

AN ACT

To amend chapter 324, RSMo, by adding thereto sixteen new sections relating to the licensing of clinical laboratory science personnel, with penalty provisions.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF MISSOURI,
AS FOLLOWS:

Section A. Chapter 324, RSMo, is amended by adding thereto sixteen new sections, to be known as sections 324.1300, 324.1303, 324.1306, 324.1309, 324.1312, 324.1315, 324.1318, 324.1321, 324.1324, 324.1326, 324.1328, 324.1332, 324.1334, 324.1336, 324.1338, and 324.1340 to read as follows:

324.1300. Sections 324.1300 to 324.1340 shall be known and may be cited as the "Clinical Laboratory Science Practice Act".

324.1303. As used in sections 324.1300 to 324.1340, the following terms, unless otherwise indicated within the context, shall mean:

(1) "Approved national certification examination", a competency based certification examination that is administered by a national non-profit credentialing agency approved by the board;

(2) "Board", the Missouri clinical laboratory science board appointed by the governor;

(3) "Categorical laboratory scientist", an individual eligible under sections 324.1300 to 324.1340, with oversight by the laboratory director, to perform the functions of a clinical laboratory scientist in one or more categories of laboratory testing, such as microbiology, virology, clinical chemistry, immunology, hematology, immunohematology, molecular diagnostics,

or other areas specified by the board;

(4) "CLIA", refers to the final regulations promulgated by the United States Department of Health and Human Services implementing the Clinical Laboratory Improvement Amendments of 1988, P.L. 100-578, and 42 CFR 493;

(5) "Clinical laboratory" or "laboratory", any site or location in which clinical laboratory tests or examinations are performed;

(6) "Clinical laboratory assistant", an individual responsible for obtaining a blood specimen by venipuncture or capillary puncture according to established and approved protocols and also qualified to perform waived or point-of-care testing under the direction of a clinical laboratory scientist, clinical laboratory technician, laboratory supervisor, or laboratory director;

(7) "Clinical laboratory scientist", an individual eligible under sections 324.1300 to 324.1340, to perform any clinical laboratory test including those that require the exercise of independent judgment. In addition, this individual is responsible for, with oversight by the laboratory director, the establishment and implementation of protocols, quality assessment, method development and selection, equipment selection and maintenance, and all activities related to the pre-analytic, analytic, and post analytic phases of testing. The clinical laboratory scientist may also direct, supervise, consult, educate, and perform research functions;

(8) "Clinical laboratory technician", an individual eligible under sections 324.1300 to 324.1340, who is qualified to

perform clinical laboratory tests in accordance with established and approved protocols which require limited exercise of independent judgment and which are performed with oversight from a clinical laboratory scientist, laboratory supervisor, or laboratory director;

(9) "Clinical laboratory test" or "laboratory test", a microbiological, serological, molecular, chemical, biological, hematological, immunological, immunohematological, biophysical, or any other test or procedure performed on material derived from or present within a human body which provides information for the diagnosis, prevention, or monitoring treatment of a clinical condition. Clinical laboratory testing encompasses the pre-analytical, analytical, and post-analytical phases of testing;

(10) "Department", the Missouri department of insurance, financial institutions and professional registration;

(11) "Director", the director of the Missouri division of professional registration;

(12) "Laboratory director", an individual eligible under CLIA and licensed in this state or board certified by a credentialing agency approved by the board. A laboratory director is responsible for all aspects of laboratory operation and administration including appointing personnel who are competent to perform test procedures and record and report test results promptly, accurately, and proficiently; and assuring compliance with the applicable regulations. A laboratory director may delegate his or her duties to qualified individuals, but shall remain responsible for insuring that all duties are properly performed. The laboratory director shall be accessible,

but not be required to be on-site when laboratory testing is performed;

(13) "Point-of-care testing", clinical laboratory testing that is critical to patient care and must be performed immediately at the patient's location. Tests which meet this definition provide clinically relevant information which determines the patient's therapy, are limited to procedures that produce accurate data within a short period of time, meet the current standards of quality in clinical laboratory science, and comply with all standards of accrediting agencies. Point-of-care testing must be under the direction, authority, jurisdiction, and responsibility of a person licensed under sections 324.1300 to 324.1340;

(14) "Trainee" or "student", 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;

(15) "Waived", "provider performed microscopy", "moderate complexity", and "high complexity", the categories of clinical laboratory test complexity as defined by CLIA.

