

1.1 Senator moves to amend S.F. No. 1830 as follows:

1.2 Delete everything after the enacting clause and insert:

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

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

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

1.10 Subd. 3. **Advisory Council of Medical Laboratory Science or advisory council.**
1.11 "Advisory Council of Medical Laboratory Science" or "advisory council" means the
1.12 advisory council established in section 148F.05.

1.13 Subd. 4. **Commissioner.** "Commissioner" means the commissioner of the
1.14 Minnesota Department of Health or a designee.

1.15 Subd. 5. **Categorical medical laboratory scientist.** "Categorical medical
1.16 laboratory scientist" means an individual eligible for licensure under this chapter who
1.17 performs the functions of a medical laboratory scientist in one of the following areas of
1.18 the laboratory: chemistry, hematology, immunohematology, or microbiology.

1.19 Subd. 6. **CLIA.** "CLIA" means the Clinical Laboratory Improvement Amendments
1.20 of 1988 and includes Public Law 10-578 and Code of Federal Regulations, title 42, section
1.21 493.

1.22 Subd. 7. **Cytotechnologist.** "Cytotechnologist" means an individual eligible for
1.23 licensure under this chapter who specializes in the cellular analysis of patient samples
1.24 from all body sites, for the purpose of evaluating, detecting, and providing prognostic
1.25 information regarding disease processes, including those that require the exercise of
1.26 independent judgment, and who:

1.27 (1) assists health care providers with the collection, detection, and interpretation
1.28 of normal and abnormal cells, infectious agents, and other noncellular material from
1.29 submitted specimens;

1.30 (2) performs a variety of ancillary tests to ascertain information to help
1.31 in classification, prognosis, or disease detection including, but not limited to,
1.32 immunohistochemical and molecular techniques; and

2.1 (3) as delegated by the laboratory director, establishes and implements protocols,
2.2 quality control, method selection, equipment selection and maintenance, and activities
2.3 related to the preanalytic, analytic, and postanalytic phases of testing.

2.4 Subd. 8. **Histotechnician.** "Histotechnician" means an individual eligible for
2.5 licensure under this chapter who:

2.6 (1) prepares tissue specimens for microscopic examination;

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

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

2.12 (4) as delegated by the laboratory director, establishes and implements protocols,
2.13 quality assurance, and quality control related to the following procedures: histochemical,
2.14 immunohistochemical, electron microscopy, cytopreparation, in situ hybridization, enzyme
2.15 histochemical, DNA hydrolysis, laser capturing, molecular techniques, and research; and

2.16 (5) as delegated by the laboratory director, participates in method selection,
2.17 development, equipment selection and maintenance, and activities related to the
2.18 preanalytical and analytical phases of tissue preparation.

2.19 Subd. 9. **Histotechnologist.** "Histotechnologist" means an individual eligible for
2.20 licensure under this chapter who:

2.21 (1) prepares tissue specimens for microscopic examination;

2.22 (2) as delegated by the laboratory director, monitors, performs, selects, develops,
2.23 evaluates, correlates, and ensures accuracy and validity of laboratory testing and
2.24 procedures including, but not limited to, techniques in fixation, processing, embedding,
2.25 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) as delegated by the laboratory director, establishes and implements protocols,
2.29 quality assurance, and quality control related to the following procedures: histochemical,
2.30 immunohistochemical, electron microscopy, cytopreparation, in situ hybridization, enzyme
2.31 histochemical, DNA hydrolysis, laser capturing, molecular techniques, and research;

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 (6) as delegated by the laboratory director, establishes and implements new
3.2 protocols and procedures dealing directly in quality assessment, method development, and
3.3 equipment selection and maintenance; and

3.4 (7) educates personnel and performs research functions.

3.5 Subd. 10. **Medical laboratory or laboratory.** "Medical laboratory" or "laboratory"
3.6 means any facility or office located in Minnesota in which medical laboratory tests are
3.7 performed.

3.8 Subd. 11. **Medical laboratory scientist or generalist.** "Medical laboratory
3.9 scientist" or "generalist" means an individual eligible for licensure under this chapter who:

3.10 (1) performs medical laboratory tests, including tests that require the exercise of
3.11 independent judgment; and

3.12 (2) as delegated by the laboratory director, establishes and implements protocols,
3.13 quality assessment, method development and selection, equipment selection and
3.14 maintenance, and activities related to the preanalytic, analytic, and postanalytic phases of
3.15 laboratory testing.

