

SENATE
STATE OF MINNESOTA
EIGHTY-SEVENTH LEGISLATURE

S.F. No. 1426

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DATE	D-PG	OFFICIAL STATUS
05/16/2011	2059	Introduction and first reading Referred to Health and Human Services
03/14/2012	4380a	Comm report: To pass as amended and re-refer to State Government Innovation and Veterans
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A bill for an act
relating to health occupations; establishing licensure for medical laboratory
science professionals; creating the Board of Medical Laboratory Science;
establishing fees; proposing coding for new law as Minnesota Statutes, chapter
148F.
BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[148F.01] DEFINITIONS.**

Subdivision 1. **Applicability.** For purposes of this chapter, the following terms
have the meanings given them.

Subd. 2. **Accredited medical laboratory educational program.** "Accredited
medical laboratory educational program" means a program to provide instruction and
experience in medical laboratory science that has been accredited by an accrediting agency
recognized by the United States Department of Health and Human Services.

Subd. 3. **Categorical medical laboratory scientist.** "Categorical medical
laboratory scientist" means an individual eligible for licensure under this chapter who
performs the functions of a medical laboratory scientist in one or more of the following
areas of the laboratory depending upon the certification examinations passed: chemistry,
hematology, immunohematology, and microbiology.

Subd. 4. **CLIA.** "CLIA" means Clinical Laboratory Improvement Amendments of
1988 and includes Public Law 10-578 and Code of Federal Regulations, title 42, section
493. CLIA regulations provide a minimum foundation upon which personnel standards
for entry level technical personnel in this state are built. Qualifications and responsibilities
for laboratory director, technical supervisor, and technical consultant are as specified in
CLIA regulations. All medical laboratory personnel are under the supervision, control,
and responsibility of the laboratory director.

2.1 Subd. 5. **Commissioner.** "Commissioner" means the commissioner of health or the
2.2 commissioner's designee.

2.3 Subd. 6. **Cytotechnologist.** "Cytotechnologist" means an individual who
2.4 specializes in the cellular analysis of patient samples from all body sites, for the purpose
2.5 of evaluating, detecting, and identifying potential disease processes through the exercise
2.6 of independent technical judgment, under the supervision, control, and responsibility of
2.7 the laboratory director, and who:

2.8 (1) assists health care providers with the collection, detection, and identification
2.9 of normal and abnormal cells, infectious agents, and other noncellular material from
2.10 submitted specimens;

2.11 (2) performs a variety of medical laboratory tests that may include the use of
2.12 molecular techniques with approval and oversight of a medical director, to ascertain
2.13 information to help in classification of a specimen consistent with the scope of work
2.14 provided under the Clinical Laboratory Improvement Amendments of 1988;

2.15 (3) establishes and implements protocols, quality control, method selection,
2.16 equipment selection and maintenance, and activities related to the preanalytic, analytic,
2.17 and postanalytic phases of testing; and

2.18 (4) may direct, supervise, consult, and educate and perform research functions.

2.19 Subd. 7. **Histotechnician.** "Histotechnician" means an individual who, with the
2.20 approval, supervision, and control of a board-certified anatomic pathologist, may perform
2.21 the following functions:

2.22 (1) prepares tissue specimens for microscopic examination;

2.23 (2) monitors, performs, selects, develops, evaluates, correlates, and ensures accuracy
2.24 and validity of laboratory testing and procedures, including, but not limited to, techniques
2.25 in fixation, processing, embedding, microtomy, cryotomy, ultramicrotomy, and staining;

2.26 (3) prepares gross specimens as defined by and under the direction of a
2.27 board-certified anatomic pathologist;

2.28 (4) establishes and implements protocols, quality assurance, and quality control
2.29 related to the following procedures: histochemical, immunohistochemical, electron
2.30 microscopy, cytopreparation, in situ hybridization, enzyme histochemical, DNA
2.31 hydrolysis, laser capturing, molecular techniques, and research; and

2.32 (5) participates in method selection, development, equipment selection and
2.33 maintenance, and activities related to the preanalytical and analytical phases of tissue
2.34 preparation.

3.1 Subd. 8. **Histotechnologist.** "Histotechnologist" means an individual who, with
3.2 the approval, supervision, and control of a board-certified anatomic pathologist, may
3.3 perform the following functions:

3.4 (1) prepares tissue specimens for microscopic examination;

3.5 (2) monitors, performs, selects, develops, evaluates, correlates, and ensures accuracy
3.6 and validity of laboratory testing and procedures including, but not limited to, techniques
3.7 in fixation, processing, embedding, microtomy, cryotomy, ultramicrotomy, and staining;

3.8 (3) prepares gross specimens as defined by and under the direction of a
3.9 board-certified anatomic pathologist;

3.10 (4) establishes and implements protocols, quality assurance, and quality control
3.11 related to the following procedures: histochemical, immunohistochemical, electron
3.12 microscopy, cytopreparation, in situ hybridization, enzyme histochemical, DNA
3.13 hydrolysis, laser capturing, molecular techniques, and research;

3.14 (5) establishes and implements new protocols and procedures dealing directly in
3.15 quality assessment, method development, and equipment selection and maintenance and
3.16 all activities related to preanalytical and analytical phases of tissue preparation; and

3.17 (6) may direct, supervise, consult, educate, and perform research functions.