324.1306. Sections 324.1300 to 324.1340 do not apply to:

(1) Licensed health care professionals whose scope of practice includes blood collection or the performance of waived or provider performed microscopy testing as defined by CLIA;

(2) Individuals holding a doctorate in chemical, physical, or biological sciences or medicine and board certified as defined by CLIA;

(3) Clinical laboratory practitioners employed by the

United States government or any bureau, division, or agency thereof, while in the discharge of the employee's official duties;

(4) Clinical laboratory science professionals 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 an accredited clinical laboratory science education program provided that their activities constitute a part of a planned course in the program, that the individuals are designated by title as intern, trainee, or student, and the individuals work under the direct supervision of a duly licensed clinical laboratory practitioner who is responsible for reporting test results.

324.1309. 1. Any person who holds a license under sections 324.1300 to 324.1340 may use the titles "clinical laboratory scientist", "categorical laboratory scientist", "clinical laboratory technician", or "clinical laboratory assistant". No other person may use such titles or shall assume any title or use any abbreviation or any other words, letters, signs, or devices to indicate that the person using the same is a clinical laboratory scientist, categorical laboratory scientist, clinical laboratory technician, or a clinical laboratory assistant.

2. No person shall practice or offer to practice within the scope of practice of licensees under sections 324.1300 to 324.1340 for compensation or use any title, sign, abbreviation, card, or device to indicate that such person is practicing unless he has been duly licensed under the provisions of sections

324.1300 to 324.1340.

324.1312. 1. There is hereby created within the division of professional registration, the "Clinical Laboratory Science Board" which shall guide, advise, and make recommendations to the division and fulfill other responsibilities designated by sections 324.1300 to 324.1340. The board shall approve the examinations required by and shall assist the division in carrying out the provisions of sections 324.1300 to 324.1340.

2. The board shall consist of seven voting members, including one public member, appointed by the governor with the advice and consent of the senate. Each member of the board shall be a citizen of the United States, a resident of this state for at least one year and a registered voter. Except for the public member, board membership shall consist of one licensed physician, one non-physician laboratory director, one licensed physician who is not a laboratory director or pathologist, two clinical laboratory scientists, and one clinical laboratory technician. Members shall serve on the board until a successor is appointed by the governor.

3. Beginning with the appointments made after August 28, 2009, three voting members shall be appointed for four years, two voting members shall be appointed for three years and two voting members shall be appointed for two years. Thereafter, all voting members shall be appointed to serve four-year terms. The membership of the board shall reflect the differences in work experience and the professional affiliations with consideration being given to race, gender and ethnic origins.

4. A vacancy in the office of a member shall be filled by

appointment by the governor for the remainder of the unexpired term.

5. The board shall hold an annual meeting at which it shall elect from its membership a chairperson and vice chairperson. The board may hold such additional meetings as may be required in the performance of its duties. A quorum of the board shall consist of a majority of its voting members.

6. The governor may remove a board member for misconduct, incompetence or neglect of official duties after giving the board member written notice of the charges and allowing the board member an opportunity to be heard. Members can also be terminated for the following reasons: change of legal residence by moving out of the state; missing three consecutive meetings; or having the professional license revoked or suspended.

7. The public member shall at the time of appointment, not have been a member of any profession licensed or regulated under sections 324.1300 to 324.1340 or an immediate family member of such a person; and may not have had a material, financial interest in either the providing of any service governed by sections 324.1300 to 324.1340 or in an activity or organization directly related to any profession licensed or regulated by sections 324.1300 to 324.1340. The duties of the public member shall not include any determination of the technical requirements to be met for licensure, whether a candidate for licensure meets such technical requirements, or of the technical competence or technical judgment of a licensee or a candidate for licensure.

8. Notwithstanding any other provision of law to the contrary, any appointed member of the board shall receive as

compensation an amount established by the director of the division of professional registration not to exceed seventy dollars per day for commission business plus actual and necessary expenses.

9. No licensing activity or other statutory requirements shall become effective until expenditures or personnel are specifically appropriated for the purpose of conducting the business as required to administer the provisions of sections 324.1300 to 324.1340 and the initial rules filed have become effective.

10. The board shall keep records of its official acts, and certified copies of any such records attested by a designee of the board shall be received as evidence in all courts to the same extent as the board's original records would be received.

