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H. 4611

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Summary: Medical Laboratory Personnel Act

HISTORY OF LEGISLATIVE ACTIONS

DateBodyAction Description with journal page number1/17/2012HouseIntroduced and read first time (House Journal-page 10)1/17/2012HouseReferred to Committee on Medical, Military, Public and Municipal Affairs

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VERSIONS OF THIS BILL

 $\underline{1/17/2012}$

See Bill Below

2 3 4 5 6 7 8 **A BILL** 9 10 TO AMEND THE CODE OF LAWS OF SOUTH CAROLINA, 11 1976, BY ADDING CHAPTER 48 TO TITLE 40 SO AS TO 12 13 ENACT THE "MEDICAL LABORATORY PERSONNEL ACT", PROVIDE CERTAIN DEFINITIONS, TO IMPOSE 14 TO OF **15 REQUIREMENTS** FOR LICENSURE **MEDICAL** 16 LABORATORY PERSONNEL, TO CREATE THE SOUTH 17 CAROLINA BOARD OF CLINICAL LABORATORY SCIENCE 18 AND TO PROVIDE FOR ITS MEMBERSHIP, POWERS, AND 19 DUTIES, AND TO PROVIDE REMEDIES FOR VIOLATIONS 20 OF THIS CHAPTER, AMONG OTHER THINGS. 21 22 Be it enacted by the General Assembly of the State of South 23 Carolina: 24 25 SECTION 1. Title 40 of the 1976 Code is amended by adding: 26 27 **"CHAPTER 48** 28 29 South Carolina Medical Laboratory Personnel Act 30 31 Section 40-48-10. This chapter may be cited as the 'Medical 32 Laboratory Personnel Act'. 33 34 Section 40-48-20. The purpose of this chapter is to protect the 35 public health, safety, and welfare of the people of this State from the hazards of inappropriate collection of specimens and improper 36 performance and reporting of test results by medical laboratory 37 personnel. Medical laboratories provide essential services to 38 practitioners of the healing arts by furnishing vital information that 39 40 is necessary to the determination of the nature, cause and extent of the condition involved and the monitoring of therapy. Unreliable 41 42 and inaccurate reports may cause unnecessary anxiety, suffering,

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and financial burdens and may even contribute directly to death.
 The protection of public and individual health requires the
 licensure of medical laboratory personnel who meet minimum
 educational and training requirements for safe practice. Medical
 laboratory technology continues to advance rapidly. Therefore,
 adherence to practice standards and demonstration of continuing
 competence through documented continuing education is
 imperative for medical laboratory personnel.

9

10 Section 40-48-30. The following terms when used in the 11 chapter mean the following, unless the context requires otherwise:

12 (1) 'Board' means the South Carolina Board of Clinical13 Laboratory Science.

14 (2) 'Department' means Department of Labor, Licensing and15 Regulation.

16 (3) 'Clinical laboratory science' or 'medical laboratory17 technology' means the science related to disease detection,18 diagnosis, and subsequent medical treatment.

(4) 'CLIA' refers to the final regulations promulgated by the 19 20 United States Department of Health and Human Services 21 implementing the Clinical Laboratory Improvement Amendments of 1988 and includes statue number P.L. 200-578 and 42 C.F.R. 22 23 493 from the Code of Federal Regulations, as these regulations 24 may be amended from time to time. CLIA regulations provide a minimum foundation for which personnel standards for entry level 25 26 technical personnel are built. Qualifications and responsibilities for 27 laboratory director, technical supervisor, and technical consultant 28 are as specified in CLIA regulations. All medical laboratory 29 personnel are under the supervision, control, and responsibility of 30 the laboratory director.

(5) 'Clinical laboratory test' or 'laboratory test' means a 31 32 microbiological, serological, molecular, chemical, biological, 33 immunological, hematological, immunohematological, cytogenetics, stem cell processing, 34 electron microscopy, 35 histocompatibility, cellular immunology, flow cytometry, or any 36 other test or procedure performed on material derived from or present within a human body which provides information for the 37 38 diagnosis, prevention, or monitoring treatment of a clinical 39 condition. Clinical laboratory testing encompasses the 40 preanalytical, analytical, and postanalytical phases of testing.