3.16 Subd. 12. **Medical laboratory specialist in cytogenetics.** "Medical laboratory
3.17 specialist in cytogenetics" means an individual eligible for licensure under this chapter
3.18 who performs standard cytogenetic testing procedures.

3.19 Subd. 13. **Medical laboratory specialist in molecular biology/pathology.**
3.20 "Medical laboratory specialist in molecular biology/pathology" means an individual
3.21 eligible for licensure under this chapter who performs all aspects of molecular analysis
3.22 including, but not limited to, recombinant DNA technology, polymerase chain reaction,
3.23 and hybridization techniques.

3.24 Subd. 14. **Medical laboratory specialist in histocompatibility.** "Medical
3.25 laboratory specialist in histocompatibility" means an individual eligible for licensure
3.26 under this chapter who performs histocompatibility testing by molecular and serological
3.27 techniques.

3.28 Subd. 15. **Medical laboratory technician.** "Medical laboratory technician" means
3.29 an individual eligible for licensure under this chapter who performs medical laboratory
3.30 tests pursuant to protocols established and approved by the laboratory director and
3.31 requiring limited exercise of independent judgment.

3.32 Subd. 16. **Medical laboratory test or laboratory test.** "Medical laboratory
3.33 test" or "laboratory test" means a microbiological, serological, chemical, biological,
3.34 hematological, immunological, immunohematological, radiobioassay, cytological,

4.1 histological preparation, molecular, biophysical, or any other test or procedure performed
4.2 on material derived from or existing in a human body, which provides information for
4.3 the diagnosis, prevention, or monitoring of a disease or impairment or assessment of a
4.4 medical condition. A medical laboratory test includes components of the preanalytic,
4.5 analytic, and postanalytic phases of testing, which occur in the laboratory.

4.6 Subd. 17. **Other medical laboratory specialists.** "Other medical laboratory
4.7 specialists" means individuals eligible for licensure under this chapter who perform the
4.8 functions of a medical laboratory scientist in a subspecialty or clinical laboratory that is
4.9 not one of the specific categorical areas of the laboratory.

4.10 Subd. 18. **Pathologist's assistant.** "Pathologist's assistant" means an individual
4.11 specializing in prediagnostic surgical pathology and autopsy pathology who assists
4.12 pathologists by:

4.13 (1) processing surgical samples, including dissection and description of pertinent
4.14 features, submission of tissue samples for microscopic examination, assistance in frozen
4.15 section preparation, and other ancillary duties to be performed under the supervision of
4.16 a pathologist; and

4.17 (2) performing functions in autopsy pathology, including prosection, selection of
4.18 tissues for microscopic examination, and other ancillary duties to be performed under
4.19 the supervision of a pathologist.

4.20 Subd. 19. **Phlebotomist.** "Phlebotomist" means an individual who is qualified to
4.21 obtain blood samples for testing by means of venipuncture, capillary puncture, or access
4.22 of venous access devices, to perform specimen processing and preparation of samples for
4.23 testing, and to perform waived and point-of-care testing.

4.24 Subd. 20. **Point-of-care testing.** "Point-of-care testing" means analytical patient
4.25 testing activities provided within a facility, which do not require permanent dedicated
4.26 space including, but not limited to, analytic instruments that are temporarily brought to a
4.27 patient care location. Point-of-care testing must be under the direction of an individual
4.28 licensed under this chapter at the baccalaureate degree level or who qualifies as a
4.29 laboratory director under the federal CLIA regulations.

4.30 Subd. 21. **Trainee/student.** "Trainee/student" means an individual who has
4.31 not fulfilled the educational requirements to take an approved nationally recognized
4.32 certification examination or who needs to obtain full-time comprehensive experience
4.33 under supervision.

