FIRST REGULAR SESSION

HOUSE BILL NO. 550

93RD GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE WASSON.

Read 1st time February 15, 2005 and copies ordered printed.

STEPHEN S. DAVIS, Chief Clerk

1393L.01I

AN ACT

To amend chapter 324, RSMo, by adding thereto twelve new sections relating to clinical laboratories, 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 twelve new sections, to

- 2 be known as sections 324.1160, 324.1163, 324.1166, 324.1169, 324.1172, 324.1175, 324.1178,
- 3 324.1181, 324.1184, 324.1187, 324.1190, 324.1193, to read as follows:

324.1160. As used in sections 324.1160 to 324.1193 the following terms shall mean:

- 2 (1) "Accredited clinical laboratory science/medical technology education program", 3 a program designed to provide a predetermined amount of instruction and experience in 4 clinical laboratory science/medical technology, that has been accredited by an accrediting 5 agency defined by the board or a program recognized by the United State Department of
- **Education**;

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- (2) "Approved national certification examination", a competency based certification examination approved by the department that is administered by a national nonprofit certifying organization including the National Credentialing Agency, Board of Registry of the American Society for Clinical Pathology, and American Medical Technologists, or others as determined by the board;
- (3) "Board", the clinical laboratory science board appointed by the governor;
- 13 (4) "Categorical technologist/scientist", an individual eligible under sections 14 324.1160 to 324.1193 who is responsible for performance, interpreting, and reporting 15 clinical laboratory testing in one or more category or categories of laboratory testing, such

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

as microbiology, clinical chemistry, immunology, hematology, immunohematology, molecular diagnostics, or other areas specified by the board. The categorical technologist/scientist is responsible for the establishment and implementation of protocols, quality assessment, method development and selection, equipment selection and maintenance, and all activities related to the preanalytical, analytical and postanalytical phases of testing in his or her specialty area. The categorical technologist/scientist may also direct, supervise, consult, educate, and perform research functions in his or her specialty area;

- (5) "Clinical laboratory" or "laboratory", any site or location in which clinical laboratory tests or examinations are performed;
- (6) "Clinical laboratory improvement amendments", the final regulations promulgated by the United states Department of Health and Human Services implementing the clinical laboratory improvement amendments of 1988, as such regulations may be amended from time to time;
- (7) "Clinical laboratory practitioner", a clinical laboratory director, supervisor, technologist, or technician who performs or is responsible for laboratory test procedures, but the term does not include trainees, persons who perform screening for blood banks or plasmapheresis centers, phlebotomists, laboratory assistants, or persons employed by a clinical laboratory to perform manual pretesting duties or clerical, personnel, or other administrative responsibilities, or persons engaged in waived testing as defined by and performed in laboratories regulated by the clinical laboratory improvement amendments;
- (8) "Clinical laboratory scientist/medical technologist", an individual eligible under sections 324.1160 to 324.1193 who is responsible for performance, interpreting, and reporting any clinical laboratory test including those that require the exercise of independent judgment. In addition, this individual is responsible for the establishment and implementations of protocols, quality assessment, method development and selection, equipment selection and maintenance, and all activities related to the preanalytical, analytical and postanalytical phases of testing. The clinical laboratory scientist/medical technologist may also direct, supervise, consult, educate, and perform research functions;
- (9) "Clinical laboratory technician/medical laboratory technician", an individual eligible under sections 324.1160 to 324.1193 who is responsible for performance, interpreting and reporting clinical laboratory tests under established and approved protocols which require limited exercise of independent judgment and which are performed with oversight from a clinical laboratory scientist/medical technologist, technical consultant/supervisor or laboratory director as defined by the clinical laboratory improvement amendments;

(10) "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 existing in a human body which provides information for the diagnosis, prevention or monitoring of a disease or impairment or assessment of a clinical condition. Clinical laboratory testing encompasses the preanalytical, analytical and postanalytical phases of testing;

