2) Making any material misrepresentation for the purpose of obtaining licensure or violating any provision of this chapter;
- (3) Failing to adhere to the recognized standards of ethics of the medical laboratory science profession as adopted by board rule;
- (4) Engaging in dishonorable, unethical or unprofessional conduct as defined by rule;
- (5) Excessive use or abuse of alcohol and the inability to practice laboratory science;
- (6) Directly or indirectly contracting to perform medical laboratory tests in a manner that offers or implies an offer of rebate, fee-splitting inducements or arrangements, or other remuneration;
- (7) Aiding or assisting another person in violating any provision of this chapter or any rule adopted hereunder;
- (8) Practicing or offering to practice beyond the scope of medical laboratory science practice, as defined in this chapter, or failing to meet the standard of a medical laboratory scientist provided by other qualified medi-

cal laboratory scientists and medical laboratory technicians in the same or similar communities;

- (9) Engaging in the performance of substandard care, as defined by rule, by a medical laboratory practitioner due to an intentional, negligent or reckless act or failure to act;
- (10) Having had a license revoked or suspended, other disciplinary action taken or an application for licensure refused, revoked or suspended by the proper authorities of another state, territory or country, or omitting such information from any application to the board, or failure to divulge such information when requested by the board;
- (11) Interfering with an investigation or disciplinary proceeding by willful misrepresentation of facts or by use of threats or harassment against any patient or witness to prevent such person from providing evidence in a disciplinary proceeding, investigation or other legal action; or
 - (12) Failing to comply with an order of the board.

- 54-5813. DUE PROCESS PROCEDURES. The proceedings for the revocation, suspension or limiting of any license may be initiated by any person, corporation, association or public officer, or by the board, by the filing of written charges with the board. The procedures for notification and hearing on such charges, unless dismissed by the board as unfounded or trivial, shall be conducted as provided in chapter 52, title 67, Idaho Code.
- MEDICAL LABORATORY BOARD. (1) There is hereby created a med-54-5814. ical laboratory board within the bureau of occupational licenses. The board shall consist of five (5) members appointed by the governor from a list submitted by organizations of medical laboratory practitioners, or the governor may consider recommendations for appointment to the board from any medical laboratory technology association or any individual residing in this state, four (4) of whom shall be medical laboratory practitioners licensed pursuant to the provisions of this chapter as of July 1, 2017, one (1) public member who is not associated with or financially interested in the practice of medical laboratory science, and all of whom shall be residents of Idaho at the time of their appointment and for their term of service. The persons appointed to the board who are required to be licensed under this chapter shall have been engaged in rendering medical laboratory services to the public, or in teaching, or in research in medical laboratory science for at least two (2) of the five (5) years immediately preceding their appointments.
- (2) The governor, within sixty (60) days following the effective date of this chapter, shall appoint one (1) board member for a term of one (1) year; two (2) board members for a term of two (2) years; and two (2) board members for a term of three (3) years. Appointments made thereafter shall be for three (3) year terms, but no person shall be appointed to serve more than two (2) consecutive terms. Terms shall begin on July 1 of each year or until successors are appointed.
- (3) Except for the initial appointments to the board, each medical laboratory scientist shall be currently licensed and in good standing to engage in medical science practice in this state. The initial medical laboratory scientist members of the board must meet the qualifications for licensure under this chapter.

(4) Whenever a vacancy shall occur on the board, the governor shall appoint a successor for the remainder of the unexpired term.

- (5) Each member of the board shall be compensated as provided in section 59-509(n), Idaho Code.
- (6) The governor may remove any member from the board for neglect of any duty required by law or for incompetency or unprofessional or dishonorable conduct.
- (7) The board shall meet at such times as required to conduct the business of the board and shall annually elect from its members a chairman, vice chairman and such other officers as it chooses. Three(3) members shall constitute a quorum, and the vote of a majority of members present at a meeting wherein a quorum is present shall determine the action of the board.
- 54-5815. BOARD POWERS AND DUTIES. (1) The board shall enforce the provisions of this chapter, evaluate the qualifications of the applicants for licensure, and may issue subpoenas, examine witnesses, and administer oaths, and may investigate practices that are alleged to violate the provisions of this chapter. The board shall review the applications of all applicants for licensure and make decisions concerning issuance of licenses, revocation of licenses, rules to be promulgated under this chapter, other disciplinary action and any other matters pursuant to the provisions of this chapter.
 - (2) The board shall establish standards for professional conduct.
- (3) The board shall establish, by rule, criteria for the continuing education of medical laboratory science practitioners as required for licensure renewal.
- (4) The board shall authorize, by written agreement, the bureau of occupational licenses to act as its agents in its interests as set out in the written agreement.
- 54-5816. DISPOSITION OF RECEIPTS -- EXPENSES. (1) All fees received under the provisions of this chapter shall be deposited in the state treasury to the credit of the occupational licenses account, and all costs and expenses incurred by the board under the provisions of this chapter shall be a charge against and paid from said account for such purposes, and the funds collected hereunder shall be immediately available for the administration of this chapter.
- (2) Money paid into the board account pursuant to this chapter is hereby appropriated to the board for expenditure in the manner prescribed herein to defray the expenses of the board in carrying out and enforcing the provisions of this chapter.
- 54-5817. RULES. The board shall promulgate and adopt rules necessary to carry out the provisions of this chapter, pursuant to chapter 52 title 67, Idaho Code.
- 54-5818. APPLICATION PROCEDURE. (1) Licensure applicants shall submit their application for licensure to the board upon the forms prescribed and furnished by the board and shall pay the designated fees.

(2) Upon receipt of application and payment of fees, the board may issue a license for a medical laboratory scientist or technologist, a medical laboratory technician, categorical medical laboratory scientist or an appropriate license to any person who meets the qualifications specified in this chapter and the rules promulgated hereunder.

- (3) The board may establish, by rule, procedure for issuance of temporary licenses to individuals otherwise qualified under this chapter to engage in medical laboratory science practice in this state for a limited time not to exceed twelve (12) months.
- 54-5819. MISREPRESENTATION. (1) The board may bring any action in district court for a temporary restraining order, preliminary injunction or permanent injunction against any person who violates the provisions of this chapter, or who falsely holds himself out as a medical laboratory scientist or technologist, medical laboratory technician or categorical medical laboratory scientist, or against any person who provides medical laboratory services in violation of this chapter.
- (2) It shall be unlawful and a misdemeanor for any person to engage in any of the following acts:
 - (a) To practice medical laboratory science or to represent himself to be a licensed medical laboratory scientist or technologist, medical laboratory technician or categorical medical laboratory scientist as defined in this chapter without having, at the time of so doing, a valid license issued under this chapter; or
 - (b) To use in connection with his name or place of business the title medical laboratory scientist or technologist, medical laboratory technician or categorical medical laboratory scientist or any words indicating or implying that the person holds a medical laboratory scientist license unless he is licensed in accordance with this chapter.