11. All funds received by the board under the provisions of sections 324.1300 to 324.1340 shall be collected by the director who shall transmit the funds to the department of revenue for deposit in the state treasury to the credit of the "Clinical Laboratory Science Fund" which is hereby created. The state treasurer shall be custodian of the fund and shall approve disbursements from the fund in accordance with sections 30.170 and 30.180, RSMo. Upon appropriation, money in the fund shall be used solely for the administration of sections 324.1300 to 324.1340. Notwithstanding the provisions of section 33.080, RSMo, to the contrary, money in this fund shall not be transferred and placed to the credit of general revenue until the amount in the fund at the end of the biennium exceeds three times the amount of the appropriation from the fund for the preceding

fiscal year. The state treasurer shall invest moneys in the fund in the same manner as other funds are invested. Any interest and moneys earned on such investments shall be credited to the fund.

324.1315. 1. The board is authorized to promulgate rules and regulations regarding:

(1) The content of license applications and the procedures for filing an application for an initial or renewal license in this state;

(2) The content, conduct and administration of the licensing examinations required by sections 324.1300 to 324.1340;

(3) Educational or experience requirements for licensure;

(4) The standards and methods to be used in assessing competency as a clinical laboratory scientist, categorical laboratory scientist, clinical laboratory technician, or a clinical laboratory assistant;

(5) All applicable fees, set at a level to produce revenue which shall not exceed the cost and expense of administering the provisions of sections 324.1300 to 324.1340;

(6) Establishment of procedures for granting reciprocity with other states.

2. Any rule or portion of a rule, as that term is defined in section 536.010, RSMo, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536, RSMo, and, if applicable, section 536.028, RSMo. This section and chapter 536, RSMo, are nonseverable and if any of the powers vested with the general assembly under chapter 536, RSMo, to review, to delay the effective date, or to disapprove and

annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2009, shall be invalid and void.

324.1318. The division shall:

(1) Employ, within the funds appropriated, any such employees, as defined in section 620.010 that are necessary to carry out the provisions of sections 324.1300 to 324.1340; and

(2) Exercise all budgeting, purchasing, reporting and other related management functions.

324.1321. 1. Any applicant for a license under sections 324.1300 to 324.1340 shall authorize the board to conduct a criminal background check.

2. The cost of such background check shall be paid by the applicant.

324.1324. 1. Applications for licensure as a clinical laboratory scientist, categorical laboratory scientist, clinical laboratory technician, and clinical laboratory assistant shall be in writing, submitted on forms prescribed by the board and furnished to the applicant. Each application shall contain a statement that it is made under oath or affirmation and that the information contained therein is true and correct to the best knowledge and belief of the applicant, subject to the penalties provided for the making of a false affidavit or declaration.

Each application shall be accompanied by the fees required by the board.

2. An applicant for licensure under subsection 1 of this section shall be at least 18 years of age.

3. Each applicant shall furnish evidence to the board of

the applicant's education, experience, and such other information as the board may require.

4. Licenses shall be awarded to applicants as follows:

(1) The board shall issue a clinical laboratory scientist's license to an individual who possesses a baccalaureate degree from a regionally accredited college or university, has acceptable clinical laboratory experience or training, and passes a nationally recognized certification examination authorized by the board;

(2) The board shall issue a categorical clinical laboratory scientist's license to an individual who possesses a baccalaureate degree from a regionally accredited college or university, has acceptable clinical laboratory experience or training, and passes a nationally recognized certification examination in a recognized discipline of laboratory science authorized by the board. The laboratory discipline will be specified on the license;

(3) The board shall issue a clinical laboratory technician's license to an individual who possesses an associate degree from a regionally accredited college or university, has acceptable laboratory experience or training, and passes a nationally recognized certification examination authorized by the board;

(4) The board shall issue a clinical laboratory assistant's license to an individual who possesses a high school diploma or equivalent, has acceptable experience or training, and passes a nationally recognized certification examination authorized by the board, if applicable.

5. The board shall issue a temporary license to practice without examination to an applicant who has duly become licensed in any profession to practice within the scope of practice of licensees under sections 324.1300 to 324.1340 to the laws of another state, territory, or foreign country if the applicant meets the qualifications required of such licensee in this state at the time the applicant was originally licensed in the other state, territory, or foreign country. Temporary license shall be issued to an applicant eligible to sit for and registered to take the next scheduled certification examination, has taken the examination and is awaiting the results, or is seeking to qualify for the certification examination by completing the supervised clinical laboratory experience required if the applicant meets the education requirements for licensure. Upon application, the board shall issue a temporary license to an applicant who has made a prima facie showing that the applicant meets all of the requirements for such a license. The temporary license shall be effective only until the board shall have had the opportunity to investigate the applicant's qualifications for licensure under subsection 1 of this section and to notify the applicant that his or her application for a license has been either granted or rejected. In no event shall such temporary license be in effect for more than twelve months after the date of its issuance nor shall such temporary license be renewed or reissued to the same applicant. The holder of a temporary license which has not expired, or been suspended or revoked, shall be deemed to be the holder of a license issued under sections 324.1300 to 324.1340 until such temporary license expires, is terminated or is

suspended or revoked.