41 (6) 'Medical laboratory' or 'clinical laboratory' means any site 42 or location in which clinical laboratory tests or examinations are 43 performed. These examinations include, but are not limited to,

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procedures to determine, measure, or otherwise describe the
 presence or absence of various substances or organisms in the
 human body. A facility which only collects or prepares specimens,
 or both, or only serves as a mailing service and does not perform
 on site testing is not a medical laboratory.

6 (7) 'Laboratory director' is an individual eligible under CLIA 7 to direct a clinical laboratory.

8 (8) 'Practice of clinical laboratory science' means the 9 performance by any individual, other than a board-certified 10 physician, of laboratory testing, analysis, or examination of human 11 specimens.

12 (9) 'Medical laboratory practitioner' or 'clinical laboratory 13 personnel' or 'medical laboratory personnel' means any and all individuals engaged in the practice of clinical laboratory science 14 which includes a health care professional who withdraws blood 15 16 from the human body by venipuncture or capillary puncture or who performs clinical laboratory tests or who is engaged in 17 18 management, education, consulting or research in clinical 19 laboratory science, and includes laboratory directors, supervisors, 20 medical laboratory scientists (technologists) and technicians 21 working in a clinical laboratory. This does not include persons 22 employed by a clinical laboratory to perform supportive functions not related to direct performance of laboratory tests. 23

(10) 'Licensed clinical laboratory personnel' means personsworking in a clinical laboratory setting who have met thequalifications of this chapter.

27 (11) 'Medical laboratory scientist' or 'MLS' means an 28 individual who performs medical laboratory tests and procedures in a clinical laboratory setting which require the exercise of 29 30 independent technical judgment and responsibility, including, but not limited to, the performance of all laboratory tests as stated in 31 32 the Clinical Laboratory Improvement Amendments of 1988 and the rules and regulations promulgated pursuant thereto. This is 33 subject to the supervision, control, responsibility and direction of 34 35 the laboratory director. A medical laboratory scientist may 36 maintain equipment and records, establish and implement 37 protocols, select or develop test methodology, and perform quality 38 assurance activities related to test performance. In addition this individual is responsible for, with oversight by the laboratory 39 40 director, the establishment and implementation of protocols, quality assessment, method development and selection, equipment 41 selection and maintenance, and all activities related to the 42 43 preanalytic, analytic, and postanalytic phases of testing. The

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1 medical laboratory scientist also may direct, supervise, consult,

2 educate, and perform research functions. The medical laboratory3 scientist may perform the functions of the phlebotomist without

4 additional certification.

5 (12) 'Independent technical judgment' means the performance 6 of clinical laboratory tests and assumption of responsibility for the determination of the validly of clinical laboratory test results 7 8 without intervention by or the supervision of another health care 9 provider authorized by law to assume responsibility for the conduct and validity of clinical laboratory tests. This means 10 11 procedures, duties, and tests are not subject to review, upon 12 completion, by a supervisor. Pertaining to clinical laboratory 13 personnel, the authorized exercise of independent judgment must 14 not be considered to include or permit the exercise of independent 15 medical judgment in the diagnosis of or treatment of patients except as authorized in accordance with CLIA. 16

(13) 'Independent medical judgment' means in the laboratory,
the performance of only pathologists to make independent medical
judgment in the diagnosis and treatment decisions related to
clinical laboratory tests.

21 (14) 'Categorical medical laboratory scientist' means an 22 individual who performs the functions of a medical laboratory scientist but limited under the individual's national certification or 23 24 national qualification to perform in one or more categories of 25 laboratory testing, such as microbiology, clinical chemistry, 26 hematology, blood banking, molecular biology, cytogenetics, 27 cytometry, immunohistochemistry, laboratory informatics, or other 28 areas specified by the board, under the supervision, control, 29 responsibility and direction of the laboratory director. This 30 individual has been certified in only one or more areas by a 31 national certification agency and therefore can perform testing and 32 procedures related to just that specialty. The categorical medical 33 laboratory scientist may perform the functions of the phlebotomist 34 without additional certification.

35 (15) 'Medical laboratory technician' or 'MLT' means an 36 individual who performs medical laboratory tests and procedures 37 of high and moderate complexity under supervision as defined 38 under CLIA and the rules and regulations promulgated pursuant 39 thereto. The medical laboratory technician may perform the 40 functions of the phlebotomist without additional certification.