5.1 Subd. 22. **Waived test.** "Waived test" means a laboratory examination or procedure
5.2 as determined by the United States Food and Drug Administration, which has an
5.3 insignificant risk of an erroneous result, including those which:

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

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

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

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

5.10 This chapter does not apply to:

5.11 (1) laboratory directors, technical supervisors, or technical consultants. These
5.12 personnel must meet the qualifications established under CLIA;

5.13 (2) other licensed or registered health care professionals performing functions within
5.14 their scope of practice as defined in their respective licensure regulations;

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

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

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

5.25 (6) professionals engaged exclusively in providing phlebotomy services;

5.26 (7) pathologist assistants or individuals performing pathology assistant activities
5.27 under supervision by pathologists;

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

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

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

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

6.1 (9) individuals who only perform waived tests in accordance with the federal
6.2 CLIA regulations;

6.3 (10) testing personnel performing point-of-care or other testing provided that the
6.4 laboratory complies with the following requirements:

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

6.7 (A) designing and providing or supervising the training programs for the testing
6.8 personnel;

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

6.11 (C) assisting in the selection of technology;

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

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

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

6.18 (11) in the case of a declared emergency, as defined in section 12.03, that reduces
6.19 laboratory capacity or increases testing demands, or other loss of critical laboratory
6.20 capacity, practitioners who are not licensed in any state, but are certified by one of the
6.21 agencies recognized in this chapter, may practice as needed in the emergency situation.

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

6.24 **Subdivision 1. Unlicensed practice prohibited.** Effective January 1, 2009, no
6.25 individual shall perform a medical laboratory test unless the individual is licensed under
6.26 this chapter as a medical laboratory scientist, categorical medical laboratory scientist,
6.27 medical laboratory technician, cytotechnologist, histotechnician, histotechnologist,
6.28 medical laboratory specialist in cytogenetics, medical laboratory specialist in molecular
6.29 biology/pathology, or medical laboratory specialist in histocompatibility or is exempt from
6.30 licensure under section 148F.02.

6.31 **Subd. 2. Protected titles and restrictions on use.** No individual shall use the
6.32 phrase "medical laboratory scientist," "categorical medical laboratory scientist," "medical
6.33 laboratory technician," "cytotechnologist," "histotechnician," "histotechnologist,"
6.34 "medical laboratory specialist in cytogenetics," "medical laboratory specialist in molecular
6.35 biology/pathology," or "medical laboratory specialist in histocompatibility," or the initials

7.1 "MLS," "MLT," "CT," or "HT" alone or in combination with any other words or initials
7.2 to form an occupational title, or to indicate or imply that the individual is licensed as a
7.3 medical laboratory scientist, categorical medical laboratory scientist, medical laboratory
7.4 technician, cytotechnologist, histotechnician, histotechnologist, medical laboratory
7.5 specialist in cytogenetics, medical laboratory specialist in molecular biology/pathology,
7.6 or medical laboratory specialist in histocompatibility, unless that individual is licensed
7.7 under this chapter.

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

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

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

- 7.16 (1) the production of test data;
7.17 (2) monitoring the accuracy, precision, and utility of laboratory testing;
7.18 (3) correlating and interpreting test data; and
7.19 (4) designing, evaluating, and implementing new laboratory test methods.

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

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

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

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

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

7.31 (3) issue licenses to qualified individuals;

7.32 (4) collect and deposit fees as established under section 148F.18;

7.33 (5) authorize or approve future nationally recognized, validated, competency-based
7.34 written, oral, or practical examinations developed by the National Credentialing Agency,
7.35 the American Society for Clinical Pathology Board of Registry, American Medical

8.1 Technologists and American Society for Histocompatibility and Immunogenetics for
8.2 purposes of licensure of medical laboratory science professionals as provided for in this
8.3 chapter; and

8.4 (6) maintain a roster of the names and addresses of individuals currently licensed
8.5 under this chapter and of all individuals who have been disciplined under this chapter.

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

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

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

8.14 (1) at least one nonphysician laboratory director;

8.15 (2) one medical laboratory scientist;

8.16 (3) one medical laboratory technician;

8.17 (4) one cytotechnologist;

8.18 (5) one histotechnician or histotechnologist; and

8.19 (6) one specialist in cytogenetics, histocompatibility, or molecular biology.

8.20 (c) Two members must be physicians certified by the American Board of Pathology
8.21 or the American Board of Osteopathic Pathology. At least one must be certified in clinical
8.22 pathology.