6. Any person licensed to practice in this state who has retired or may hereafter retire such practice shall not be required to register as required under sections 324.1300 to 324.1340, provided such person shall file with the board an affidavit which states the date on which the person retired from the practice and such other facts as shall tend to verify the person's retirement as the board deems necessary; provided, however, that if such person thereafter reengage in practice regulated under sections 324.1300 to 324.1340, the person shall reapply with the board as provided by subsections 1 to 3 of this section. The retired applicant shall and will be required to submit evidence of satisfactory completion of the applicable continuing education requirements as well as submitting the current renewal fee as established by the board.

324.1326. 1. All persons collecting blood specimens, processing laboratory specimens, performing, or reporting laboratory tests or consulting regarding clinical laboratory tests, or currently practicing as clinical laboratory practitioners on December 26, 2009, who are certified by or eligible for certification by an agency acceptable to the board, and who have applied to the board on or before December 26, 2009, and have complied with all necessary requirements for such application may continue to perform the duties until the expiration of twelve months after the filing of such application, the denial of the application by the board, or the withdrawal of the application, whichever occurs first.

2. Persons not meeting the education, training, and

experience qualifications for any license described in sections 324.1300 to 324.1332 prior to August 28, 2011, shall be considered to have met the qualifications provided they have three years of acceptable experience at the professional level for which licensure is sought during the five-year period immediately prior to August 28, 2009, and submit to the board the job description of the position which the applicant has most recently performed, attested to by his or her employer. The board shall determine the type of license for which the applicant is eligible.

3. Effective August 28, 2011, no initial license shall be issued until an applicant meets all of the requirements under section 324.1300 to 324.1340 and successfully passes a board approved certification examination. This section does not apply to temporary licenses.

324.1328. 1. The division shall mail a renewal notice to the last known address of each licensee prior to the renewal date. Failure to receive this notice does not relieve the licensee of the obligation to renew the license to practice.

2. A new license to replace any license lost, destroyed or mutilated may be issued subject to the rules of the board upon payment of a fee.

324.1332. 1. A licensee may choose not to renew his or her license and thereby allow such license to lapse, or may ask to be put on inactive status, provided such person does not practice during such period that the license is lapsed or the practitioner is on inactive status. If a person with a lapsed license desires to resume professional practice, the person shall apply for

licensure under the licensing requirements in effect at the time the person applies to resume practice and pay the required fee and meet the continuing education requirement as established by the board. If the person desires to maintain such license on an inactive status and in order to avoid lapsing of such license, the person shall pay the required fee as established by the board for maintaining an inactive license. An inactive license shall be renewed biennially. An inactive license may be reactivated by the board as provided by rule.

2. Any person who practices as a clinical laboratory scientist, categorical laboratory scientist, clinical laboratory technician, or a clinical laboratory assistant during the time his or her license is inactive or lapsed shall be considered an illegal practitioner and shall be subject to the penalties for violation of sections 324.1300 to 324.1340.

324.1334. 1. The board may refuse to issue any license or renew any license required by the provisions of sections 324.1300 to 324.1340 for one or any combination of reasons stated in subsection 2 of this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of the right to file a complaint with the administrative hearing commission as provided in chapter 621, RSMo.

