AN ACT RELATING TO HEALTH AND SAFETY -- LABORATORIES

Introduced By: Senators Euer, Goldin, Miller, Crowley, and Coyne

Date Introduced: February 25, 2020

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. Sections 23-16.2-2, 23-16.2-6 and 23-16.2-7 of the General Laws in Chapter 23-16.2 entitled "Laboratories" are hereby amended to read as follows:


When used in this chapter:

(1) "Analytical laboratory" means a facility for the biological, microbiological, chemical, physical, and radiochemical examination of potable water, nonpotable water or other environmental matrices.

(2) "Clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, radiobioassay, cytological, pathological, or other examination of materials derived from the human body for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of or the assessment of the health of human beings.

(3) "Director" means the director of the department of health.

(4) "Persons" means any individual, firm, partnership, corporation, company, association, or joint stock association.

(5) "Station" means a facility for the collection, processing, and transmission of the materials described in subdivisions (1) and (2) for the purposes described in subdivisions (1) and (2).

(6) "Certification" means the determination by the department of health that an analytical
laboratory is capable of performing specific tests or analyses of environmental samples in accordance with the requirements of the regulations promulgated pursuant to this chapter.

(7) “Clinical laboratory test” or “laboratory test” means a microbiological, serological, chemical, hematological, radiobiological, cytological, immunological, or other pathological examination that is performed on material derived from the human body, the test or procedure conducted by a clinical laboratory that provides information for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition.

(8) “Nationally recognized certification examination” means an appropriate examination, as determined by the director, covering both academic and practical knowledge, including but not limited to those offered by the American Society of Clinical Pathologists (ASCP), American Medical Technologists (AMT), National Credentialing Agency (NCA), or the American Association of Bioanalysts Board of Registry (AAB), and including any appropriate categorical or specialty examinations.

23-16.2-6. Issuance or denial of license.

Not less than thirty (30) days from the time any application for the license is received, the director shall grant the application and issue a license to maintain a laboratory or station if the director shall be satisfied that the applicant complies with the rules and regulations promulgated in accordance with this chapter establishing standards for the qualifications of personnel and adequacy of equipment and facilities. The standards for qualification of personnel who perform clinical laboratory tests shall require, as a minimum, successful completion of a nationally recognized certification examination. Notwithstanding this requirement, the director may establish, by regulation, alternative criteria for individuals who previously qualified under federal regulatory requirements, such as 42 C.F.R. § 493.1433 of the March 14, 1990 federal register, or other criteria that may be established to have met the requirements of this chapter shall include provisions for minimum standards of professional education or experience, as determined by the director. The director may provide for the examination of applicants to determine their qualifications.

Notwithstanding the preceding statements in this section, upon payment of any applicable license fees, the director may grant immediate licensure to any clinical laboratory licensed as a clinical laboratory in another state and certified under the Clinical Laboratory Improvement Act of 1988, when the clinical laboratory has been asked to perform a clinical laboratory service which is not offered by any other clinical laboratory then licensed in this state.

23-16.2-7. Suspension and revocation of license.

(a) The department of health may revoke or suspend the license or specific certification of any laboratory or station for conduct by or chargeable to the laboratory or stations as follows:
(1) Failure to observe any term of the license or specific certification issued under authority of this chapter by the department of health;
(2) Failure to observe any order made under authority of this chapter or under the statutory authority vested in the department of health;
(3) Engaging in, aiding, abetting, causing, or permitting any action prohibited under this chapter;
(4) Failing to observe any regulations promulgated by the department of health.

(b) Whenever the director shall have reason to believe that any laboratory or station, for the maintenance of which the director has issued a license or specific certification as provided for in § 23-16.2-4, is being maintained in violation of the rules and regulations provided in § 23-16.2-5, the director may, pending an investigation and hearing, suspend for a period not exceeding thirty (30) days, any license or specific certification issued under authority of this chapter and may, after due notice and hearing, revoke the license or specific certification if the director finds that the laboratory or station is being maintained in violation of the rules and regulations. The holder of a license shall upon its revocation promptly surrender the license or specific certification to the director.

c) The director may revoke or suspend the license, or may impose appropriate fines as promulgated in regulation, of any laboratory or station that does not ensure that all personnel meet the requirements of this chapter.