41 (16) 'Clinical laboratory assistant' also known as 'phlebotomist'
42 or 'phlebotomy technician' or 'donor phlebotomy technician'
43 means an individual who performs an invasive procedure to

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1 withdraw blood from the human body by venipuncture or capillary

2 puncture according to established and approved protocols in order 3 to collect samples including blood donations and to perform 4 specimen processing and preparation of samples for testing. This 5 individual is also qualified to perform waived and point-of-care 6 testing under the direction of a medical laboratory scientist, 7 medical laboratory technician, or laboratory director.

8 (17) 'Point-of-care testing' means clinical laboratory testing 9 provided within a facility, which does not require permanent dedicated space including, but not limited to analytic instruments 10 11 that are temporarily brought to a patient care location. Tests which meet this definition provide clinically relevant information which 12 13 determines the patient's therapy, are limited to procedures that 14 produce accurate data within a short period of time, meet the 15 current standards of quality in clinical laboratory science and comply with all standards of accrediting agencies. Point-of-care 16 testing must be under the direction, authority, jurisdiction, and 17 18 responsibility of a medical laboratory scientist, medical laboratory 19 technician, laboratory supervisor, or laboratory director.

20 (18) 'Waived', 'Provider-performed microscopy' or 'PPM', 21 'moderate complexity', and 'high complexity' are categories of the 22 clinical laboratory test complexity as defined by CLIA.

23 (19) 'Waived test' means a laboratory examination or procedure 24 as determined by the United States Food and Drug Administration 25 (FDA) which has an insignificant risk of an erroneous result, 26 including those which have been approved by the FDA for home 27 use. These tests employ methodologies that are so simple and 28 accurate as to render the likelihood of erroneous results negligible 29 or pose no reasonable risk of harm to the patient if performed 30 incorrectly.

(20) 'Medical assistant' means an individual who performs
routine administrative and clinical tasks in the offices and clinics
of physicians, podiatrists, chiropractors and optometrists and
whose duties vary from office to office but may include clerical
duties and performance of routine office laboratory procedures in
accordance with CLIA regulations.

37 (21) 'National certification' means a competency-based
38 certification awarded to those individuals who meet educational
39 and training requirements and who pass the appropriate
40 examination that is administered by a national nonprofit
41 credentialing agency such as American Society of Clinical
42 Pathologists (ASCP) Board of Certification (BOC) and American
43 Medical Technologists (AMT).

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1 (22) 'Student' or 'Trainee' means an individual having 2 qualifying education and who is enrolled in a National Accrediting 3 Agency for Clinical Laboratory Science (NAACLS) accredited 4 clinical laboratory training program. Trainees may perform 5 procedures under direct supervision of licensed medical laboratory 6 practitioners.

7 (23) 'Direct supervision' means the medical laboratory scientist, 8 medical laboratory technician, laboratory supervisor, or laboratory 9 director personally authorizes the procedures, duties, and tests to 10 be performed and remains in the laboratory while the procedures, 11 duties, and tests are being performed and reviews the test results.

12 (24) 'Temporary license' means a license issued to:

13 (a) an applicant eligible to sit for a national certification 14 examination; or

15 (b) an applicant who meets the educational requirements for 16 the certification and is seeking to qualify for the certification 17 examination by completing the supervised clinical laboratory 18 experience requirements.

(25) 'Continuing education' means an organized educational
program designed to expand an individual's knowledge base
beyond the basic entry-level educational requirements for medical
laboratory personnel. Course content must relate to health care
whether the subject is research, treatment, documentation,
education, or management.

25 (26) 'Effective date' means one hundred twenty days after 26 passage of the chapter. During this time the board must be 27 appointed and bylaws established.

(27) 'Enactment of the chapter' means twenty-four months afterthe effective date.