3.18 Subd. 9. **Independent medical judgment.** In the laboratory, "independent medical
3.19 judgment" is exercised only by a pathologist or other licensed physician in the diagnosis
3.20 and treatment decisions related to clinical laboratory tests.

3.21 Subd. 10. **Independent technical judgment.** "Independent technical judgment"
3.22 means the performance or conduct of clinical laboratory tests and assumption of
3.23 responsibility for determination of the validity of clinical laboratory test. The authorized
3.24 exercise of independent technical judgment shall not be deemed to include or permit the
3.25 exercise of independent medical judgment in the diagnosis or treatment of, or reporting of
3.26 clinical laboratory test results or their interpretation to patients, except as authorized by a
3.27 laboratory director and according to CLIA.

3.28 Subd. 11. **Medical laboratory or laboratory.** "Medical laboratory" or "laboratory"
3.29 means any facility or office in Minnesota in which medical laboratory tests are performed.

3.30 Subd. 12. **Medical laboratory scientist or generalist.** "Medical laboratory
3.31 scientist" or "generalist" means an individual eligible for licensure under this chapter who:

3.32 (1) performs medical laboratory tests, including tests that require the exercise of
3.33 independent technical judgment;

3.34 (2) establishes and implements protocols, quality assessment, method development
3.35 and selection, equipment selection and maintenance, and all activities related to the
3.36 preanalytic, analytic, and postanalytic phases of laboratory testing; and

(3) may direct, supervise, consult, educate, and perform research functions.

Subd. 13. Medical laboratory specialist. "Medical laboratory specialist" means an individual certified and eligible for licensure in one of the categories described in subdivisions 14, 15, and 16, to perform testing, including tests that require the exercise of independent technical judgment needed to establish and implement protocols, quality assessment, method development and selection, equipment selection and maintenance, and all activities related to the preanalytic, analytic, and postanalytic phases of laboratory testing, and who direct, supervise, consult, and educate in a specific specialized section of the laboratory.

Subd. 14. Medical laboratory specialist in cytogenetics. "Medical laboratory specialist in cytogenetics" means an individual eligible for licensure under this chapter to perform standard cytogenetic and molecular testing procedures used to evaluate possible genetic anomalies.

Subd. 15. Medical laboratory specialist in molecular biology/pathology. "Medical laboratory specialist in molecular biology/pathology" means an individual eligible for licensure under this chapter to perform all aspects of molecular analysis, including, but not limited to, recombinant DNA technology, polymerase chain reaction, and hybridization techniques.

Subd. 16. Medical laboratory specialist in histocompatibility. "Medical laboratory specialist in histocompatibility" means an individual eligible for licensure under this chapter to perform histocompatibility testing procedures, including, but not limited to, molecular and serological techniques.

Subd. 17. Medical laboratory technician. "Medical laboratory technician" means an individual eligible for licensure under this chapter who performs medical laboratory tests at all CLIA complexity levels according to established and approved protocols and requiring limited exercise of independent judgment.

Subd. 18. Medical laboratory test or laboratory test. "Medical laboratory test" or "laboratory test" means a microbiological, serological, chemical, biological, hematological, immunological, immunohematological, radiobioassay, cytological, histological preparation, molecular, 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. A medical laboratory test includes components of the preanalytic and postanalytic phases of testing, as well as the analytic phase, that occurs in the laboratory.

Subd. 19. Medical laboratory subspecialists. "Medical laboratory subspecialists" means an individual eligible for licensure under this chapter to perform the functions

of a medical laboratory scientist in a subspecialty or esoteric clinical laboratory that is not one of the general categorical areas of the laboratory. The subspecialty/esoteric laboratories may be disease or medical specialty-oriented or utilize advanced technology not routinely used in the clinical laboratory. These subspecialty/esoteric laboratories may be subspecialized areas within the hematology, chemistry, immunology, transfusion, medicine, genetics, or microbiology disciplines.

Subd. 20. **Nationally recognized certification agency.** "Nationally recognized certification agency" means an agency that provides certification examinations for medical laboratory professionals. As the agency defines new certification examinations, the commissioner and the advisory council will recognize these examinations.

Subd. 21. **Pathologist's assistant.** "Pathologist's assistant" means an individual specializing in prediagnostic surgical pathology and autopsy pathology who assists pathologists.

Subd. 22. **Phlebotomist.** "Phlebotomist" means an individual who is qualified to obtain blood samples for testing by means of venipuncture, capillary puncture, or access of venous access devices, to perform specimen processing and preparation of samples for testing, and to perform waived and point-of-care testing.

Subd. 23. **Point-of-care testing.** "Point-of-care testing" means analytical patient testing activities provided within a facility that do not require permanent dedicated space, including, but not limited to, analytic instruments that are temporarily brought to a patient care location. Point-of-care testing must be under the direction of an individual licensed under this chapter at the baccalaureate degree level or who qualifies as a laboratory director under federal CLIA regulations.

Subd. 24. **Trainee/student.** "Trainee/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.

Subd. 25. **Waived test.** "Waived test" means a laboratory examination or procedure as determined by the United States Food and Drug Administration that has an insignificant risk of an erroneous result, including those that:

(1) have been approved by the United States Food and Drug Administration for home use;

(2) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or

(3) pose no reasonable risk of harm to the patient if performed incorrectly.

Sec. 2. [148F.02] EXCEPTIONS.