- (11) "Department", the department of economic development created under section 620.010, RSMo;
- (12) "Director", the director of the division of professional registration created under section 620.010, RSMo;
- (13) "Phlebotomist", an individual eligible under sections 324.1160 to 324.1193 who is responsible for obtaining a blood specimen by venipuncture or capillary puncture under established and approved protocols and which are performed with oversight of a clinical laboratory scientist/medical technologist, technical consultant/supervisor or laboratory director as defined by the clinical laboratory improvement amendments;
- (14) "Point of care testing/bedside testing", clinical laboratory testing that is so critical to patient care that it must be performed immediately at or near the patient. Tests meeting this definition provide clinically relevant information which direct therapy, are limited to procedures that produce accurate and precise data in a short period of time, meet the current standards of quality in clinical laboratory science, and comply with all standards of accrediting agencies;
- (15) "Provider performed microscopy procedures", microscopy testing as defined by the clinical laboratory improvement amendments;
- (16) "Waived", "moderate complexity and high complexity", refers to the categories of clinical laboratory test complexity as defined by the clinical laboratory improvement amendments;

324.1163. 1. Sections 324.1160 to 324.1193 shall not apply to:

- (1) Physicians certified by the American Board of Pathology or American Board of Osteopathic Pathology and licensed by the state and PhD clinical laboratory directors as defined by the clinical laboratory improvement amendments;
- (2) 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;
- (3) Clinical laboratory 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;

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11 (4) Students or trainees enrolled in an accredited clinical laboratory 12 science/medical technology education program provided that their activities constitute a 13 part of a designed course in the program, that the persons are designated by title such as 14 intern, trainee, or student, and the persons work under the direct supervision of a duly 15 licensed clinical laboratory practitioner who is responsible for reporting test results;

- (5) Any person solely performing waived tests as defined by clinical laboratory improvement amendments;
- (6) Respiratory therapists, respiratory care practitioners, and perfusionists licensed in the state to the extent that such practitioners perform tests within the scope of their professional practice and training;
- (7) Personnel who perform provider performed microscopy procedures and meet the requirements as defined by clinical laboratory improvement amendments;
 - (8) Personnel performing point of care/bedside testing provided.
- 2. A licensed clinical laboratory scientist/medical technologist, categorical scientist/technologist, clinical laboratory technician/medical laboratory technician or licensed physician shall be responsible for:
- (1) Designing and providing or supervising the training programs for the point of care/bedside testing personnel;
- (2) Supervising and monitoring the quality assurance and quality control activities of the testing;
 - (3) Assisting in the selection of technology;
- 32 (4) Reviewing the results of proficiency testing and recommending corrective action, if necessary; and
 - (5) Monitoring the continued competency of the testing personnel.
 - 324.1166. 1. In this state no person shall perform, interpret, report, or consult regarding clinical laboratory tests unless licensed under sections 324.1160 to 324.1193. The department may grant a temporary license to any candidate it deems properly qualified.
 - 2. All persons performing, interpreting, reporting, or consulting regarding clinical laboratory tests or defined as a clinical laboratory practitioner on the effective date of sections 324.1160 to 324.1193, existing practitioners, who are certified by or eligible for certification by an agency acceptable to the department, and who have applied to the department on or before the effective date and have complied with all necessary requirements for such application may continue to perform clinical laboratory tests until:
 - (1) The expiration of twelve months after the filing of such application; or
 - (2) The denial of the application by the department; or
- 12 (3) The withdrawal of the application, whichever occurs first.

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3. Effective twenty four months after the effective date of sections 324.1160 to 324.1193, no initial license shall be issued until an applicant meets all of the requirements under sections 324.1160 to 324.1193 and successfully passes an approved national certification examination.

4. A person not meeting the education, training, and experience qualifications for any license described herein, prior to twenty-four months after the effective date of sections 324.1160 to 324.1193, shall be considered to have met the qualifications providing he or she has three years of acceptable experience at the professional level for which licensure is sought during the five-year period immediately prior to the effective date of sections 324.1160 to 324.1193, and submits to the board the job description of the position which the applicant has most recently performed, attested to by his or her employer.