30

31 Section 40-48-40. The provisions of this chapter do not apply 32 to:

(1) medical laboratory practitioner employed by the United
States government, or any bureaus, divisions, or agencies, while
performing duties within the scope of the professional's federal
employment;

37 (2) a nonprofit laboratory operated and maintained exclusively
38 for instruction and research involving no individual patient or
39 public health care service, provided the results of any examination
40 performed in such a clinical laboratory are not used directly in the
41 diagnosis, evaluation, or treatment of human disease or disorder;

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1 (3) any board-certified physician licensed by the State of South 2 Carolina; any doctorate in chemical, physical, or biological 3 sciences or medicine, or laboratory director;

(4) other licensed or registered health care professionals 4 5 performing functions within the professional's scope of practice. This includes any clinical perfusionist acting within the scope of 6 7 practice of perfusion in the support, treatment, measurement, or 8 supplementation of the cardiopulmonary and circulatory system of 9 an individual patient. This includes any pulmonary function technician acting within the scope of performance of the practice 10 11 of respiratory therapy. This includes registered nurse practitioners 12 or physician assistants who perform provider-performed 13 microscopy procedures in a physician office setting;

14 (5) individuals exclusively performing only waived testing in15 an institution meeting current CLIA regulations;

16 (6) pathologist assistants, histotechnologists, histotechnicians,
17 and cytotechnologists that are qualified or otherwise allowed to
18 perform these functions in accordance with CLIA regulations;

19 (7) medical laboratory science professionals engaged in the 20 education of medical laboratory science professionals or in 21 research, provided that the results of any examination performed 22 are not used in health maintenance, diagnosis or treatment of 23 disease;

24 (8) any individual whose duties might include demonstrating 25 or instructing, or both; the development of assays, or 26 management-related activities in the clinical laboratory; the use of 27 any automated or digital instrument, device, machine, or similar 28 mechanical equipment and related procedures utilized to assist in 29 the practice of clinical laboratory science, provided the results 30 furnished by such equipment during such a demonstration or instruction are not used in the diagnosis, evaluation, or treatment 31 32 of human disease or disorder;

(9) students or trainees enrolled in a NAACLS accredited
medical laboratory science education program provided that the
activities performed by the student or trainee constitute a part of a
planned course in the program; the student or trainee is clearly
designated as intern, trainee, or student; and the student or trainee
si directly supervised by an individual licensed under this chapter
to practice clinical laboratory science;

40 (10) individuals performing forensic testing and examination of 41 body fluids, tissues, cells, or blood solely for the purpose of law 42 enforcement and the state's criminal justice system;

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1 (11) clinical laboratory assistants performing blood collection 2 and waived testing;

3 (12) laboratory testing personnel employed in a physician office 4 laboratory (POL) or other out-patient facility to include public 5 health facilities, specialty laboratories, and reference laboratories;

6 (13) laboratory testing personnel employed in a hospital-based 7 laboratory within a hospital facility with less than 200 beds.

8

9 Section 40-48-50. (A) Clinical laboratory professionals
10 licensed under this chapter shall collect human blood specimens
11 for clinical laboratory testing and perform clinical laboratory tests
12 and provide test results to physicians and patients upon request or
13 upon physician referral in accordance with CLIA.

14 (B) The practice of clinical laboratory science includes, but is 15 not limited to:

16 (1) the production of test data;

17 (2) monitoring the accuracy, precision, and utility of 18 laboratory testing;

19 (3) analytical correlation and interpretation of test data; and

20 (4) designing, evaluation, and implementing new laboratory 21 test methods.

(C) The services provided by clinical laboratory professionalsmust be consistent with good practice and sound professionalethics.

(D) The practice of clinical laboratory science does not include
the exercise of independent medical judgment that is performed by
pathologists who provide such judgment in the diagnosis and
treatment decisions related to clinical laboratory tests.

29

30 Section 40-48-60. (A) Effective July 1, 2012, no individual 31 shall perform nonwaived clinical laboratory tests typically 32 performed by medical laboratory scientists or medical laboratory 33 technicians or shall take, use, or exhibit the title of 'medical 34 laboratory scientist', or 'categorical medical laboratory scientist', 35 or 'medical laboratory technician' unless that person is South 36 Carolina state licensed or exempt under this chapter.

(B) No person knowingly may employ or designate as a
medical laboratory practitioner who does not hold a license issued
by the State of South Carolina unless that employee is exempt
under this chapter.