This chapter does not apply to:

(1) the qualifications as established by federal CLIA for laboratory directors, technical supervisors, or technical consultants;

(2) other licensed or registered professionals performing functions within the professional's scope of practice;

(3) medical laboratory science professionals employed by the United States government, or any bureau, division, or agency, while performing duties within the scope of the professional's federal employment;

(4) medical laboratory science professionals engaged exclusively in basic science or investigative research, provided that the results of any examination performed are not used in health maintenance, diagnosis, or treatment of disease as described in federal CLIA regulations under Code of Federal Regulations, title 42, section 493;

(5) professionals engaged exclusively in assay development or management-related activities in the clinical laboratory, provided the results of any examination performed are not used in health maintenance, diagnosis, or treatment of disease as described in federal CLIA regulations;

(6) professionals engaged exclusively in the education of medical laboratory science professionals, provided that results of any examination performed are not used in health maintenance, diagnosis, or treatment of disease as described in federal CLIA regulations;

(7) professionals engaged exclusively in providing phlebotomy services;

(8) pathologist's assistants or individuals performing pathology assistant activities under supervision by pathologists;

(9) students or trainees enrolled in a medical laboratory science education program provided that:

(i) the activities performed by the student or trainee constitute a part of a planned course in the program;

(ii) the student or trainee is clearly designated as intern, trainee, or student; and

(iii) the student or trainee is working directly under an individual licensed under this chapter to practice medical laboratory science or by a professional who is exempt under this section;

(10) individuals who only perform waived tests or moderately complex point-of-care tests under the direction of a qualified CLIA laboratory director according to federal CLIA regulations; and

(11) individuals who perform moderately complex testing as defined by federal CLIA regulations provided that the laboratory complies with the following requirements:

(i) within the laboratory, a licensed medical laboratory scientist or individual who qualifies as a laboratory director under federal CLIA regulations is responsible for:

(A) designing, providing, and supervising the training programs for the testing personnel;

(B) supervising and monitoring the quality assurance and quality control activities of the testing site;

(C) assisting in the selection of technology;

(D) reviewing the results of proficiency testing and recommending corrective action, if necessary; and

(E) monitoring the continued laboratory testing competency of the testing personnel;

(ii) documented personnel evaluation processes are in place, which ensure and document the continued competency of the testing personnel; and

(iii) after July 1, 2012, the licensed medical laboratory scientist or individual who qualifies as a laboratory director under CLIA regulations must ensure that new employees have initial certification as a certified or registered medical assistant or certified office laboratory technician by the American Medical Technologists (AMT) or the American Association of Medical Assistants (AAMS) or other national certification agency recognized by the commissioner. Individuals employed as a medical assistant or office laboratory technician on July 1, 2012, are not required to be certified. Failure of a laboratory to comply with the requirements described in clause (11) subjects the individual to the requirements of this chapter and requires the individual to be licensed as required under this chapter.

This chapter does not apply to a declared emergency as defined in section 12.03 that reduces laboratory capacity or increases testing demands, or other loss of critical laboratory capacity. Practitioners who are not licensed in any state, but are certified by one of the agencies recognized in this chapter or deemed competent by the affected laboratory director, may practice as needed in the emergency situation.

Sec. 3. [148F.03] LICENSURE REQUIRED; TITLES USED, RESTRICTED, AND ALLOWED.

Subdivision 1. Unlicensed practice prohibited. Effective January 1, 2014, no individual shall perform a medical laboratory test unless the individual is licensed under this chapter as a medical laboratory scientist, categorical medical laboratory scientist, medical laboratory technician, medical laboratory specialist in cytogenetics, medical laboratory specialist in molecular biology/pathology, or medical laboratory specialist in

histocompatibility, medical laboratory subspecialist, cytotechnologist, histotechnician, or histotechnologist, or is exempt from licensure under section 148F.02.

Subd. 2. **Protected titles and restrictions on use.** No individual shall use the phrase medical laboratory scientist, categorical medical laboratory scientist, medical laboratory technician, medical laboratory specialist in cytogenetics, medical laboratory specialist in molecular biology/pathology, or medical laboratory specialist in histocompatibility, or medical laboratory subspecialist, cytotechnologist, histotechnician, or histotechnologist, or the initials MLS, MLT, CT, HT, or HTL, alone or in combination with any other words or initials to form an occupational title, or to indicate or imply that the person is licensed as one of the professionals listed, unless the individual is licensed under this chapter.

Subd. 3. **Persons licensed or certified in other states.** An individual who is licensed under this chapter and licensed or certified in another state may use the designation licensed or certified with a protected title only if the state of licensure or certification (if other than Minnesota) is clearly indicated.

Sec. 4. **[148F.035] SCOPE OF PRACTICE.**

Medical laboratory professionals licensed under this chapter shall perform laboratory tests and provide test results to physicians and patients upon request or upon physician referral according to CLIA. The practice of medical laboratory science includes:

- (1) the production of test data;
- (2) monitoring the accuracy, precision, and utility of laboratory testing;
- (3) analytical correlation and interpretation of test data;
- (4) designing, evaluating, and implementing new laboratory test methods; and
- (5) documenting and reporting test results.

The services provided by medical laboratory professionals must be consistent with good practice and sound professional ethics.