324.1169. 1. The provisions of sections 324.1160 to 324.1193 shall be administered by the department. The director shall promulgate rules consistent with the provisions of sections 324.1160 to 324.1193 for the administration and enforcement thereof, and may prescribe forms which shall be issued in connection therewith. The rules shall include standards and criteria for licensure and professional conduct and discipline. The department shall consult with the board in promulgating rules. Notice of proposed rulemaking shall be transmitted to the board and the department shall review the board's response and any recommendations made therein. The department shall notify the board in writing with an explanation of its deviations from the board's recommendations and response. The department shall solicit the advice and expert knowledge of the board on any matter relating to the administration and enforcement of sections 324.1160 to 324.1193. The department shall issue to the board a quarterly report of the status of all complaints related to the profession received by the department.

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 pursuant to 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, 2005, shall be invalid and void.

324.1172. 1. The "Clinical Laboratory Science Board" shall be established within the department and shall be composed of seven members appointed by the governor. One member of the board shall be a practicing clinical laboratory director, two members of the board shall be practicing clinical laboratory supervisors, two members of the board shall

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be practicing clinical laboratory practitioners, two members of the board shall be citizens of the state who have never been licensed health care practitioners and who are not, and have never been, licensed as clinical laboratory personnel and who are in no way connected with the practice of such profession.

- 2. Within ninety days after passage of sections 324.1160 to 324.1193 the governor shall appoint two members for a term of two years, two members for a term of three years, and three members for a term of four years. As terms of the initial members expire, the governor shall appoint successors for terms of four years. A member whose term has expired shall continue to serve on the board until such time as a replacement is appointed. Whenever a vacancy shall occur on the board by reason other than the expiration of a term of office, the governor shall appoint a successor of like qualifications for the remainder of the unexpired term. No member shall serve for more than the remaining portion of a previous member's unexpired term, plus two consecutive four-year terms of the member's own appointment thereafter.
- 324.1175. 1. The department shall prescribe minimum standards for clinical laboratory practitioners and shall issue a license to any person who meets the minimum standards and who demonstrates the education, training, and ability to qualify for the license category sought. The department shall issue a clinical laboratory scientist/medical technologist license to an individual who meets standards as promulgated by the department to include successful passing of an approved clinical laboratory scientist/medical technologist certification examination and at least one of the following:
- (1) Baccalaureate degree in clinical laboratory science/medical laboratory sciences from an accredited college or university, and successful completion of one of the following:
- (a) An accredited clinical laboratory science/medical technology education program;
- (b) Successful completion of a fifty-week or more military medical laboratory training program; or
- 14 (2) Baccalaureate degree from an accredited college or university and completion 15 of thirty-six semester hours in the biological, chemical, or medical laboratory sciences, in 16 addition to or part of the baccalaureate degree, and successful completion of one of the 17 following:
- 18 (a) An accredited clinical laboratory science/medical technology education 19 program;
- 20 **(b)** Successful completion of a fifty-week or more military medical laboratory 21 training program; or
- 22 (3) Baccalaureate degree from an accredited college or university and completion

of thirty-six semester hours in the biological, chemical, or medical laboratory sciences, in addition to or part of the baccalaureate degree. Certified as a clinical laboratory technician/medical laboratory technician, and completion of the equivalent of two years of full-time clinical laboratory work experience as defined by the board;

- (4) Baccalaureate degree from an accredited college or university and completion of thirty-six semester hours in the biological, chemical, or medical laboratory sciences, and completion of acceptable clinical laboratory work experience as defined by the board.
- 2. The department shall issue a categorical scientist/technologist license to an individual who meets such standards as promulgated by the department, to include successful passing of an approved certification examination at the categorical level and at least one of the following:
- (1) For the categories of microbiology and chemistry, a baccalaureate degree from an accredited college or university, successful completion of thirty semester hours in the biological, chemical, or medical laboratory sciences; and
- (a) Successful completion of a structured training program that is under the auspices of an accredited clinical laboratory science/medical technology education program in the category for which licensure is sought;
- (b) One year of full-time experience in the category for which licensure is sought. Completion of the clinical laboratory work experience shall be under the supervision of a licensed clinical laboratory scientist/medical technologist;
- (2) For the categories of hematology, immunology, and immunohematology, a baccalaureate degree from an accredited college or university, successful completion of thirty semester hours in the biological, chemical, or medical laboratory sciences; and
- (a) Successful completion of a structured training program that is under the auspices of an accredited clinical laboratory science/medical technology education program in the category for which licensure is sought;
- (b) Two years of full-time experience in the category for which licensure is sought. Completion of the clinical laboratory work experience shall be under the supervision of a licensed clinical laboratory scientist/medical technologist; or
- (3) A masters or doctorate in a chemical, biological, or medical laboratory science from an accredited college or university and six months of full-time acceptable clinical laboratory experience or clinical laboratory training in the category for which licensure is sought;