SECTION 2. Title 23 of the General Laws entitled "HEALTH AND SAFETY" is hereby amended by adding thereto the following chapter:

CHAPTER 16.5

MEDICAL LABORATORY SCIENCE PRACTICE

23-16.5-1. Short title.
This chapter shall be known and may be cited as the "Medical Laboratory Science Practice Act".


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

23-16.5-3. Definitions.

The following words and terms when used in this chapter have the following meaning
unless otherwise indicated within the context:

1. "Accredited medical laboratory program" means a program planned to provide a
   predetermined amount of instruction and experience in medical laboratory science that has been
   accredited by one of the accrediting agencies recognized by the United States Department of
   Education.

2. "Board" means the medical laboratory science board appointed by the director of health.

3. "Department" means the Rhode Island department of health.

4. "Director" means the director of the Rhode Island department of health.

5. "Limited function test" means a test conducted using procedures which, as determined
   by the director, have an insignificant risk of an erroneous result, including those which:
   (i) Have been approved by the United States Food and Drug Administration for home use;
   (ii) Employ methodologies that are so simple and accurate as to render the likelihood of
       erroneous results negligible; or
   (iii) The director has determined, pose no reasonable risk of harm to the affected patient if
       performed incorrectly;

6. "Medical laboratory" or "laboratory" means any facility or office in which medical
   laboratory tests of either an analytical or clinical nature are performed.

7. "Medical laboratory science practitioner" or "one who engages in the practice of
   medical laboratory science" means a health care professional who performs medical laboratory
   tests or who is engaged in management, education, consulting, or research in medical laboratory
   science, and includes laboratory directors, supervisors, medical laboratory scientists
   (technologists), specialists, and technicians working in a laboratory, but does not include persons
   employed by a medical laboratory to perform supportive functions not related to direct performance
   of laboratory tests and does not include medical laboratory trainees. Provided, however, nothing
   contained in this chapter shall apply to a medical perfusionist engaged in the testing of human
   laboratory specimens for extracorporeal functions, which shall include those functions necessary
   for the support, treatment, measurement, or supplementation of the cardiopulmonary or circulatory
   system of a patient.

8. "Medical laboratory scientist" and/or "technologist" means a person who performs
medical laboratory tests pursuant to established and approved protocols requiring the exercise of
independent judgment and responsibility, maintains equipment and records, performs quality
assurance activities related to test performance, and may supervise and teach within a medical
laboratory setting.
(9) “Medical laboratory technician” means a person who performs laboratory tests,
pursuant to established and approved protocols, which require limited exercise of independent
judgment and responsibility, maintains equipment and records, and performs quality assurance
activities related to test performance.
(10) “Medical laboratory test” or “laboratory test” means a microbiological, serological,
chemical, hematological, radiobioassay, cytological, immunological, or other pathological
examination which is performed on material derived from the human body, the test or procedure
conducted by a medical laboratory which provides information for the diagnosis, prevention, or
treatment of a disease or assessment of a medical condition.

23-16.5-4. Exceptions.

This chapter shall not apply to:
(1) Any person performing medical laboratory tests within the scope of their practice and
for which they are licensed, pursuant to any other provisions of the general laws.
(2) Medical laboratory science practitioners employed by the United States government or
any bureau, division, or agency of the United States government, while in the discharge of their
official duties.
(3) Medical laboratory science practitioners (clinical laboratory scientists) employed by
the state of Rhode Island or any bureau, division, or agency of the state, while in the discharge of
their official duties.
(4) Medical laboratory science practitioners engaged in teaching or research, provided that
the results of any examination performed, are not used in health maintenance, diagnosis, or
treatment of disease.
(5) Students or trainees enrolled in a medical laboratory science education program;
provided that, these activities constitute a part of a planned course in the program that the persons
are designated by title such as intern, trainee, or student, and the persons work directly under the
supervision of an individual licensed by this state to practice laboratory science.
(6) Individuals performing limited function tests.