Sec. 5. **[148F.04] DUTIES OF THE COMMISSIONER.**

The commissioner, with the advice of the advisory council, shall:

(1) administer the procedures for this chapter, including, but not limited to, verifying the qualifications and standards for education, experience, examinations, and continuing education, as established by the certification agencies recognized in this chapter, and other methods for determining whether an applicant or licensee is qualified, as specified under this chapter;

(2) enforce standards for professional conduct found in the Code of Professional Ethics;

(3) issue licenses to qualified individuals;
(4) collect and deposit fees as established under section 148F.16;
(5) on the recommendation of the advisory council, approve future nationally recognized, validated, competency-based written, oral, or practical examinations developed by the American Society for Clinical Pathology Board of Certification, American Medical Technologists, American Association of Bioanalysts, and American Society for Histocompatibility and Immunogenetics, or successor organizations, for purposes of licensure of medical laboratory science professionals as provided for in this chapter; and
(6) maintain a roster of the names and addresses of individuals currently licensed under this chapter and of all individuals whose licenses have been disciplined under this chapter.

Sec. 6. **[148F.05] MEDICAL LABORATORY SCIENCE PROFESSIONAL LICENSING ADVISORY COUNCIL.**

Subdivision 1. Membership and qualifications of advisory council. (a) The commissioner shall appoint a 11-member advisory council that may include applicants recommended by laboratory professional associations. Members must be actively employed for at least two years in their specific area of practice.

(b) Six members must be medical laboratory science professionals who are licensed under this chapter and include:

- (1) one nonphysician laboratory director;
- (2) one medical laboratory scientist;
- (3) one medical laboratory technician;
- (4) one specialist in cytogenetics, histocompatibility, or molecular biology;
- (5) one cytotechnologist; and
- (6) one histotechnician or histotechnologist.

(c) Three members must be physicians certified by the American Board of Pathology or the American Board of Osteopathic Pathology. Two must be certified in clinical pathology.

(d) One of the members must be a physician who is not a laboratory director and is not a pathologist.

(e) One member must be a public member as defined in section 214.02.

Subd. 2. Duties. The advisory council shall:

(1) advise and make recommendations to the commissioner regarding the medical laboratory science practitioner licensure standards;

(2) advise the commissioner on enforcement of this chapter;

(3) provide for distribution of information regarding medical laboratory science practitioners licensure standards;

(4) review applications upon the request of the commissioner and make recommendations on granting or denying licensure or licensure renewal;

(5) advise the commissioner on issues related to receiving and investigating complaints, conducting objective hearings, and imposing disciplinary action in relation to complaints received against medical laboratory science practitioners; and

(6) perform other duties requested by the commissioner.

Subd. 3. **Organization.** The advisory council shall be organized and administered under section 15.059. The advisory council shall select a chair from its membership at the first meeting of the advisory council.

Subd. 4. **Support.** The commissioner shall provide the necessary staff support and meeting space for the advisory council.

Sec. 7. **[148F.06] TEMPORARY REQUIREMENTS FOR LICENSURE; TRANSITION PERIOD.**

Subdivision 1. **Experienced medical laboratory science professionals transition.**
(a) Notwithstanding section 148F.03, an individual who is certified by or eligible to be certified by a certification agency recognized by the commissioner to perform medical laboratory testing, or meets the subspecialty requirements in section 148F.07, subdivision 7, may perform medical laboratory tests without the appropriate license provided the individual has applied to the commissioner for licensure and the application:

(1) has not been denied by the commissioner; or

(2) has not been withdrawn.

(b) This subdivision expires January 1, 2014.

Subd. 2. **Employed medical laboratory science professional transition.** (a) An individual who does not meet the education, training, and experience qualifications for any license described in this chapter on July 1, 2012, has until January 1, 2014, to be licensed under this subdivision.

(b) The commissioner shall issue a license under this subdivision if the applicant:

(1) is practicing in the field on July 1, 2012, or has six months of acceptable experience of at least half time, 1040 hours per year, in the three years immediately prior to July 1, 2012; and

(2) on a form provided by the commissioner, submits the job, title, description of the position, period of employment, and confirmation of competent practice, as attested by

the applicant's employer, who shall submit a signed statement stating that the applicant is not the subject of a disciplinary action or past disciplinary action in their employment, professional association membership, or under any credentialing authority in this or another jurisdiction, and is not disqualified on the basis of section 148F.14.

(c) The commissioner and advisory council shall determine which type of license the applicant is eligible for and issue the license if the requirements of this subdivision are met.

(d) An initial license issued under this subdivision must be renewed following the procedures required under section 148F.10, provided the license is maintained without interruption.

(e) This subdivision expires January 1, 2013.

Sec. 8. **[148F.07] STANDARDS FOR LICENSURE.**

Subdivision 1. **Medical laboratory scientist (MLS).** (a) The commissioner shall issue a medical laboratory scientist's license to an individual who meets the following requirements in paragraph (b):

(1) possesses a baccalaureate degree from a regionally accredited college or university and verified by the nationally recognized certification agencies;

(2) has met the medical laboratory experience and training required by the recognized certification agencies; and

(3) passes a nationally recognized certification examination administered by the American Society for Clinical Pathology Board of Certification, American Medical Technologists, American Association of Bioanalysts, or successor organizations.

(b) The commissioner shall issue a medical laboratory scientist's license to an individual who has completed an official military training program of at least 50 weeks, which was approved by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) or a national accrediting agency acceptable to the commissioner, and held the military enlisted occupational specialty of medical laboratory specialist and possesses a baccalaureate degree from a regionally accredited college or university.