8.23 (d) One of the members must be a physician who is not a laboratory director and is
8.24 not a pathologist. This member may be a clinic-based physician who directs a physician
8.25 office laboratory.

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

8.27 Subd. 2. **Duties.** The advisory council shall:

8.28 (1) advise the commissioner regarding the medical laboratory science practitioner
8.29 licensure standards;

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

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

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

- 9.1 (5) advise the commissioner on issues related to receiving and investigating
 9.2 complaints, conducting hearings, and imposing disciplinary action in relation to
 9.3 complaints received against medical laboratory science practitioners; and
 9.4 (6) perform other duties requested by the commissioner.

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

9.8 Sec. 7. **[148F.06] TEMPORARY REQUIREMENTS FOR LICENSURE DURING**
 9.9 **TRANSITION PERIOD.**

9.10 Subdivision 1. **Experienced medical laboratory science professional transition.**

9.11 (a) Notwithstanding section 148F.03, an individual who is certified by or eligible to be
 9.12 certified by a certification agency recognized by the commissioner to perform medical
 9.13 laboratory testing may perform medical laboratory tests without the appropriate license
 9.14 provided the individual has applied to the commissioner for licensure and:

- 9.15 (1) the application has not been denied by the commissioner; or
 9.16 (2) the application has not been withdrawn.

9.17 (b) This subdivision expires January 1, 2010.

9.18 Subd. 2. **Employed medical laboratory science professional transition.** (a) An
 9.19 individual who does not meet the education, training, and experience qualifications for
 9.20 any license described in this chapter may apply to the commissioner for a license.

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

9.22 (1) is practicing in the field on July 1, 2008, or has six months of medical laboratory
 9.23 experience of at least half time, 1,040 hours per year, in the three years immediately
 9.24 prior to July 1, 2008; and

9.25 (2) on a form provided by the commissioner submits the job title, description of the
 9.26 position, and period of employment as attested to by the applicant's employer.

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

9.30 (d) An initial license issued under this subdivision must be renewed following the
 9.31 procedures required under section 148F.11, provided the license is maintained without
 9.32 interruption.

9.33 (e) This subdivision expires January 1, 2010.

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

10.1 Subdivision 1. **Medical laboratory scientist (MLS).** The commissioner shall issue
10.2 a medical laboratory scientist's license to an individual who:

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

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

10.7 (3) passes a nationally recognized certification examination administered by the
10.8 American Society for Clinical Pathology Board of Registry, the National Credentialing
10.9 Agency, or the American Medical Technologists, or successor organizations.

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

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

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

10.16 (3) passes a nationally recognized certification examination administered by the
10.17 American Society for Clinical Pathology Board of Registry, the National Credentialing
10.18 Agency, or the American Medical Technologists, or successor organizations.

10.19 Subd. 3. **Medical laboratory technician (MLT).** The commissioner shall issue a
10.20 medical laboratory technician's license to an individual who:

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

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

10.25 (3) passes a nationally recognized certification examination administered by the
10.26 American Society for Clinical Pathology Board of Registry, the National Credentialing
10.27 Agency, or the American Medical Technologists, or successor organizations.

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

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

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

11.1 (3) passes a nationally recognized certification examination administered by the
11.2 American Society for Clinical Pathology Board of Registry or the National Credentialing
11.3 Agency, or successor organizations.

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

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

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

11.10 (3) passes a nationally recognized certification examination administered by the
11.11 National Credentialing Agency or successor organizations.

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

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

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

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

11.20 Subd. 7. **Other specialists and categoricals.** The commissioner may license
11.21 individuals who have a baccalaureate degree in a science field and are employed in
11.22 subspecialty or esoteric clinical laboratories. Individuals applying for an initial license
11.23 under this subdivision are not required to take a certification examination. If a national
11.24 examination becomes available in the specific specialty area, the commissioner may
11.25 require an applicant or a licensee upon renewal to pass the examination before a license is
11.26 issued or renewed.

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

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

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

11.33 (3) passes a nationally recognized certification examination administered by the
11.34 American Society for Clinical Pathology Board of Registry or successor organization.

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

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

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

12.7 (3) passes a nationally recognized certification examination administered by the
12.8 American Society for Clinical Pathology Board of Registry or successor organization.

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

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

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

12.15 (3) passes a nationally recognized certification examination administered by the
12.16 American Society for Clinical Pathology Board of Registry or successor organization.