The department may establish other categorical technologist/scientist licenses as necessary,

59 provided such licenses require a baccalaureate or graduate degree in a

60 chemical, biological, or medical laboratory science, clinical training or work experience 61 and passing of a certification exam.

- 3. The department shall issue a clinical laboratory technician/medical laboratory technician license to an individual who meets standards as promulgated by the department, to include successful passing of a certification examination at the clinical laboratory technician/medical laboratory technician
- 66 level and at least one of the following:

- (1) Associate's degree or sixty semester hours from an accredited postsecondary academic institution and successful completion of an accredited clinical laboratory technician/medical laboratory technician education program; or
- (2) Associate's degree or sixty semester hours from an accredited postsecondary academic institution with twenty-four semester hours of college course work in the biological, chemical, or medical laboratory sciences, including six semester hours of chemistry and six semester hours of biology and successful completion of a fifty-week or more military medical
- 75 laboratory training program; or
 - (3) Associate's degree or sixty semester hours from an accredited postsecondary academic institution with twenty-four semester hours of college course work in the biological, chemical, or medical laboratory sciences, including six semester hours of chemistry and six semester hours of biology and successful completion of an approved laboratory/clinical assistant education program, and completion of an acceptable clinical laboratory work experience as defined by the board. Clinical laboratory work experience shall be under the supervision of a certified clinical laboratory scientist/medical technologist, clinical laboratory technician/medical laboratory technician, categorical scientist/technologist or the equivalent; or
 - (4) Associate's degree or sixty semester hours from an accredited postsecondary academic institution with twenty-four semester hours of college course work in the biological, chemical, or medical laboratory sciences, including six semester hours of chemistry and six semester hours of biology and completion of acceptable clinical laboratory work experience as defined by the board. Completion of the laboratory work experience shall be under the supervision of a certified clinical laboratory scientist/medical technologist, clinical laboratory technician/medical laboratory technician, categorical scientist/technologist or the equivalent.
 - 4. The department shall issue a phlebotomist license to an individual who meets standards as promulgated by the department, to include successful passing of a

95 certification examination at the phlebotomist level and a high school degree or equivalent.

324.1178. 1. Licensure applicants that qualify by education, experience, or training but have not taken or passed an approved certification examination may be granted a temporary license that will allow that individual to engage in the practice of clinical laboratory science at the appropriate level. The temporary license shall be valid for twelve months and can be renewed once upon failure to pass an approved recognized certification examination authorized by the department.

2. Internationally trained licensure applicants shall have their transcripts evaluated by a transcript evaluation agency acceptable to the department and submitted directly to an approved national certification agency. The evaluation shall indicate the applicant's education is equivalent to that which is required for licensure of United States graduates at the level of licensure being sought. Upon submission of proof to the department of acceptance to sit for the certification examination the individual may apply for a temporary license in the corresponding category.

324.1181. 1. The department shall promulgate rules providing procedures for waiver of the requirements under section 324.1175 for all applicants who hold a valid license or equivalent issued by another state; provided that the requirements under which that license or equivalent was issued are equivalent to or exceed the standards required by sections 324.1160 to 324.1193.

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 pursuant to 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, 2005, shall be invalid and void.

324.1184. 1. The department, by rule, shall establish fees to be paid for application, licensing and renewal, reinstatement, and recordmaking and recordkeeping. The department may also establish, by rule, a delinquency fee. The department shall establish fees that are adequate to ensure the continued operation of the board and to fund the proportionate expenses incurred by the department in carrying out its licensure and other related responsibilities under sections 324.1160 to 324.1193. Fees shall be based on departmental estimates of the revenue required to implement this subsection and the provisions of law with respect to the regulation of clinical laboratory practitioners.