Subd. 2. **Medical laboratory scientist, categorical.** The commissioner shall issue a categorical medical laboratory scientist's license to an individual who:

(1) possesses a baccalaureate degree from a regionally accredited college or university and verified by the nationally recognized certification agencies;

(2) has met the medical laboratory experience and training required by the recognized certification agencies; and

(3) passes a nationally recognized certification examination administered by the American Society for Clinical Pathology Board of Certification, American Medical Technologists, American Association of Bioanalysts, or successor organizations.

Subd. 3. Medical laboratory technician (MLT). (a) The commissioner shall issue a medical laboratory technician's license to an individual who meets the following requirements in paragraph (b):

(1) possesses an associate degree from a regionally accredited college or university verified by the nationally recognized certification agencies;

(2) has met the medical laboratory experience and training required by the recognized certification agencies; and

(3) passes a nationally recognized certification examination administered by the American Society for Clinical Pathology Board of Certification, American Medical Technologists, American Association of Bioanalysts, or successor organizations.

(b) The commissioner shall issue a medical laboratory technician's license to an individual who has completed an official military training program of at least 50 weeks, which was approved by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) or a national accrediting agency acceptable to the commissioner, and held the military enlisted occupational specialty of medical laboratory specialist and possesses an associate degree from a regionally accredited college or university.

Subd. 4. Medical laboratory specialist in molecular biology. The commissioner shall issue a medical laboratory specialist in molecular biology license to an individual who:

(1) possesses a baccalaureate degree from a regionally accredited college or university verified by the recognized certification agencies;

(2) meets the medical laboratory experience and training required by the nationally recognized certification agencies, or alternatively one year of on-the-job training; and

(3) either passes a nationally recognized certification examination administered by the American Society for Clinical Pathology Board of Certification, American Association of Bioanalysts, or successor organizations.

Subd. 5. Medical laboratory specialist in cytogenetics. The commissioner shall issue a medical laboratory specialist in cytogenetics license to an individual who:

(1) possesses a baccalaureate degree from a regionally accredited college or university verified by the nationally recognized certification agencies;

(2) has met the medical laboratory experience and training required by the nationally recognized certification agencies or alternatively one year of on-the-job training; and

(3) passes a nationally recognized certification examination administered by the American Society for Clinical Pathology Board of Certification, or successor organizations.

Subd. 6. **Histocompatibility technologist.** The commissioner shall issue a medical laboratory specialist in histocompatibility license to an individual who:

(1) possesses a baccalaureate degree from a regionally accredited college or university verified by the nationally recognized certification agencies;

(2) has met the medical laboratory experience and training required by the nationally recognized certification agencies or alternatively one year of on-the-job training; and

(3) passes a nationally recognized certification examination administered by the American Board of Histocompatibility and Immunogenetics.

Subd. 7. **Medical laboratory subspecialist.** The commissioner shall issue a medical laboratory subspecialist license to an individual who:

(1) possesses a baccalaureate from a regionally accredited college or university verified by the recognized certification agencies;

(2) has met the required medical laboratory experience and training through one year of on-the-job training; and

(3) either is deemed competent via written confirmation by the respective laboratory director or passes a nationally recognized certification examination administered by the American Society for Clinical Pathology Board of Certification, or successor organizations.

Subd. 8. **Cytotechnologist.** The commissioner shall issue a cytotechnologist license to an individual who:

(1) possesses a baccalaureate degree from a regionally accredited college or university required and verified by the recognized certification agencies;

(2) has met the medical laboratory experience and training required by the recognized certification agencies; and

(3) passes a nationally recognized certification examination administered by the American Society for Clinical Pathology Board of Certification, or successor organizations.

Subd. 9. **Histotechnologist.** The commissioner shall issue a histotechnologist license to an individual who:

(1) possesses a baccalaureate degree from a regionally accredited college or university required and verified by the recognized certification agencies;

(2) has met the medical laboratory experience and training required by the recognized certification agencies; and

(3) passes a nationally recognized certification examination administered by the American Society for Clinical Pathology Board of Certification, or successor organizations.

Subd. 10. **Histotechnician.** The commissioner shall issue a histotechnician license to an individual who:

(1) possesses an associate degree from a regionally accredited college or university required and verified by the recognized certification agencies;

(2) has medical laboratory experience and training required by the recognized certification agencies; and

(3) passes a nationally recognized certification examination administered by the American Society for Clinical Pathology Board of Certification, or successor organizations.

Sec. 9. **[148F.08] RECIPROCITY.**

Subdivision 1. **Licensure.** The commissioner may waive the licensure requirements for an applicant who holds a valid license or its equivalent issued by another state provided that the requirements under which that license or its equivalent was issued are equivalent to or exceed the standards required by this chapter. Once the license is up for renewal, the applicant shall be issued a Minnesota license upon meeting the license renewal requirements in section 148F.11.

Subd. 2. **Current credentials required.** An applicant applying for licensure by reciprocity must provide all necessary evidence to the commissioner that the applicant holds a current and unrestricted license for the practice of medical laboratory science in another jurisdiction that has requirements equivalent to or higher than the standards required to be licensed as a medical laboratory professional in one of the categories defined in this chapter.