12.17 Subd. 11. **CLIA regulations.** Nothing in this chapter is intended to preempt or
12.18 exclude medical laboratory professionals from meeting the professional standards and
12.19 regulations established under CLIA.

12.20 Sec. 9. **[148F.08] LICENSE BY RECIPROCITY.**

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

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

12.33 Subd. 3. **Verification of credentials required.** An applicant for licensure under
12.34 this section must have maintained the appropriate and unrestricted credentials in each

13.1 jurisdiction during the last five years as demonstrated by submitting letters of verification
13.2 to the commissioner. Each letter must state the applicant's name, date of birth, credential
13.3 number, date of issuance, a statement regarding disciplinary actions, if any, taken against
13.4 the applicant, and the terms under which the credential was issued.

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

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

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

13.9 (2) meets the educational requirements of the recognized certification agency and is
13.10 seeking to qualify for the certification examination by completing the required supervised
13.11 medical laboratory experience.

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

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

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

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

13.21 (a) Applicants must submit an application for licensure to the commissioner upon the
13.22 forms prescribed and furnished by the commissioner, and shall submit with the application
13.23 the designated application fee as specified in section 148F.18.

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

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

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

13.32 Subd. 2. **Renewal applications.** In order to renew a license, a licensee must submit:

13.33 (1) a completed and signed application for renewal on a form prescribed by the
13.34 commissioner;

- 14.1 (2) the applicable renewal fee as specified in section 148F.18; and
14.2 (3) documentation that the licensee has completed the continuing education
14.3 requirements as prescribed by the recognized certification agencies.

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

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

- 14.7 (1) apply for licensure renewal according to section 148F.11 and document
14.8 compliance with the continuing education requirements as prescribed by the recognized
14.9 certification agency since the applicant's license lapsed; or
14.10 (2) fulfill the requirements of section 148F.08 and provide evidence of compliance
14.11 with the continuing education requirements as prescribed by one of the recognized
14.12 certification agencies.

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

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

14.16 Sec. 15. **[148F.14] INVESTIGATION PROCESS AND GROUNDS FOR**
14.17 **DISCIPLINARY ACTION.**

14.18 (a) The commissioner may impose disciplinary action as described in paragraph
14.19 (b) against an applicant or licensee whom the commissioner, by a preponderance of the
14.20 evidence, determines has:

14.21 (1) violated a statute, rule, or order or other disciplinary action either issued by the
14.22 commissioner or which the commissioner is empowered to enforce;

14.23 (2) been convicted of or pled guilty to a felony, gross misdemeanor, misdemeanor,
14.24 or petty misdemeanor, an essential element of which is dishonesty, or of any crime, which
14.25 is directly related to the practice of the profession;

14.26 (3) made a misrepresentation for the purpose of obtaining licensure, either on
14.27 an application provided by the commissioner, or in response to either oral or written
14.28 questions from the commissioner;

14.29 (4) engaged in dishonorable, unethical, or unprofessional conduct likely to deceive,
14.30 defraud, or harm the public;

14.31 (5) failed to perform services with reasonable judgment, skill, or safety due to the
14.32 use of alcohol, drugs, or to other physical or mental impairment;

14.33 (6) aided or assisted another person in violating any provision of this chapter or any
14.34 rule adopted under this chapter;

15.1 (7) made any misrepresentation with regard to the existence or category of license or
15.2 other certification or professional qualification held in connection with any employment
15.3 application;

15.4 (8) intentionally submitted false or misleading information in response to a written
15.5 request by the commissioner or advisory council;

15.6 (9) failed, within 30 days, to provide information in response to a written request
15.7 by the commissioner or advisory council;

15.8 (10) performed services for which the license is issued in an incompetent manner or
15.9 in a manner that falls below community standards;

15.10 (11) violated any provision of this chapter;

15.11 (12) been convicted of violating any state or federal law, rule, or regulation, which
15.12 directly relates to the practice related to the discipline for which the individual is licensed;

15.13 (13) violated a federal or state court order, including a conciliation court judgment,
15.14 or a disciplinary order issued by the commissioner, related to the licensee's practice for
15.15 which they are licensed under this chapter;

15.16 (14) aided or abetted another person in violating any provision of this chapter;

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

15.20 (16) not cooperated with the commissioner or the advisory council in an investigation
15.21 conducted according to this chapter.