2. An application for a clinical laboratory practitioner license shall be made under

oath on the forms prescribed and furnished by the department, and the applicant shall pay
the designated nonrefundable application fee.

- 3. Upon receipt of a nonrefundable initial application fee and payment of a license fee, the department shall issue a license for a clinical laboratory scientist/medical technologist, categorical scientist/technologist, clinical laboratory technician/medical laboratory technician, phlebotomist to any person who meets the qualifications specified in sections 324.1160 to 324.1193 and the rules and regulations promulgated hereunder.
- 4. 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 pursuant to 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, 2005, shall be invalid and void.
- 324.1187. 1. The department shall adopt rules establishing a procedure for the biennial renewal of clinical laboratory practitioner licenses. A license issued under sections 324.1160 to 324.1193 shall expire two years after receipt. The license of any person who fails to pay a required fee or otherwise fails to qualify within sixty days after the date of expiration of such license shall be automatically canceled without notice or further proceedings unless the individual has made application for inactive status.
- 2. A licensee may request that their license be placed in an inactive status by making application to the department and paying a fee in an amount set by the department. A license that has been inactive for more than one year may be reactivated upon application to the department. The department shall prescribe, by rule, continuing education requirements as a condition of reactivating a license. The continuing education requirements for reactivating a license shall not exceed twelve contact hours for each year the license was inactive not to exceed thirty-six hours total, except for phlebotomists which require three contact hours for each year the license was inactive, not to exceed nine hours total.
- 3. Every person licensed under sections 324.1160 to 324.1193 shall be issued a renewal license upon:
- **(1) Submission of an application for renewal on a form prescribed by the** 20 **department; and**
 - (2) Payment of an appropriate fee determined by the department; and

22 (3) Upon certification by the board that the licensee has demonstrated continued competence.

- 4. Periodic demonstration of competency is required under sections 324.1160 to 324.1193.
 - (1) As part of the license renewal procedure, the department, by rule, shall require proof of completion, in the period since the license was first issued or last renewed, of at least twenty-four hours of continuing education courses, clinics, lectures, training programs, seminars, or other programs related to clinical laboratory practice which are approved or accepted by the department; or proof of recertification by an approved certification agency that mandates an annual minimum of twelve hours of continuing education.
 - (2) Phlebotomists shall be required to have an annual minimum of three hours of continuing education courses, clinics, lectures, training programs, seminars, or other programs related to clinical laboratory practice which are approved or accepted by the department.
 - (3) The department may require other such evidence of competency as it shall deem reasonably appropriate as a prerequisite to the renewal of any license provided for in sections 324.1160 to 324.1193, so long as such 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.
 - 5. 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 pursuant to 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, 2005, shall be invalid and void.
 - 324.1190. 1. The department may refuse to issue or renew, or may revoke a license, or may suspend, place on probation, censure or reprimand a licensee, or may take such other disciplinary action as the department may deem appropriate, including the imposition of a civil penalty not to exceed five thousand dollars for unprofessional, unethical, or unlawful conduct that may include but not necessarily be limited to:
 - (1) Providing a material misstatement in furnishing information to the department;
 - (2) Violating or demonstrating a negligent or intentional disregard of sections 324.1160 to 324.1193, or of the rules or regulations promulgated hereunder;

- 9 (3) Being convicted or entering a plea of nolo contendere of any crime under the laws of the United States or any state or territory thereof which is a felony or which is a misdemeanor, which directly relates to the activities of clinical laboratory practice, including moral turpitude, dishonesty, and elderly or child abuse;
 - (4) Making any misrepresentation for the purpose of obtaining registration or violating any provision of sections 324.1160 to 324.1193;
 - (5) Demonstrating professional incompetence or making consistent errors in the performance of clinical laboratory testing or erroneous reporting;
 - (6) Malpractice;