23-16.5-5. License required.
(a) No person shall practice medical laboratory science or hold themself out as a medical
laboratory science practitioner in this state, unless they are licensed pursuant to this chapter.
(b) All persons who were engaged in the practice of medical laboratory science on July 1, 1992, who are certified by or eligible for certification by an agency approved by the department of health, and who have applied to the department of health on or before July 1, 1994, and have complied with all necessary requirements for the application, may continue to perform medical laboratory tests until July 1, 1995, unless the application is denied by the department of health, or the withdrawal of the application, whichever occurs first.

(c) Persons not meeting the education, training, and experience qualifications for any license described in this chapter may be considered to have met the qualifications providing they have:

(1) Three (3) years acceptable experience between January 1, 1986 and January 1, 1996 and submit to the department of health the job description of the position which the applicant has most recently performed, attested to by their employer and notarized; or

(2) No less than twelve (12) years acceptable experience prior to 1993 and submits to the department of health the job description of the position which the applicant has most recently performed, attested to by their employer and notarized on or before December 1, 2001.

(d) After December 1, 2001, no initial license shall be issued until an applicant meets all of the requirements under this chapter, and successfully completes a nationally recognized certification examination, such as NCA, DHHS, ASCP, state civil service examination, or others including appropriate categorical and specialty exams. Provided, however, that the provisions of this subsection shall not be available to any individual who has been previously denied a license as a medical laboratory science practitioner by the department of health.

23-16.5-6. Administration.

(a) There is created within the division of professional regulation of the department of health, a medical laboratory advisory board which shall consist of seven (7) members who have been residents of the state for at least two (2) years prior to their appointment, and who are actively engaged in their areas of practice. The director of the department of health, with the approval of the governor, shall make appointments to the board from lists submitted by organizations of medical laboratory science practitioners and organizations of physicians and pathologists.

(b) The board shall be composed of:

(1) One physician certified by the American Board of Pathology or American Board of Osteopathic Pathology;

(2) One physician who is not a laboratory director nor a pathologist;

(3) Four (4) medical laboratory science practitioners, one of whom is a non-physician laboratory director, one of whom is a medical laboratory scientist (technologist), and one of whom
is a medical laboratory technician, whom, except for their initial appointments, hold active and 
valid licenses as medical laboratory science practitioners in this state, and one of whom is a medical 
laboratory science practitioner, not falling in one of the first three (3) categories; and 
(4) One public member who is not associated with nor has a financial interest in the practice 
of medical laboratory science. 
(c) Board members shall serve for a term of three (3) years, and until their successors are 
appointed and qualified, except that the initial appointments, which shall be made within sixty (60) 
days after July 1, 2020, shall be as follows:
(1) One pathologist, one non-physician laboratory director, and one medical laboratory 
scientist, shall be appointed to serve for three (3) years; 
(2) One public representative and one non-pathologist physician, shall be appointed to 
serve for two (2) years; and 
(3) The remaining two (2) members shall be appointed to serve for one year. 
(d) The membership of the board shall receive no compensation for their services. 
(e) Whenever a vacancy shall occur on the board by reason other than the expiration of a 
term of office, the director of the department of health, with the approval of the governor, shall 
appoint a successor of like qualifications for the remainder of the unexpired term. No person shall 
be appointed to serve more than two (2) successive three (3) year terms. 

