

BILL ANALYSIS

Senate Research Center
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S.B. 805
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AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Currently, Texas does not have a licensure process for clinical laboratory testing personnel. This presents a significant risk to patients who may be subjected to unnecessary, inappropriate, and improper treatment as a result of errors made by unqualified laboratory personnel. As laboratory personnel are not regulated by the state, there is not statewide database of current laboratory testing personnel which could be used to determine if shortages exist and identify specific needs of communities throughout the state. There is also no statewide means to contact laboratory personnel to perform critical microbiological testing the in event of an act of bioterrorism, as occurred in 2001.

Research shows that certified laboratory personnel perform better than non-certified personnel on proficiency testing. Unqualified and under-qualified clinical laboratory personnel increase costs to health care in time, money, and lives. Without licensure, there is no assurance that individuals performing laboratory tests meet minimum education and certification standards.

S.B 805 provides a mechanism to license specific clinical laboratory test personnel. This legislation fills in gaps between no state licensure and the Federal Clinical Laboratory Improvement Amendments (CLIA) legislation. S.B. 805 recognizes existing national certifications, already held by the majority of Texas laboratory technicians and scientists, and brings existing personnel into licensure.

As proposed, S.B. 805 amends current law relating to the licensing and regulation of medical laboratory science professionals and provides penalties.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 1 (Sections 703.051, 703.156, and 703.158, Occupations Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Subtitle M, Title 3, Occupations Code, by adding Chapter 703, as follows:

CHAPTER 703. MEDICAL LABORATORY SCIENCE PROFESSIONALS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 703.001. **SHORT TITLE.** Provides that this chapter may be cited as the Medical Laboratory Science Practice Act.

Sec. 703.002. **PUBLIC POLICY; LEGISLATIVE PURPOSE.** (a) Provides that the legislature declares as a policy of this state that the practice of medical laboratory science by health care professionals affects the public health, safety, and welfare and is subject to control and regulation in the public interest, and medical laboratories and medical laboratory science professionals provide essential services to health care professionals by

furnishing vital information that may be used in the diagnosis, prevention, and treatment of diseases or impairments and the assessment of human health.

(b) Provides that the purpose of this chapter is to ensure better protection of the public health by requiring minimum qualifications for medical laboratory science professionals, and ensuring that medical laboratory tests are performed with the highest degree of professional competency by individuals engaged in providing the services in this state.

Sec. 703.003. DEFINITIONS. Defines, in this chapter, "advisory committee," "categorical medical laboratory scientist," "CLIA," "commissioner," "department," "executive commissioner," "laboratory director," "medical laboratory," "medical laboratory assistant," "medical laboratory science professional," "medical laboratory scientist," "medical laboratory scientist services," "medical laboratory technician," "medical laboratory technician services," "medical laboratory test," "point-of-care testing," "practice of medical laboratory science," "trainee," and "waived test."

Sec. 703.004. EXEMPTIONS. Provides that this chapter does not apply to:

(1) an individual licensed under another law of this state and engaged in health care services within the scope of the license holder's licensed practice;

(2) an individual engaged in the practice of medical laboratory science in the employ of the federal government or a federal bureau, division, or agency and in the discharge of the employee's official duties;

(3) an individual engaged in the practice of medical laboratory science and engaged exclusively in research, provided that the results of an examination performed are not used in health maintenance, diagnosis, or treatment of disease;

(4) an intern, student, or trainee enrolled in a medical laboratory science education program, provided that the activities constitute a part of a planned course in the program, the individual is designated by title as an intern, student, or trainee, and the individual works directly under an individual licensed by this state to practice medical laboratory science or an individual exempt from this chapter under Subdivision (3);

(5) an individual solely performing waived or provider-performed microscopy tests under the federal Clinical Laboratory Improvement Amendments, 42 C.F.R. Part 493 (CLIA);

(6) an individual performing point-of-care testing categorized under CLIA as moderate complexity in an acute care facility, if the facility complies with the following requirements:

(A) in the laboratory, a medical laboratory scientist or laboratory director is responsible for designing and providing or supervising the training programs for the point-of-care testing personnel, supervising and monitoring the quality assurance and quality control activities of the testing site, assisting in the selection of technology, reviewing the results of proficiency testing and recommending corrective action, if necessary, and monitoring the continued competency of the test personnel; and

(B) processes are in place at the facility and are acceptable to the Department of State Health Services (DSHS) to ensure and document the continued competency of the point-of-care testing personnel;

(7) an individual solely performing histopathology testing, as described by CLIA;

(8) an individual solely performing or interpreting cytology testing, including the performance or interpretation of molecular testing on cytological specimens, as described by CLIA; or

(9) a medical laboratory assistant who performs non-testing pre-analytical duties, including processing specimens, assessment, loading specimens into analyzers, or preparing specimens for referral testing.