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

15.24 (1) refuse to grant or renew a license;

15.25 (2) revoke a license;

15.26 (3) suspend a license;

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

15.30 (5) censure or reprimand the licensee;

15.31 (6) impose a civil penalty not to exceed \$10,000 for each separate violation,
15.32 the amount of the civil penalty must be fixed to deprive the applicant or licensee of
15.33 any economic advantage gained by reason of the violation charged, to discourage
15.34 similar violations, or to reimburse the commissioner for the cost of the investigation and
15.35 proceeding including, but not limited to, fees paid for services provided by the Office of
15.36 Administrative Hearings, legal and investigative services provided by the Office of the

16.1 Attorney General, court reporters, witnesses, reproduction of records, staff time, and travel
16.2 costs and expenses incurred by staff and advisory council members; or

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

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

16.10 (d) An individual whose license has been suspended may request and provide
16.11 justification for reinstatement following the period of suspension specified by the
16.12 commissioner. The requirement of this chapter for renewing a license and any other
16.13 conditions imposed with the suspension must be met before a license may be reinstated.

16.14 (e) The commissioner shall contract with the health professional services program as
16.15 authorized by sections 214.31 to 214.37 to provide services to individuals licensed under
16.16 this chapter. The health professionals services program does not affect the commissioner's
16.17 authority to discipline violations of this chapter.

16.18 Sec. 16. **[148F.15] PROFESSIONAL AND ETHICAL CONDUCT.**

16.19 The commissioner has grounds to take action under section 148F.14 if a licensee
16.20 fails to:

16.21 (1) maintain a high standard of practice in establishing, performing, and evaluating
16.22 laboratory testing;

16.23 (2) maintain strict confidentiality of patient information and test results in accordance
16.24 with state and federal laws;

16.25 (3) safeguard the dignity and privacy of patients and to provide accurate information
16.26 to other health care professionals about services that the medical laboratory professional
16.27 provides;

16.28 (4) maintain individual competence in judgment and performance of medical
16.29 laboratory testing services and to safeguard patients from incompetent or illegal practices;

16.30 (5) perform services in an accurate, precise, timely, and responsible manner; or

16.31 (6) use laboratory resources in a prudent and cost-effective manner.

16.32 Sec. 17. **[148F.16] REPORTING OBLIGATIONS.**

16.33 Subdivision 1. **Permission to report.** An individual who has knowledge of any
16.34 conduct constituting grounds for disciplinary action relating to the practice of medical
16.35 laboratory science under this chapter may report the violation to the commissioner.

17.1 Subd. 2. **Institutions.** A state agency, political subdivision, agency of a local unit
17.2 of government, private agency, hospital, clinic, prepaid medical plan, or other health
17.3 care institution or organization located in this state shall report to the commissioner any
17.4 action taken by the agency, institution, or organization or any of its administrators or
17.5 medical or other committees to revoke, suspend, restrict, or condition a medical laboratory
17.6 professional's privilege to practice in the institution, or as part of the organization, any
17.7 other disciplinary action for conduct that might constitute grounds for disciplinary action
17.8 by the commissioner under this chapter. The institution, organization, or governmental
17.9 entity shall also report the resignation of any medical laboratory science professional
17.10 before the conclusion of any disciplinary action proceeding for conduct that may constitute
17.11 grounds for disciplinary action under this chapter, or before the commencement of formal
17.12 charges but after the practitioner has knowledge that formal charges were contemplated
17.13 or were being prepared.

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

17.21 Subd. 4. **Licensed professionals.** A licensed health professional shall report to the
17.22 commissioner personal knowledge of any conduct that the licensed health professional
17.23 reasonably believes constitutes grounds for disciplinary action under this chapter by a
17.24 medical laboratory science professional, including conduct indicating that the individual
17.25 may be medically incompetent, or may be medically or physically unable to engage safely
17.26 in the provision of services.

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

17.34 Subd. 6. **Deadlines; forms.** Reports required under this section must be submitted
17.35 no later than 30 days after the reporter learns of the occurrence of the reportable event

18.1 or transaction. The commissioner may provide forms for the submission of the reports
18.2 required by this section, may require that reports be submitted on the forms provided, and
18.3 may adopt rules necessary to ensure prompt and accurate reporting.