23-16.5-7. Duties and powers of the medical laboratory advisory board. 
In addition to any other power conferred upon the board pursuant to this chapter, the board 
shall recommend to the director: 
(1) Rules and regulations necessary for the implementation of this chapter including, but 
not limited to, regulations that delineate qualifications for licensure of medical laboratory science 
practitioners, as defined in this chapter, specify requirements for the renewal of licensure, establish 
standards of professional conduct, and potential amendments to or the repeal of certain rules and 
regulations. Following their adoption, the rules and regulations shall govern and control the 
professional conduct of every person who holds a license to perform medical laboratory tests or 
otherwise engages in the profession of medical laboratory science; 
(2) Standard written, oral, or practical examinations for purposes of licensure of medical 
laboratory science practitioners, necessary for licensure, as provided for in § 23-16.5-5; 
(3) Rules and regulations governing qualifications for licensure of specialists in those 
medical laboratory science specialties that the board may determine in accordance with § 23-16.5- 
8; 
(4) Rules and regulations governing personnel performing tests in limited function
laboratories;

(5) A schedule of fees for applications and renewals;

(6) Establish criteria for the continuing education of medical laboratory science practitioners, as may be required for license renewal;

(7) Any other rules and regulations necessary to implement and further the objectives of this chapter.


(a) Medical laboratory scientist (technologist). The department of health shall issue a medical laboratory scientist's license to an individual who meets the qualifications adopted by the board, including at least one of the following qualifications:

(1) A baccalaureate degree in medical laboratory science (medical technology) from an accredited college or university whose curriculum included appropriate medical education;

(2) A baccalaureate degree in biological, chemical, or physical science from an accredited college or university, and subsequent to graduation has at least twelve (12) months of appropriate medical education in an accredited medical laboratory science program;

(3) A baccalaureate degree which includes a minimum of thirty-six (36) semester (or equivalent) hours in the biological, chemical, and physical sciences from an accredited college or university, plus two (2) years of full-time work experience, including a minimum of four (4) months in each of the four (4) major disciplines of laboratory practice (medical chemistry, medical microbiology, hematology, immunology/immunohematology);

(4) A baccalaureate degree consisting of ninety (90) semester (or equivalent) hours, thirty-six (36) of which must be in the biological, chemical, or physical sciences, from an accredited college or university, and appropriate medical education, in an accredited medical laboratory science program; or

(5) A medical laboratory scientist (technologist) who previously qualified under federal regulatory requirements such as 42 CFR § 493.1433 of the March 14, 1990 Federal Register or other regulations or criteria which may be established by the board.

(b) Medical laboratory technician. The department of health shall issue a medical laboratory technician's license to an individual who meets the qualifications promulgated by the board, including at least one of the following qualifications:

(1) An associate degree or completion of sixty (60) semester (or equivalent) hours from a medical laboratory technician program (MLT), or equivalent, accredited by an agency recognized by the United States Department of Education, that included a structured curriculum in medical laboratory techniques;
(2) A high school diploma (or equivalent) and:

   (i) Completion of twelve (12) months in a technician training program, such as CLA (ASCP) medical laboratory assistant (American Society of Clinical Pathologists), (CLA) (ASCP) in an accredited school and medical laboratory technician-certificate (MLT-C) programs approved by the board; or

   (ii) Successful completion of an official military medical laboratory procedure course of at least fifty (50) weeks duration and has held the military enlisted occupational specialty of medical laboratory specialist (laboratory technician); or

(3) A medical laboratory technician who previously qualified under federal regulatory requirements such as 42 CFR § 493.1441 of the March 14, 1990 Federal Register which meet or exceed the requirements for licensure set forth by the board.

(c) Medical histologic technician. The department of health shall issue a medical histologic technician license to an individual who meets the qualifications promulgated by the board, including at least one of the following:

   (1) An associate degree or at least sixty (60) semester hours (or equivalent) from an accredited college or university, to include a combination of mathematics and at least twelve (12) semester hours of biology and chemistry, and successful completion of an accredited program in histologic technique or one full year of training in histologic technique under the supervision of a certified histotechnologist or an appropriately certified histopathology supervisor, with at least three (3) years' experience.

   (2) A high school diploma (or equivalent) and two (2) years full-time acceptable experience under the supervision of a certified/licensed medical histologic technician at a licensed medical laboratory in histologic technique.