Sec. 703.005. APPLICATION OF SUNSET ACT. Provides that the Medical Laboratory Science Advisory Committee is subject Chapter 325 (Texas Sunset Act), Government Code. Provides that unless continued in existence as provided by that chapter, the advisory committee is abolished and this chapter expires September 1, 2023.

[Reserves Sections 703.006-703.050 for expansion.]

SUBCHAPTER B. EXECUTIVE COMMISSIONER, COMMISSIONER, AND DEPARTMENT POWERS AND DUTIES

Sec. 703.051. RULES. (a) Requires the executive commissioner of the Health and Human Services Commission (executive commissioner) to adopt rules necessary to administer this chapter, including rules on:

- (1) the qualifications for licensure under each category of medical laboratory science professional;
- (2) the renewal of licensure;
- (3) standards of professional conduct for each category of medical laboratory science professional;
- (4) authorization or approval of nationally recognized and validated certification examinations for medical laboratory science professionals; and
- (5) criteria for the continuing education of medical laboratory science professionals as required for license renewal.

(b) Requires the executive commissioner by rule to prescribe the activities that are authorized to be performed by each category of license holder under this chapter.

Sec. 703.052. FEES. Requires the executive commissioner to establish and collect reasonable and necessary fees in amounts sufficient to cover the costs of administering this chapter.

Sec. 703.053. DEPARTMENT POWERS AND DUTIES. (a) Authorizes DSHS to authorize disbursements necessary to implement this chapter, including disbursements for office expenses, equipment costs, and other necessary facilities.

(b) Authorizes DSHS to examine any criminal conviction or guilty plea of an applicant for issuance or renewal of a license, including by obtaining any criminal history record information permitted by law.

Sec. 703.054. PERSONNEL. Authorizes DSHS to employ personnel necessary to administer this chapter.

Sec. 703.055. REGISTRY OF LICENSE HOLDERS. (a) Requires DSHS to maintain a registry of the name and addresses of each individual licensed under this chapter and each individual whose license has been suspended or revoked.

(b) Requires DSHS to post the registry on DSHS's Internet website and make copies of the registry available to the public on request.

Sec. 703.056. CONSUMER INTEREST INFORMATION. (a) Requires DSHS to prepare information of consumer interest describing the functions performed by DSHS under this chapter, and the rights of a consumer affected by this chapter.

(b) Requires that the information describe the procedure by which a consumer complaint is filed with and resolved by DSHS.

(c) Requires DSHS to make the information available to the public.

[Reserves Sections 703.057-703.100 for expansion.]

SUBCHAPTER C. MEDICAL LABORATORY SCIENCE ADVISORY COMMITTEE

Sec. 703.101. ADVISORY COMMITTEE. (a) Provides that the Medical Laboratory Science Advisory Committee (advisory committee) is an advisory body to DSHS and the executive commissioner.

(b) Provides that the advisory committee consists of nine members appointed by the executive commissioner. Sets forth the composition of the advisory committee.

(c) Authorizes the executive commissioner to make appointments to the advisory committee from lists submitted by organizations of medical laboratory science professionals and organizations of physician pathologists.

(d) Provides that Chapter 2110 (State Agency Advisory Committees), Government Code, does not apply to the advisory committee.

Sec. 703.102. TERMS; VACANCIES. (a) Provides that members serve staggered six-year terms and until their successors are appointed and qualified.

(b) Requires that a vacancy be filled for the remainder of the unexpired term in the same manner as an original appointment.

(c) Prohibits a member from serving more than two consecutive terms.

Sec. 703.103. PUBLIC MEMBER ELIGIBILITY. Prohibits a member who represents the public from being:

(1) an officer, director, or employee of an individual regulated under this chapter;

(2) an individual required to register as a lobbyist under Chapter 305 (Registration of Lobbyists), Government Code; or

(3) an individual related to an individual described by Subdivision (1) or (2) within the second degree by affinity or consanguinity.

Sec. 703.104. COMPENSATION; REIMBURSEMENT. Provides that a member of the advisory committee serves without compensation. Entitles an advisory committee member, if authorized by the executive commissioner, to reimbursement for actual and necessary expenses incurred while performing the functions of the advisory committee subject to the General Appropriations Act.

Sec. 703.105. MEETINGS. Requires the advisory committee to meet annually and authorizes it to meet at other times at the call of the executive commissioner.

Sec. 703.106. **ADVISORY COMMITTEE DUTIES.** Requires the advisory committee to provide advice and recommendations to DSHS and executive commissioner on technical matters relevant to the administration and enforcement of this chapter, including examination approval, licensing standards and qualifications, renewal requirements, standards of professional conduct, and continuing education requirements.

[Reserves Sections 703.107-703.150 for expansion.]

SUBCHAPTER D. LICENSE REQUIREMENTS

Sec. 703.151. **LICENSE REQUIRED.** Prohibits an individual, except as provided by Section 703.004, from performing or offering to perform medical laboratory tests or represent that the individual is a medical laboratory science professional unless the individual holds an appropriate license issued under this chapter.