Subd. 3. **Verification of credentials required.** An applicant for licensure under this section must have maintained the appropriate and unrestricted credentials in each jurisdiction during the last five years as demonstrated by submitting letters of verification to the commissioner. Each letter must state the applicant's name, date of birth, credential number, date of issuance, a statement regarding disciplinary actions, if any, taken against the applicant, and the terms under which the credential was issued.

Sec. 10. **[148F.09] TEMPORARY LICENSE REQUIREMENTS.**

(a) The commissioner may issue a temporary license to an applicant who:

(1) is eligible to sit for and registered to take a certification examination or has taken the examination and is awaiting results;

(2) meets the educational requirements of the nationally recognized certification agency and is seeking to qualify for the certification examination by completing the required supervised medical laboratory experience; or

(3) meets the educational requirements for the position and is undergoing the required on-the-job training necessary for a specialized clinical laboratory.

(b) A temporary license shall be issued for a 12-month period and may be renewed for two additional 12-month periods at the discretion of the commissioner, in order to allow the applicant to complete the required supervised medical laboratory experience or retake a certification examination, or be deemed competent by the laboratory director.

(c) A temporary license expires 12 months after it is issued or on the date the commissioner issues or denies a permanent license to the holder.

(d) A temporary license authorizes the holder to perform medical laboratory tests only in the area of practice for which the individual seeks to be permanently licensed.

Sec. 11. **[148F.10] LICENSURE APPLICATION PROCEDURES.**

(a) Applicants must submit an application for licensure to the commissioner upon the forms prescribed and furnished by the commissioner, and must submit with the application the designated application fee as specified in section 148F.16.

(b) Upon receipt of the application and the application fee, the commissioner shall issue a license for a medical laboratory scientist, a medical laboratory technician, or an appropriate specialty license to an individual who meets the qualifications specified in this chapter.

(c) The commissioner shall approve, approve with conditions, or deny licensure. The commissioner shall act on an application for licensure according to paragraphs (b) to (d).

(d) The commissioner shall determine if the applicant meets the requirements for licensure. The commissioner, or the advisory council at the commissioner's request, may investigate information provided by an applicant to determine whether the information is accurate and complete.

(e) The commissioner shall notify an applicant of action taken on the application, and if licensure is denied or approved with conditions, the grounds for the commissioner's determination.

(f) An applicant denied licensure or granted licensure with conditions may make a written request to the commissioner, within 30 days of the date of the commissioner's determination, for reconsideration of the commissioner's determination. Individuals

requesting reconsideration may submit information that the applicant wants considered in the reconsideration. After reconsideration of the commissioner's determination to deny licensure or grant licensure with conditions, the commissioner shall determine whether the original determination should be affirmed or modified. An applicant is allowed no more than one request in any one biennial licensure period for reconsideration of the commissioner's determination to deny licensure or approve licensure with conditions.

Sec. 12. **[148F.11] LICENSURE RENEWAL.**

Subdivision 1. **Renewal term.** Licenses issued under this chapter must be renewed every two years. The renewal term is the effective date of the initial license or renewed license to the date of expiration of the license.

Subd. 2. **Renewal applications.** In order to renew a license, a licensee must submit:
(1) a completed and signed application for renewal on a form prescribed by the commissioner;

(2) the applicable renewal fee as specified in section 148F.16; and

(3) documentation that the licensee has completed continuing education requirements as prescribed by the recognized certification agencies or 12 hours of documented continuing education.

Sec. 13. **[148F.12] LICENSURE FOLLOWING LAPSE OF LICENSURE STATUS.**

For an applicant whose licensure status has lapsed, the applicant must:

(1) apply for licensure renewal according to section 148F.11 and document compliance with the continuing education requirements as prescribed by the nationally recognized certification agency since the applicant's license lapsed; and

(2) fulfill the requirements of section 148F.07 and provide evidence of compliance with the continuing education requirements as prescribed by one of the nationally recognized certification agencies.

Sec. 14. **[148F.13] CONTINUING EDUCATION REQUIREMENTS.**

Continuing education requirements shall be as described by the applicable certification agencies recognized under this chapter.

Sec. 15. **[148F.14] INVESTIGATION PROCESS; GROUNDS FOR DISCIPLINARY ACTION.**

- 17.1 Subdivision 1. **Disciplinary action.** (a) The commissioner may impose disciplinary
17.2 action as described in paragraph (b) against an applicant or licensee whom the
17.3 commissioner, by a preponderance of the evidence, determines:
- 17.4 (1) has violated a statute, rule, or order that the commissioner issued or is empowered
17.5 to enforce;
- 17.6 (2) has been convicted of or pled guilty to a felony, gross misdemeanor,
17.7 misdemeanor, an essential element of which is dishonesty, or of any crime that is directly
17.8 related to the practice of the profession;
- 17.9 (3) has made a misrepresentation for the purpose of obtaining licensure, either on
17.10 an application provided by the commissioner or in response to oral or written questions
17.11 from the commissioner;
- 17.12 (4) violated the code of professional conduct in subdivisions 2 to 4;
- 17.13 (5) engaged in dishonorable, unethical, or unprofessional conduct of a character
17.14 likely to deceive, defraud, or harm the public;
- 17.15 (6) failed to perform services with reasonable judgment, skill, or safety due to the
17.16 use of alcohol, drugs, or other physical or mental impairment;
- 17.17 (7) aided or assisted another person in violating any provision of this chapter or
17.18 any applicable rules;
- 17.19 (8) made any misrepresentation with regard to the existence or category of license or
17.20 other certification or professional qualification held in connection with any employment
17.21 application;
- 17.22 (9) intentionally submitted false or misleading information in response to a written
17.23 request by the commissioner or advisory council;
- 17.24 (10) failed, within 30 days, to provide information in response to a written request
17.25 by the commissioner or advisory council;
- 17.26 (11) performed services for which the license is issued in an incompetent manner or
17.27 in a manner that falls below community standards;
- 17.28 (12) violated any provision of this chapter;
- 17.29 (13) been convicted of violating any state or federal law, rule, or regulation which
17.30 directly relates to the practice related to the discipline for which the individual is licensed;
- 17.31 (14) violated a federal or state court order, including a conciliation court judgment,
17.32 or a disciplinary order issued by the commissioner, related to the individual's practice for
17.33 which they are licensed under this chapter;
- 17.34 (15) aided or abetted another person in violating any provision of this chapter;