(d) Cytotechnologist. The department of health shall issue a cytotechnologist license to an individual who meets the qualifications promulgated by the board including at least one of the following:

   (1) A baccalaureate degree from an accredited college or university with: twenty (20) semester hours, thirty (30) quarter hours of biological science; eight (8) semester hours, twelve (12) quarter hours of chemistry; three (3) semester hours, four (4) quarter hours of mathematics; and successful completion of a twelve (12) month cytotechnology program.

   (2) A baccalaureate degree from an accredited college or university with: twenty (20) semester hours, thirty (30) quarter hours of biological science; eight (8) semester hours, twelve (12) quarter hours of chemistry; three (3) semester hours, four (4) quarter hours of mathematics; and five (5) years full-time acceptable medical laboratory experience, including cytopreparatory
techniques, microscopic analysis, and evaluation of the body systems within the last ten (10) years.

At least two (2) of these years must be subsequent to the completion of the academic component and at least two (2) years must be under the supervision of a licensed physician who is a pathologist, certified, or eligible for certification, by the American Board of Pathology in anatomic pathology or has other suitable qualifications acceptable to the board.

(3) A cytotechnologist who previously qualified under federal regulatory requirements such as 42 CFR § 493.1437 of the March 14, 1990 Federal Register.

(e) The board shall recommend standards for any other medical laboratory science practitioners specializing in areas such as nuclear medical technology, radioimmunoassay, electron microscopy, forensic science, molecular biology, or similar recognized academic and scientific disciplines, with approval of the director of the department of health.

23-16.5-9. Waiver of requirements.

The board shall recommend regulations providing procedures for waiver of the requirements of § 23-16.5-8, for all applicants who hold a valid license or its equivalent issued by another state; provided that the requirements under which that license or its equivalent was issued, meet or exceed the standards required by this chapter, with the approval of the director. The board may also recommend regulations it deems appropriate for individuals who hold valid licenses or their equivalent from other countries.

23-16.5-10. Licensure application procedures.

(a) Licensure applicants shall submit their application for licensure to the department of health using the forms prescribed and furnished by the department of health, and shall pay the designated application or examination fee.

(b) Upon receipt of application and payment of a fee, the department of health shall issue a license for a medical laboratory scientist or technologist, a medical laboratory technician, or an appropriate specialty license to any person who meets the qualifications established by this chapter and the regulations promulgated under this chapter.

(c) The board may recommend a procedure for issuance of temporary permits to individuals otherwise qualified under this chapter who intend to engage in medical laboratory science practice in this state for a limited period of time not to exceed eighteen (18) months.

(d) The board may recommend a procedure for issuance of provisional licenses to individuals, who otherwise qualify under this chapter, but are awaiting the results of their certification application. A provisional license so issued shall be converted to a license under the provisions of § 23-16.5-8 or expire not more than twelve (12) months after its issuance. At the discretion of the board, the provisional license may be reissued at least one time, with the director's
23-16.5-11. Licensure renewal.

(a) Licenses issued pursuant to this chapter shall expire on a date and time specified by the department of health.

(b) Every person licensed pursuant to this chapter shall be issued a renewal license every two (2) years upon:

(1) Submission of an application for renewal, on a form prescribed by the department of health and payment of an appropriate fee recommended by the board; and

(2) Proof of completion, in the period after the license was first issued or last renewed, of at least thirty (30) hours of continuing education courses, clinics, lectures, training programs, seminars, or other programs related to medical laboratory practice, which are approved or accepted by the board; or proof of re-certification by a national certification organization that mandates an annual minimum of fifteen (15) hours of continuing education, such as the National Certification Agency for Medical Laboratory Personnel.

(c) The board may recommend any other evidence of competency it shall deem reasonably appropriate as a prerequisite to the renewal of any license governed by this chapter, as long as these requirements are uniform as to application, are reasonably related to the measurement of qualification, performance, or competence, and are desirable and necessary for the protection of the public health.