41

42 Section 40-48-70. (A) The following types of South Carolina 43 licenses must be issued by the department:

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1 (1) Medical Laboratory Scientist. The board shall issue a 2 medical laboratory scientist's license to an individual who 3 possesses a baccalaureate degree from a regionally accredited 4 college or university, has acceptable clinical laboratory experience 5 and training, and passes a nationally recognized certification examination administered by the American Society for Clinical 6 Pathology Board of Certification or American Medical 7 8 Technologists or successor organizations at the medical laboratory 9 science level.

10 (2) Categorical Medical Laboratory Scientist: The board 11 shall issue a categorical medical laboratory scientist license to an individual who possesses a baccalaureate degree from a regionally 12 13 accredited college or university, has acceptable clinical laboratory experience and training, and passes a nationally recognized 14 certification examination administered by the American Society 15 16 for Clinical Pathology Board of Certification or American Medical Technologists or successor organizations in a recognized discipline 17 18 of laboratory science. The laboratory discipline will be specified 19 on the state license and the individual's practice must be limited to 20 the category or categories listed.

21 (3) Medical Laboratory Technician: The board shall issue a 22 medical laboratory technician license to an individual who possesses an associate degree in medical technology from a 23 24 regionally accredited college or university, or has successfully completed sixty semester hours of academic credit at an accredited 25 26 institution including chemistry, biology, and a structured 27 curriculum in medical laboratory techniques, and has at least one 28 year of pertinent full-time experience or training, or both, or has 29 equivalent training and experience in the United States Armed 30 Forces and passes a nationally recognized certification examination administered by the American Society for Clinical 31 32 Pathology Board of Certification or American Medical 33 Technologists or successor organizations at the level of a medical laboratory technician. 34

35 (B) Any medical laboratory scientist or medical laboratory 36 technician who obtains the required minimum education 37 requirements and is nationally certified by the above specified 38 national certification agencies is considered to have met the 39 qualifications for licensure by the South Carolina Board of Clinical 40 Laboratory Science, and upon application, must be issued an initial 41 license at the appropriate level.

42 (C) Nothing is this chapter limits, enlarges, or affects the 43 practice of a licensed clinical laboratory practitioner.

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1 2 Section 40-48-80. (A) The board shall waive the above 3 requirements for persons seeking licensure as medical laboratory scientist or medical laboratory technician if the person: 4 (1) makes application for licensure within twenty-four 5 6 months after effective date of this chapter; (2) is currently working and is performing duties associated 7 8 with an MLS or MLT: and (3) otherwise complies with regulations of the board relating 9 to moral turpitude. The board will determine the type of license for 10 11 which the applicant is eligible. 12 (B) Effective twenty-four months after the effective date of this chapter, no initial license for medical laboratory scientist or 13 14 categorical medical laboratory scientist or medical laboratory 15 technician must be issued until an applicant meets all of the 16 requirements under this chapter. 17 (C) Except as otherwise exempt from the provisions of this chapter, all individuals who perform the duties of medical 18 laboratory scientist or medical laboratory technician on the 19 effective date of the chapter; all those who are either certified or 20 eligible for certification by an agency approved according to this 21 chapter and have complied with all necessary requirements for 22 such application may continue to perform the duties until the first 23 24 of the following occurs: 25 (1) the expiration of twelve months after the filing of such 26 state license application; 27 (2) the denial of the application by the board; or 28 (3) the withdrawal of the application. 29 30 Section 40-48-90. After the effective date of this chapter, all new graduates of clinical laboratory educational programs related 31 32 to the education and training of the personnel licensed in this chapter must be required to meet the stated requirements of this 33 34 chapter and apply for initial South Carolina license or temporary 35 license. 36 Section 40-48-100. (A) South Carolina state license applicants 37 who are nationally certification eligible by meeting the education, 38 experience, or training requirements but have not successfully 39 40 passed an approved certification examination as listed in this chapter may be granted a temporary license upon conclusion of 41

42 their education or training that will allow that individual to engage 43 in the practice of clinical laboratory science at the appropriate

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level. The term for the temporary license must be six months and
 may be renewed once.

3 (B) Persons seeking national qualification for such disciplines as cytometry, immunohistochemistry, or laboratory informatics or 4 other laboratory related specialties who possess a baccalaureate 5 degree or higher from a regionally accredited college or university 6 and require experience to meet the acceptable criteria for 7 8 application for the appropriate national certification examination, 9 may apply for a special temporary license for a term as necessary for eligibility for national certification. Terms for the special 10 11 temporary license must be set by the board.