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- (7) Failing, within sixty days, to provide information in response to a written request made by the department;
- (8) Having been disciplined by another state, territory, or country if at least one of the grounds for the discipline is the same or substantially equivalent to those set forth herein;
- (9) Directly or indirectly giving to or receiving from any person, firm, corporation, partnership or association any fee, commission, rebate or other form of compensation for any professional services not actually rendered;
- (10) A finding by the department that the licensee, after having his or her license placed on probationary status, has violated the terms of probation;
- (11) Willfully making or filing false records or reports in his or her practice, including but not limited to, false records filed with state agencies or departments;
 - (12) Violating any standard of professional conduct adopted by the department;
- 31 (13) Engaging in dishonorable, unethical or unprofessional conduct of a character 32 likely to deceive, defraud, or harm the public;
 - (14) Jeopardizing patient safety by providing professional services while mentally incompetent or under the influence of alcohol, a narcotic or a controlled substance that is in excess of therapeutic amounts or without valid medical indication;
 - (15) Directly or indirectly contracting to perform clinical laboratory tests in a manner which offers or implies an offer of rebate, fee-splitting inducements or arrangements, or other remuneration; or
 - (16) Aiding or assisting another person in violating any provision of sections 324.1160 to 324.1193 or any rule adopted hereunder.
 - 2. The determination by a circuit court that a licensee is subject to involuntary admission or judicial admission as provided in the mental health and developmental disabilities code operates as an automatic suspension. Only upon a finding by a court that the licensee is no longer subject to involuntary admission or judicial admission and the

issuance of an order so finding and discharging the licensee, the suspension shall be terminated and the licensee shall be allowed to resume practice.

- 3. The department may refuse to issue or may suspend the license of any person who fails to file a return, or to pay the tax, penalty or interest shown in a filed return, or to pay any final assessment of tax, penalty or interest, as required by any tax laws administered by the department of revenue, until such time as the requirements of such tax laws are satisfied.
- 324.1193. 1. If any person violates a provision of sections 324.1160 to 324.1193, the director may, in the name of the state, through the attorney general, petition for an order enjoining such violation or for an order enforcing compliance with sections 324.1160 to 324.1193. Upon the filing of a verified petition in such court, the court may issue a temporary restraining order, without notice or bond, and may preliminarily and permanently enjoin such violation, and if it is established that such person has violated or is violating this injunction, the court may punish the offender for contempt of court. Proceedings under this section shall be in addition to, and not in lieu of, all other remedies and penalties provided by sections 324.1160 to 324.1193.
 - 2. If any person shall practice as a clinical laboratory practitioner or hold himself or herself out as such without having a valid license required under the provision of sections 324.1160 to 324.1193, then any licensee, any interested party or any person injured thereby may, in addition to the director, petition for relief as provided in subsection 1 of this section.
 - 3. Whenever in the opinion of the department any person violates any provision of sections 324.1160 to 324.1193, the department may issue a rule to show cause why an order to cease and desist should not be entered against him or her. The rule shall clearly set forth the grounds relied upon by the department and shall provide a period of seven days from the date of the rule to file an answer to the satisfaction of the department. Failure to answer to the satisfaction of the department shall cause an order to cease and desist to be issued forthwith.
 - 4. The department may investigate the actions of any applicant or of any person or persons holding or claiming to hold a license to engage in the practice of clinical laboratory science. Before refusing to issue or renew a license, the department shall notify in writing the applicant or holder of the nature of the charges and that a hearing will be held on the date designated. Such notice shall be sent at least ten calendar days prior to the date set for the hearing. Such written notice may be served by personal delivery or certified or registered mail to the respondent at the address of his or her last notification to the department. At the time and place fixed in the notice, the board shall proceed to hear the

charges and the parties or his or her counsel shall be accorded ample opportunity to present such statements, testimony, evidence, and argument as may be pertinent to the charges or to the defense thereto. The board may continue such hearing.