(16) been disciplined for conduct in the practice of an occupation by the state of Minnesota, another jurisdiction, or a national professional association, if any of the grounds are the same or substantially equivalent to those in this chapter;

(17) not cooperated with the commissioner or the advisory council in an investigation conducted according to this paragraph;

(18) engaged in conduct with a patient that is sexual or may reasonably be interpreted by the patient as sexual, or in any verbal behavior that is seductive or sexually demeaning to a patient; or

(19) any other just cause related to the practice for which they are licensed under this chapter.

(b) If grounds for disciplinary action exist under paragraph (a), the commissioner may take one or more of the following actions:

(1) refuse to grant or renew a license;

(2) revoke a license;

(3) suspend a license;

(4) impose limitations or conditions on a license, including, but not limited to, practice under supervision, continued practice on the demonstration of knowledge or skill by appropriate examination or other review of knowledge, skill, and competence;

(5) censure or reprimand the licensee;

(6) impose a civil penalty not exceeding \$10,000 for each separate violation, the amount of the civil penalty to be fixed so as to deprive the applicant or licensee of any economic advantage gained by reason of the violation charged, to discourage similar violations, or to reimburse the commissioner for the cost of the investigation and proceeding, including, but not limited to, fees paid for services provided by the Office of Administrative Hearings, legal and investigative services provided by the Office of the Attorney General, court reporters, witnesses, reproduction of records, advisory council members per diem compensation, staff time, and travel costs and expenses incurred by staff and advisory council members; or

(7) any reasonable lesser action, including, but not limited to, censure, reprimand, or restriction on licensure, or any action authorized by statute.

(c) Upon notice from the commissioner denying licensure renewal or upon notice that disciplinary actions have been imposed and the person is no longer entitled to provide the services for which the person was previously licensed under this chapter, the person shall cease to provide the services under this chapter, to use the protected titles pursuant to this chapter, and to represent to the public that the person is licensed by the commissioner.

(d) A person who has had licensure suspended may request and provide justification for reinstatement following the period of suspension specified by the commissioner. The requirement of this chapter for renewing licensure and any other conditions imposed with the suspension must be met before licensure may be reinstated.

(e) The commissioner shall contract with the health professional services program as authorized by sections 214.31 to 214.37 to provide these services to practitioners under this chapter. The health professional services program does not affect the commissioner's authority to discipline violations of this chapter.

Subd. 2. Duty to patient. Medical laboratory professionals shall:

(1) be accountable for the quality and integrity of the laboratory services they provide;

(2) maintain high standards of practice and sound judgment in establishing, performing, and evaluating laboratory testing; and

(3) safeguard the dignity and privacy of patients and provide accurate information to other health care professionals about the services they provide.

Subd. 3. Duty to colleagues and profession. Medical laboratory professionals shall:

(1) uphold and maintain the dignity and respect of the profession and strive to maintain a reputation of honesty, integrity, and reliability; and

(2) actively strive to establish cooperative and respectful working relationships with other health care professionals with the primary objective of ensuring a high standard of care for the patients they serve.

Sec. 16. [148F.15] REPORTING OBLIGATIONS.

Subdivision 1. Permission to report. A person who has knowledge of any conduct constituting grounds for disciplinary action under this chapter may report the violation to the commissioner.

Subd. 2. Institutions. A state agency, political subdivision, agency of a local unit of government, private agency, hospital, clinic, prepaid medical plan, or other health care institution or organization located in this state shall report to the commissioner any action taken by the agency, institution, or organization or any of its administrators or medical or other committees to revoke, suspend, restrict, or condition a medical laboratory professional's privilege to practice in the institution, or as part of the organization, any denial of privileges, or any other disciplinary action for conduct that might constitute grounds for disciplinary action by the commissioner under this chapter. The institution, organization, or governmental entity shall also report the resignation of any medical laboratory science professional before the conclusion of any disciplinary action proceeding

for conduct that might constitute grounds for disciplinary action under this chapter, or before the commencement of formal charges but after the practitioner had knowledge that formal charges were contemplated or were being prepared.

Subd. 3. **Professional societies.** A state or local professional society for medical laboratory science professionals shall report to the commissioner any termination, revocation, or suspension of membership or any other disciplinary action taken against a medical laboratory science professional. If the society has received a complaint that might be grounds for discipline under this chapter against a member on which it has not taken any disciplinary action, the society shall report the complaint and the reason why it has not taken action on it or shall direct the complainant to the commissioner.