12 (C) The board as part of their official duties will establish the 13 policy and procedures for the issuance of special temporary 14 licenses for applicants who require experience to qualify for the national certification from organizations listed in this chapter. Such 15 16 duties shall include expiration and renewal terms which will depend on the selected route and type of national certification that 17 18 the individual is seeking to obtain. If the period of time of the 19 renewed temporary certificate passes without passage of the certification exam, the temporary license is void and the applicant 20 21 may no longer practice clinical laboratory science. Any exceptions 22 must be approved by the board.

23

24 Section 40-48-110. (A) Internationally trained license 25 applicants must have their college transcripts evaluated by a 26 transcript evaluation agency acceptable to the board and submitted 27 directly to a board-approved national certification agency.

(B) The evaluation must indicate the applicant's education isequivalent to that which is required for national certification at thelevel of license being sought.

31 (C) Upon submission of proof to the board of acceptance to sit
32 for the national certification examination, the individual may apply
33 for a temporary state license in the corresponding clinical
34 laboratory science category.

35 (D) Verification of national certifying exam certification must36 come directly from the certifying entity.

37 (E) All funds collected must be in United States currency only.

38 (F) Applicants must have United States Social Security39 number.

40

41 Section 40-48-120. (A) The board shall recognize a valid 42 license or equivalent issued by another state provided that the

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requirements under which that license was issued are equivalent to
 or exceed the standards required by this chapter.

3 (B) The applicant applying for South Carolina licensure by 4 reciprocity must provide all necessary evidence to the board that 5 the applicant holds a current and unrestricted license for the 6 practice of medical laboratory science.

7

8 Section 40-48-130. (A) There is created the South Carolina 9 Board of Clinical Laboratory Science under the administration of the Department of Labor, Licensing and Regulation. The purpose 10 of this board is to protect the public by assisting the division in 11 administering and enforcing the provisions. The board shall adopt, 12 13 publish, and enforce such rules and regulations within the scope 14 and purview of the sections as may be considered necessary or 15 proper for the effective administration and interpretation of the provisions of this chapter, and for the conduct of its business and 16 management of its internal affairs. 17

18 (B) The board must be composed of seven members to be appointed by the Governor with the advice and consent of the 19 Senate within ninety days after passage of this chapter. Board 20 21 members shall include two pathologists, one non-physician laboratory director, two medical laboratory scientists, and one 22 medical laboratory technician. One additional member must be a 23 lay member. Each member of the board must be a citizen of the 24 25 United States and a South Carolina resident. All of the medical 26 laboratory scientists and medical laboratory technicians must hold 27 active and valid South Carolina licenses. Nominations for 28 appointment to the board may be made to the Governor by an 29 individual, group, or association. The governor may appoint a 30 board member from the list of nominations or may appoint some other qualified person that meets the above position. Members 31 32 shall serve terms of two or three years and until their successors 33 are appointed and qualify. Vacancies must be filled in the manner 34 of the original appointment for the unexpired portion of the term. 35 The Governor may remove a member of the board as provided for 36 in Section 1-3-240.

37

Section 40-48-140. (A) The Department of Labor, Licensing
and Regulation shall provide all administrative, fiscal,
investigative, inspectional, clerical, secretarial, and license renewal
operations and activities of the board in accordance with Section
40-1-50.

43 (B) The board shall establish the appropriate required fees.

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1 (C) All fees are nonrefundable and may be prorated to comply 2 with established licensure renewal.

3

4 Section 40-48-150. The board may adopt rules governing its 5 proceedings as provided for in Section 40-1-60 and may adopt an 6 official seal bearing the words 'South Carolina Board of Clinical 7 Laboratory Science'. The board shall promulgate regulations 8 necessary to carry out the provisions of this chapter including, but 9 not limited to, promulgating in regulation a code of ethics.

10

11 Section 40-48-160. The board shall regulate the issuance of 12 licenses and temporary licenses and shall discipline in any manner 13 authorized by this chapter or Article 1, Chapter 1.

14

Section 40-48-170. (A) The department, on behalf of the board,
shall investigate complaints and violations of this chapter as
provided in Section 40-1-80.