23-16.5-12. Disciplinary requirements.

The board may make recommendations to the director of the department of health pertaining to the issuance, renewal, or revocation of a license, or suspension, placement on probation, censure, or reprimand of a licensee, or any other disciplinary action that the board may deem appropriate, including the imposition of a civil penalty, for conduct that may result from, but not necessarily be limited to:

(1) A material misstatement in furnishing information to the department of health;

(2) A violation or negligent or intentional disregard of this chapter, or of the rules or regulations promulgated under this chapter;

(3)(i) In the context of an action other than that related to the issuance of a license, a criminal conviction that is directly related to the duties and responsibilities of the licensee as defined by the department of health, which leads the board to conclude that the continued licensure of an individual could jeopardize patients’ health; or

(ii) A determination regarding the issuance of a license made in accordance with § 16.5-12.1.
(4) Making any misrepresentation for the purpose of obtaining registration or violating any provision of this chapter;

(5) Violating any standard of professional conduct adopted by the board;

(6) Engaging in dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public;

(7) Providing professional services while mentally incompetent, under the influence of alcohol or narcotic or controlled dangerous substance that is in excess of therapeutic amounts or without valid medical indication;

(8) Directly or indirectly contracting to perform medical laboratory tests in a manner which offers or implies an offer of rebate, fee-splitting inducements or arrangements, or other unlawful remuneration; or

(9) Aiding or assisting another person in violating any provision of this chapter or any rule adopted under this chapter.

23-16.5-12.1. Denial of licensure based on criminal conviction.

(a) The issuance of a license shall not be denied, solely or in part, based on a criminal conviction, unless it has been determined that the conviction is directly related to the duties and responsibilities of a licensee and that licensure of the applicant could jeopardize patient's health, and the decision is otherwise in conformance with the standards contained in the Equal Employment Opportunity Commission’s 2012 Enforcement Guidance, on the use of criminal records in employment.

(b) The department shall specify by regulation the offenses that may disqualify an applicant from obtaining a license under subsection (a) of this section, and shall provide the applicant an opportunity to present evidence of rehabilitation and present fitness to perform the duties of the occupation for which the license is sought, of mitigating circumstances surrounding the commission of the crime, or any other relevant evidence surrounding the applicant’s fitness for the license, notwithstanding their conviction.

(c) An applicant denied a license under this section shall have the right to appeal the decision in accordance with chapter 35 of title 42, and may reapply after two (2) years have elapsed from the date of the denial.


(a) The proceedings for the revocation, suspension or limiting of any license may be initiated by any person, corporation, association, or public officer or by the board, by the filing of written charges with the board, but no license shall be revoked, suspended, or limited without a hearing before the board, held within sixty (60) days after the filing of written charges, in
accordance with the procedures established by the board. A license may be temporarily suspended
without a hearing for the period not to exceed thirty (30) days, upon notice to the licensee following
an initial finding by the board that there exists a significant threat to the public health and approved
by the director.

(b) Any appeal from the action of the board shall be in accordance with the provisions of
chapter 35 of title 42 (the "administrative procedures act").

The department of health shall maintain a roster of the names and addresses of persons
currently licensed and registered under the provisions of this chapter, and of all persons whose
licenses have been suspended or revoked within the previous year.

The proceeds of any fees collected pursuant to the provisions of this chapter shall be
deposited as general revenues.

If any provision of this chapter or the application of any provision to any person or
circumstance shall be held invalid, that invalidity shall not affect the provisions or application of
this chapter which can be given effect without the invalid provision or application, and to this end
the provisions of the chapter are declared to be severable.

SECTION 3. This act shall take effect upon passage.

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF
AN ACT
RELATING TO HEALTH AND SAFETY – LABORATORIES

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1 This act would create a comprehensive system to promote and regulate the effective and
2 competent administration of medical laboratories by focusing on the training, qualifications and
3 licensure of their practitioners.
4 This act would take effect upon passage.

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