Subd. 4. **Licensed professionals.** A licensed health professional shall report to the commissioner personal knowledge of any conduct that the licensed health professional reasonably believes constitutes grounds for disciplinary action under this chapter by a medical laboratory science professional, including conduct indicating that the individual may be medically incompetent, or may be medically or physically unable to engage safely in the provision of services. If the information was obtained in the course of a client relationship, the client is a medical laboratory science professional, and the treating individual successfully counsels the medical laboratory science professional to limit or withdraw from practice to the extent required by the impairment, the commissioner may deem this limitation of or withdrawal from practice to be sufficient disciplinary action.

Subd. 5. **Self-reporting.** A medical laboratory science professional shall report to the commissioner any personal action that would require that a report be filed with the commissioner by any person, health care facility, business, or organization under subdivisions 2 to 4. The medical laboratory science professional shall also report the revocation, suspension, restriction, limitation, or other disciplinary action in this state and report the filing of charges regarding the practitioner's license or right of practice in another state or jurisdiction.

Subd. 6. **Deadlines; forms.** Reports required by subdivisions 2 to 5 must be submitted no later than 30 days after the reporter learns of the occurrence of the reportable event or transaction. The commissioner may provide forms for the submission of required reports, may require that reports be submitted on the forms provided, and may adopt rules necessary to ensure prompt and accurate reporting.

Subd. 7. **Immunity for reporting.** A person, health care facility, business, or organization is immune from civil liability or criminal prosecution for reporting to the commissioner violations or alleged violations of this chapter. All such reports are classified under section 13.41.

21.1 Subd. 8. **Immunity for investigation.** The commissioner, employees of the
21.2 Minnesota Department of Health, consultants to the department, and advisory council
21.3 members are immune from civil liability and criminal prosecution for any actions,
21.4 transactions, or publications in the execution of, or relating to, their duties under this
21.5 chapter.

21.6 Sec. 17. **[148F.16] FEES.**

21.7 Subdivision 1. **Initial licensure fee.** The initial licensure fee for medical laboratory
21.8 scientist, categorical medical laboratory scientist, medical laboratory specialist in
21.9 molecular biology, medical laboratory specialist in cytogenetics, histocompatibility
21.10 technologist, other specialists and categoricals, and medical laboratory technicians is
21.11 \$155. The commissioner shall prorate fees based on the number of quarters remaining
21.12 in the biennial licensure period.

21.13 Subd. 2. **Licensure renewal fee.** The biennial licensure renewal fee for medical
21.14 laboratory scientist, categorical medical laboratory scientist, medical laboratory specialist
21.15 in molecular biology, medical laboratory specialist in cytogenetics, histocompatibility
21.16 technologist, other specialists and categoricals, and medical laboratory technicians is \$115.

21.17 Subd. 3. **Late fee.** The fee for late submission of a renewal application is \$45.

21.18 Subd. 4. **Temporary licensure fee.** The fee for temporary licensure is \$50.

21.19 Subd. 5. **Verification to other states.** The fee for verification of licensure to other
21.20 states is \$25.

21.21 Subd. 6. **Verification to institutions.** The fee for verification of licensure to
21.22 institutions is \$10.

21.23 Subd. 7. **Nonrefundable fees.** All fees are nonrefundable.

21.24 Subd. 8. **Penalty fees.** (a) The penalty fee for practicing medical laboratory science
21.25 without a current license after the credential has expired and before it is renewed is the
21.26 amount of the license renewal fee for any part of the first month, plus the license renewal
21.27 fee for any part of any subsequent month up to 36 months.

21.28 (b) The penalty fee for applicants who engage in the unauthorized practice of
21.29 medical laboratory science before being issued a license is the amount of the license
21.30 application fee for any part of the first month, plus the license application fee for any part
21.31 of any subsequent month up to 36 months. This paragraph does not apply to applicants not
21.32 qualifying for a license who engage in the unauthorized practice of medical laboratory
21.33 science.

21.34 (c) The penalty fee for failing to submit a continuing education report by the due
21.35 date with the correct number or type of hours in the correct time period is \$50. The

22.1 licensee must obtain the missing number of continuing education hours by the next
22.2 reporting due date.

22.3 (d) Civil penalties and discipline incurred by licensees prior to January 1, 2014, for
22.4 conduct described in paragraph (a), (b), or (c), shall be recorded as nondisciplinary penalty
22.5 fees. For conduct described in paragraph (a) or (b) occurring after January 1, 2014, and
22.6 exceeding six months, payment of a penalty fee does not preclude any disciplinary action
22.7 reasonably justified by the individual case.

22.8 Sec. 18. **ADVISORY COUNCIL; DEADLINES.**

22.9 The commissioner of health shall complete the first appointments required by
22.10 Minnesota Statutes, section 148F.05, no later than September 1, 2012. The commissioner's
22.11 designee shall convene the first meeting of the council no later than October 1, 2012.
22.12 The council must select its chair as required by Minnesota Statutes, section 148F.05, at
22.13 the first meeting of the council.

22.14 Sec. 19. **APPROPRIATION.**

22.15 \$284,000 in fiscal year 2013 is appropriated from the state government special
22.16 revenue fund to the commissioner of health to implement this act. Base funding is
22.17 \$488,000 in fiscal year 2014 and \$376,000 in fiscal year 2015.

22.18 Sec. 20. **EFFECTIVE DATE.**

22.19 Sections 1 to 18 are effective July 1, 2012.