18 (B) The results of an investigation must be presented to the 19 board, and any subsequent hearing must be conducted in 20 accordance with Section 40-1-90.

(C) In addition to other remedies provided for in this chapter,
the board in accordance with Section 40-1-100 may issue a cease
and desist order or may petition an administrative law judge for a
temporary restraining order or other equitable relief to enjoin a
violation of this chapter.

(D) A licensee under investigation for a violation of this chapter
or a regulation promulgated under this chapter may voluntarily
surrender the license in accordance with Section 40-1-150.

(E) A person aggrieved by a final action of the board may seekreview of the decision pursuant to Section 40-1-160.

31 (F) A person found in violation of this chapter or regulations 32 promulgated under this chapter may be required to pay costs 33 associated with the investigation and prosecution of the case in 34 accordance with Section 40-1-170. All costs and fines imposed 35 pursuant to this chapter must be paid in accordance with and are 36 subject to the collection and enforcement provisions of Section 37 40-1-180.

38 (G) Investigations and proceedings conducted under this39 chapter are confidential, and all communications are privileged as40 provided for in Section 40-1-190.

41

42 Section 40-48-180. In addition to other grounds provided in 43 Section 40-1-110, the board, after notice and a hearing conducted

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1 in accordance with the Administrative Procedures Act, may restrict

2 or refuse to grant a license to an applicant or may refuse to renew

3 the license of a licensed person or may suspend, revoke, or 4 otherwise restrict the license of a licensed person who:

5 (1) violates a provision of this chapter or a regulation 6 promulgated pursuant to this chapter or an order issued by the 7 board;

8 (2) commits fraud, deception, misrepresentation, or bribery in 9 securing a license pursuant to the provisions of this section;

10 (3) impersonates any individual holding a license or allows any11 individual to use his license or diploma from any school;

12 (4) has disciplinary action by another state, territory, federal 13 agency or country upon grounds for which revocation or 14 suspension is authorized in this State;

15 (5) has been issued a license based upon a material mistake of 16 fact;

17 (6) has been adjudicated and found guilty, or entered a plea of 18 guilty or nolo contendere, in a criminal prosecution pursuant to the 19 laws of any state, the United States, for any offense reasonably 20 related to the qualification, functions, or duties of the individual 21 who is regulated, for any offense an essential element of fraud, dishonesty or act of violence, or for any offense involving moral 22 turpitude, elderly or child abuse, regardless of whether or not 23 24 sentence is imposed;

(7) has demonstrated professional incompetence, misconduct,
gross negligence, fraud, misrepresentation, or dishonesty in the
performance of specimen collection, processing or performance of
clinical laboratory testing or erroneous reporting;

(8) has wilfully made or filed false records or reports in his
practice including, but not limited to, false records filed with state
agencies or departments;

(9) has directly or indirectly given to or received from any
person, firm, corporation, partnership, or association any fee,
commission, rebate, or other form of compensation for any
professional services not actually rendered;

36 (10) has, after having his license placed on probationary status,37 violated the terms of probation;

(11) engages in dishonorable, unethical, or unprofessional
conduct of a character likely to deceive, defraud, or harm the
public or violates any standard of professional conduct adopted by
the board;

42 (12) has jeopardized patient safety by providing professional 43 services while mentally incompetent or under the influence of

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alcohol, a narcotic, or a controlled substance that is in excess of
 therapeutic amounts or without valid medical indication;

3 (13) has directly or indirectly contracted to perform clinical 4 laboratory tests in a manner which offers or implies an offer of 5 rebate, fee-splitting inducements, or arrangements, or other 6 remuneration;

7 (14) aided or assisted another individual in violating any
8 provision of this chapter or any rule adopted hereunder.
9

10 Section 40-48-190. (A) At any time after the suspension or 11 revocation of any license, the department may restore the license to 12 the accused person, upon the written recommendation of the board, 13 unless after an investigation and a hearing the board determines 14 that restoration is not in the public interest.

15 (B) Upon the revocation or suspension of any license, the 16 licensee shall forthwith surrender the license to the department, 17 and if the licensee fails to do so, the department shall have the 18 right to seize the license.