2. The board may cause a complaint to be filed with the administrative hearing commission as provided in chapter 621, RSMo, against the holder of any license required by sections 324.1300 to 324.1340 or any person who has failed to renew or has surrendered the person's license for anyone or any combination of

the following causes:

(1) Use of fraud, deception, misrepresentation or bribery in securing a license issued under the provisions of sections 324.1300 to 324.1340 or in obtaining permission to take any examination required under sections 324.1300 to 324.1340;

(2) Impersonation of any person holding a license or allowing any person to use his or her license or diploma from any school;

(3) Disciplinary action against the holder of a license or other right to practice any profession within the scope of practice of licensees under sections 324.1300 to 324.1340 by another state, territory, federal agency or country upon grounds for which revocation or suspension is authorized in this state;

(4) Issuance of a license based upon a material mistake of fact;

(5) The person has committed any criminal offense, whether or not a criminal charge has been filed:

(a) For any offense committed during the course of the practice of the profession; or

(b) For any offense reasonably related to the qualifications, functions or duties of the profession; or

(c) For any offense an essential element of which is fraud, dishonesty or act of violence; or

(d) For any offense involving moral turpitude;

(6) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of the profession that is regulated by sections 324.1300 to 324.1340;

(7) Violation of, or assisting or enabling any person to violate, any provision of sections 324.1300 to 324.1340, or any lawful rule or regulation adopted under such sections;

(8) A person is finally adjudged insane or incompetent by a court of competent jurisdiction;

(9) Use of any advertisement or solicitation that is false, misleading or deceptive to the general public or persons to whom the advertisement or solicitation is primarily directed;

(10) Obtaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation;

(11) Unlawful use or unlawful possession of any controlled substance, as defined in chapter 195, RSMo, or use of alcoholic beverages to an extent that such use impairs a person's ability to perform the work of any profession that is licensed or regulated by sections 324.1300 to 324.1340;

(12) Violation of any professional trust or confidence.

3. Any person, organization, association or corporation who reports or provides information to the board in compliance with the provisions of sections 324.1300 to 324.1340 and who does so in good faith shall not be subject to an action for civil damages as a result thereof.

4. After the filing of a complaint under subsection 2 of this section, the proceedings shall be conducted in accordance with the provisions of chapter 621, RSMo. Upon a finding by the administrative hearing commission that the grounds, provided in subsection 2 of this section, for disciplinary action are met, the board may, singly or in combination, censure or place the

person named in the complaint on probation on such terms and conditions as the board deems appropriate for a period not to exceed five years, or may suspend, for a period not to exceed three years, or revoke the license of the person. An individual whose license has been revoked shall wait three years from the date of revocation to apply for relicensure. Relicensure shall be at the discretion of the board after compliance with all requirements of sections 324.1300 to 324.1340 relative to the licensing of an applicant for the first time.

5. The board shall maintain an information file containing each complaint filed with the board relating to a holder of a license.

6. The board shall recommend for prosecution violations of sections 324.1300 to 324.1340 to an appropriate prosecuting or circuit attorney.

324.1336. 1. Upon proper application by the board, a court of competent jurisdiction may grant an injunction, restraining order, or other order as may be appropriate to enjoin a person from:

(1) Offering to engage or engaging in the performance of any acts or practices for which a certificate of registration or authority, permit or license is required by sections 324.1300 to 324.1340 upon a showing that such acts or practices were performed or offered to be performed without a certificate of registration or authority, permit or license; or

(2) Engaging in any practice or business authorized by a certificate of registration or authority, permit or license issued under sections 324.1300 to 324.1340 upon a showing that

the holder presents a probability of serious danger to the health, safety or welfare of any resident of the state or client or patient.

2. Any such actions shall be commenced either in the county in which such conduct occurred or in the county in which defendant resides.

3. Any action brought under this section shall be in addition and not in lieu of any penalty provided by law and may be brought concurrently with other actions to enforce sections 324.1300 to 324.1340.

324.1338. After twenty-four months following August 28, 2009, any person who violates any provision of sections 324.1300 to 324.1340 shall be guilty of a class A misdemeanor.

324.1340. 1. The chairperson of the board may administer oaths, issue subpoenas duces tecum and require production of documents and records. Subpoenas duces tecum shall be served by a person authorized to serve subpoenas of courts of record. In lieu of requiring attendance of a person to produce original documents in response to a subpoena duces tecum, the board may require sworn copies of such documents to be filed with it or delivered to its designated representative.

2. The board may enforce its subpoenas duces tecum by applying to a circuit court of Cole County, the county of the investigation, hearing or proceeding, or any county where the person resides or may be found, for an order upon any person who shall fail to comply with a subpoena duces tecum to show cause why such subpoena should not be enforced, which such order and a copy of the application therefore shall be served upon the person

in the same manner as a summons in a civil action, and if the circuit court shall, after a hearing, determine that the subpoena duces tecum should be sustained and enforced, such court shall proceed to enforce the subpoena duces tecum in the same manner as though the subpoena duces tecum had been issued in a civil case in the circuit court.