18.4 Sec. 18. **[148F.17] IMMUNITY.**

18.5 Subdivision 1. **Reporting.** Except for self-reporting, a person, health care facility,
18.6 business, or organization is immune from civil liability or criminal prosecution for
18.7 reporting to the commissioner violations or alleged violations of this chapter. All such
18.8 reports are classified under section 13.41.

18.9 Subd. 2. **Investigation.** The commissioner, employees of the Department of Health,
18.10 consultants to the department, and advisory council members are immune from civil
18.11 liability and criminal prosecution for any actions, transactions, or publications in the
18.12 execution of, or relating to, their duties under this chapter.

18.13 Sec. 19. **[148F.18] FEES.**

18.14 Subdivision 1. **Initial licensure fee.** The initial licensure fee for medical
18.15 laboratory scientist, categorical medical laboratory scientist, medical laboratory
18.16 specialist in molecular biology/pathology, medical laboratory specialist in cytogenetics,
18.17 histocompatibility technologist, cytotechnologist, histotechnologist, and other specialist
18.18 and categoricals, medical laboratory technicians, and histotechnicians is \$..... The
18.19 commissioner shall prorate fees based on the number of quarters remaining in the
18.20 licensure period.

18.21 Subd. 2. **Licensure renewal fee.** The licensure renewal fee for medical
18.22 laboratory scientist, categorical medical laboratory scientist, medical laboratory
18.23 specialist in molecular biology/pathology, medical laboratory specialist in cytogenetics,
18.24 histocompatibility technologist, cytotechnologist, histotechnologist, and other specialists
18.25 and categoricals, medical laboratory technicians, and histotechnicians is \$.....

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

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

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

18.30 Subd.6. **Nonrefundable fees.** All fees are nonrefundable.

18.31 Subd. 7. **Penalty fees.** (a) The penalty fee for practicing medical laboratory science
18.32 without a current license after the credential has expired and before it is renewed is the

19.1 amount of the license renewal fee for any part of the first month, plus the license renewal
19.2 fee for any part of any subsequent month up to 36 months.

19.3 (b) The penalty fee for applicants who engage in the unauthorized practice of
19.4 medical laboratory science before being issued a license is the amount of the license
19.5 application fee for any part of the first month, plus the license application fee for any part
19.6 of any subsequent month up to 36 months. This paragraph does not apply to applicants not
19.7 qualifying for a license who engage in the unauthorized practice of medical laboratory
19.8 science.

19.9 (c) The penalty fee for failing to submit a continuing education report by the due
19.10 date with the correct number or type of hours in the correct time period is \$50. The
19.11 licensee must obtain the missing number of continuing education hours by the next
19.12 reporting due date.

19.13 (d) Civil penalties and discipline incurred by licensees prior to January 1, 2010, for
19.14 conduct described in paragraph (a), (b), or (c) shall be recorded as nondisciplinary penalty
19.15 fees. For conduct described in paragraph (a) or (b) occurring after January 1, 2010, and
19.16 exceeding six months, payment of a penalty fee does not preclude any disciplinary action
19.17 reasonably justified by the individual case.

19.18 Sec. 20. **ADVISORY COUNCIL APPOINTMENTS.**

19.19 The commissioner of health shall complete the initial appointments required under
19.20 new Minnesota Statutes, section 148F.05, subdivision 1, no later than August 1, 2008.
19.21 The commissioner or the commissioner's designee shall convene the first meeting of the
19.22 council by September 1, 2008.

19.23 Sec. 21. **APPROPRIATION.**

19.24 \$...... is appropriated to the commissioner of health for setup of licensing functions
19.25 and for the creation and operation of the Advisory Council of Medical Laboratory Science.

19.26 Sec. 22. **EFFECTIVE DATE.**

19.27 This act is effective July 1, 2008."

19.28 Delete the title and insert:

19.29 "A bill for an act

19.30 relating to health occupations; establishing licensure for medical laboratory
19.31 science professionals; creating the Advisory Council of Medical Laboratory
19.32 Science; proposing coding for new law as Minnesota Statutes, chapter 148F."