19 (C) Any person who is found to have violated any provision of 20 this chapter is guilty of a misdemeanor for a first offense and, upon 21 conviction, must be imprisoned for not more than three years, and 22 is guilty of a felony for second and subsequent offense and, upon 23 conviction, must be imprisoned for not more than five years.

24

25 Section 40-48-200. (A) The board has jurisdiction over the 26 actions of licensees as provided for in Section 40-1-115. The board 27 does not have the authority to modify or expand criteria already 28 established in this chapter.

29 (B) The board has following duties that will include the 30 following, but are not limited to:

31 (1) constructing all forms necessary to administer this 32 chapter;

33 (2) setting all applicable fees; fees must be set at a level to
34 produce revenue which shall not exceed the cost and expense of
35 administering the provisions of this chapter;

36 (3) selecting the standards for continuing education to 37 include policy for inactive status;

(4) establishing the policies and procedures for temporary
(39 certifications and their renewal for personnel who require
40 on-the-job experience or training for national certification
41 eligibility; and

42 (5) establishing and adopting a clinical laboratory personnel 43 code of ethics.

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- Section 40-48-210. (A) An applicant for initial licensure must
 submit:
 - (1) a completed notarized application form;

(2) the required fee; and

6 (3) proof of passage of national certification examination 7 appropriate for applied license and administered by an approved 8 organization listed in this chapter.

9 (B) Upon receipt of application and payment of a fee, the board 10 shall issue a license at the appropriate practitioner level to any 11 person who meets the qualifications specified in this chapter.

12 (C) The board shall set the fees for original and renewal 13 licenses so that the total fees collected will be sufficient to meet 14 the expenses of administering this chapter.

15

4 5

16 Section 40-48-220. All licenses for clinical laboratory personnel 17 are valid for three years from the date on which it is issued, and it 18 is the responsibility of the licensee to renew the license whether or 19 not a notice is received.

20

Section 40-48-230. (A) The licensee shall complete the
appropriate renewal form and provide documentation of required
continuing education within sixty days of renewal date and submit
the appropriate fee.

(B) The license of any individual, who fails to pay the required fee, fails to provide documentation of required continuing education, or fails to provide the board with any information required for renewal within sixty days after the expiration of such license must be automatically canceled without notice or further proceedings to invalidate the license unless the individual has applied for inactive status.

32

33 Section 40-48-240. (A) As a condition of license renewal, a 34 licensee must be in good standing with the board and satisfactorily 35 complete education requirements as follows as evidence of 36 continued competency:

(1) medical laboratory scientists and medical laboratory
technicians must be required to complete thirty-six hours of
continuing education within three years and must submit a
completed form with renewal applications; and

41 (2) criteria for acceptable continuing education units shall 42 mimic the current ASCP's board of Certification, Certification 43 Maintenance Program (CMP). Any exceptions or deviations would

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be approved by the board. Any changes made to the CMP by
 ASCP would be approved by the board.

3 (B) The board may at random request validation of the 4 submitted continuing education.

5 (C) If the requirements of this section have not been completed 6 within one year, the application and credentials must be brought up 7 to date and resubmitted with payment of the required fee. A person 8 must comply with this section before renewal of license may be 9 granted.

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Section 40-48-250. (A) A licensed medical laboratory
practitioner may ask to be placed on inactive status, provided such
individual does not practice clinical laboratory science during such
a period that the individual is on inactive status. Individuals
requesting such status shall submit the appropriate form.

16 (B) The board may reactivate an inactive license with 17 application and the required fee. Continuing education 18 requirements must be determined by the board.

19 (C) A new license to replace any license lost, destroyed or20 mutilated may be issued upon payment of a fee."

21

22 SECTION 2. If any section, subsection, paragraph, subparagraph, 23 sentence, clause, phrase, or word of this act is for any reason held 24 to be unconstitutional or invalid, such holding shall not affect the constitutionality or validity of the remaining portions of this act, 25 26 the General Assembly hereby declaring that it would have passed 27 this act, and each and every section, subsection, paragraph, 28 subparagraph, sentence, clause, phrase, and word thereof, 29 irrespective of the fact that any one or more other sections, 30 subsections, paragraphs, subparagraphs, sentences, clauses, phrases, or words hereof may be declared to be unconstitutional, 31 32 invalid, or otherwise ineffective. 33

SECTION 3. This act takes effect upon approval by the Governor.

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