- 5. The department, at its expense, shall preserve a record of all proceedings at the formal hearing of any case involving the refusal to issue or renew a license. The notice of hearing, complaint and all other documents in the nature of pleadings and written motions filed in the proceedings, the transcript of testimony, the report of the board and orders of the department shall be the record of such proceedings.
- 6. Any circuit court may, upon application of the department or its designee, or of the applicant or licensee against whom proceedings under this section are pending, enter an order requiring the attendance of witnesses and their testimony, and the production of documents, papers, files, books, and records in connection with any hearing or investigation. The court may compel obedience to its order by proceedings for contempt.
- 7. (1) At the conclusion of the hearing, the board shall present to the director a written report of its findings and recommendations. The report shall contain a finding whether the accused person violated sections 324.1160 to 324.1193 or failed to comply with the conditions required in sections 324.1160 to 324.1193. The board shall specify the nature of the violation or failure to comply, and shall make its recommendations to the director.
- (2) The report of finding of fact, conclusions of law, and recommendations of the board shall be the basis for the department's order for refusal or for the granting of a license or for other disciplinary action. If the director disagrees in any regard with the report of the board, the director may issue an order in contravention thereof. The director shall provide a written report to the board on any deviation and shall specify with particularity the reasons for such action in the final order. The finding is not admissible in evidence against the person in a criminal prosecution brought for the violation of sections 324.1160 to 324.1193, but the hearing and finding are not a bar to a criminal prosecution brought for the violation of sections 324.1160 to 324.1193.
- 8. In any case involving the refusal to issue or renew a license, or to discipline a licensee, a copy of the board's report shall be served upon the respondent by the department, either personally or as provided in sections 324.1160 to 324.1193 for the service of the notice of hearing. Within twenty calendar days after such service, the respondent may present to the department a motion in writing for a rehearing, which motion shall specify the particular grounds therefore. If no motion for rehearing is filed, then upon the expiration of the time specified for filing such a motion, or if a motion for

rehearing is denied, then upon such denial the director may enter an order in accordance with recommendations of the reporting service, and pay for a transcript of the record within the time for filing a motion for rehearing, the twenty-calendar-day period within which such a motion may be filed shall commence upon the delivery of the transcript to the respondent.

- 9. (1) Whenever the director is not satisfied that substantial justice has been done in the revocation, suspension, or refusal to issue or renew a license, the director may order a rehearing by the same or other examiners.
- (2) The director shall have the authority to appoint any attorney duly licensed to practice law in the state to serve as the hearing officer in any action or refusal to issue or renew a license or discipline a licensee. The director shall notify the board of any such appointment. The hearing officer shall have full authority to conduct the hearing. The hearing officer shall report the finding of fact, conclusions of law, and recommendations to the board and the director. The board shall have sixty days from receipt of the report to review the report of the hearing officer and present its own findings of fact, conclusions of law and recommendations to the director. If the board fails to present its report within the sixty-day period, the director shall issue an order based on the report of the hearing officer. If the director disagrees in any regard with the report of the board or hearing officer, he or she may issue an order in contravention thereof. The director shall provide a written explanation to the board of any such deviation and shall specify with particularity the reasons for such action in the final order. At least two licensed clinical laboratory practitioner members of the board shall be present at all formal hearings on the merits of complaints brought under the provisions of sections 324.1160 to 324.1193.
- (3) An order or a certified copy thereof, over the seal of the department and purporting to be signed by the director, shall be prima facie proof of the following:
 - (a) That such signature is the genuine signature of the director;
- (b) That such director is duly appointed and qualified; and (c) The board and the members thereof are qualified to act.
- (10) (a) At any time after the suspension or revocation of any license, the department may restore the license to the accused person, upon the written recommendation of the board, unless after an investigation and a hearing the board determines that restoration is not in the public interest.
- (b) Upon the revocation or suspension of any license, the licensee shall forthwith surrender the license to the department, and if the licensee fails to do so, the department shall have the right to seize the license.
 - (c) The director may temporarily suspend the license of a clinical laboratory

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102 practitioner without a hearing, simultaneously with the institution of proceedings for a hearing of sections 324.1160 to 324.1193, if the director finds that evidence in his or her possession indicates that a clinical laboratory practitioner's continuation in practice would constitute an imminent danger to the public. In the event that the director suspends temporarily the license of a clinical laboratory practitioner without a hearing, a hearing by the board shall be held within thirty calendar days after such suspension has occurred.

(11) Any person who is found to have violated any provision of sections 324.1160 to 324.1193 is guilty of a class A misdemeanor for the first offense, and a class D felony for second and subsequent offenses.