Sec. 703.152. **APPLICATION REQUIREMENTS.** (a) Requires an applicant for a license under this chapter to submit to DSHS a completed application on a form prescribed by the commissioner of state health services (commissioner), submit to DSHS any other information required by rule, demonstrate to the satisfaction of the commissioner the qualifications required by the chapter and by rule, demonstrate the applicant's honesty, trustworthiness, and integrity, and pay the application fee.

(b) Requires DSHS to issue the appropriate license to each individual who meets the qualifications required by this chapter and by rule.

(c) Authorizes DSHS to conduct an examination of any criminal conviction of an applicant, including obtaining any criminal history record information permitted by law.

(d) Prohibits criminal history information obtained by DSHS from being released or disclosed to any person except on court order, with the written consent of the applicant that is the subject of the criminal history record information, or as provided by Section 411.110 (Access to Criminal History Record Information: Department of State Health Services), Government Code.

Sec. 703.153. **MEDICAL LABORATORY SCIENTIST.** Requires an applicant for a medical laboratory scientist license to hold at least a baccalaureate degree from a regionally accredited college or university, have successfully completed the medical laboratory experience or training required by rule, be certified by a nationally recognized certification organization approved by the executive commissioner, pay the application fee, and comply with any other requirements established by rule.

Sec. 703.154. **CATEGORICAL MEDICAL LABORATORY SCIENTIST.** Requires an applicant for a categorical medical laboratory scientist license to hold at least a baccalaureate degree from a regionally accredited college or university, have successfully completed the medical laboratory experience or training required by rule, be certified by a nationally recognized certification organization approved by the executive commissioner, pay the application fee and license fee, and comply with any other requirements established by rule.

Sec. 703.155. **MEDICAL LABORATORY TECHNICIAN.** Requires an applicant for a medical laboratory technician license to hold at least an associate degree from a regionally accredited college or university, have successfully completed the medical laboratory experience or training required by rule, be certified by a nationally recognized certification organization approved by the executive commissioner, pay the application fee and license fee, and comply with any other requirements established by rule.

Sec. 703.156. **TEMPORARY LICENSE.** (a) Authorizes the executive commissioner by rule to establish a procedure for issuance of temporary licenses to individuals under this

chapter who intend to engage in the practice of medical laboratory science in this state for a limited period not to exceed six months.

(b) Provides that a temporary license, unless otherwise noted on the license, is valid for not more than six months after the date of issuance and may be renewed once at the discretion of the commissioner.

Sec. 703.157. **PROVISIONAL LICENSE.** Authorizes DSHS to issue a provisional license under this chapter to an applicant who holds a license in another state, submits a proper application, and pays the required fees if DSHS determines that the applicant is licensed in a state in which the requirements for issuance of the license are at least as stringent as the requirements under this chapter and by rule.

Sec. 703.158. **LICENSE RENEWAL.** (a) Provides that a license issued under this chapter expires on the second anniversary of the date of issuance. Authorizes the executive commissioner by rule to adopt a system under which licenses expire on various dates during the year.

(b) Authorizes a license holder to renew the license by paying the required renewal fee and successfully completing at least 10 hours each year of continuing education courses, clinics, lectures, training programs, seminars, or other programs related to medical laboratory practice that are approved or accepted by the executive commissioner, or successfully completing recertification by a national certifying organization recognized by the executive commissioner that mandates at least 10 hours each year of continuing education for recertification.

(c) Authorizes the executive commissioner by rule to require additional evidence of competency to practice medical laboratory science as the executive commissioner considers reasonably appropriate as a prerequisite to the renewal of any license under this chapter if the requirements are uniformly applied, reasonably related to the measurement of qualification, performance, or competence, and desirable and necessary for the protection of the public health.

[Reserves Sections 703.159-703.200 for expansion.]

SUBCHAPTER E. LICENSE DENIAL AND DISCIPLINARY ACTION

Sec. 703.201. **GROUND FOR DISCIPLINARY ACTION.** Authorizes DSHS to refuse to issue or renew, revoke, or suspend a license, place on probation, censure, or reprimand a license holder, or take any other disciplinary action, including the imposition of a civil penalty under Section 703.202 or the imposition of an administrative penalty under Section 703.204, DSHS considers appropriate for:

- (1) a material misstatement in furnishing information to DSHS;
- (2) a violation or negligent or intentional disregard of this chapter or a rule adopted under this chapter;
- (3) a conviction for any crime under the laws of the United States or any state of the United States that is a felony or a misdemeanor, an essential element of which is dishonesty, or of any crime that is directly related to the practice of the profession;
- (4) a misrepresentation made to obtain a license;
- (5) a violation of any standard of professional conduct adopted by the executive commissioner;
- (6) dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public;

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

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

(9) aiding or assisting another individual in violating any provision of this chapter or a rule adopted under this chapter; or

(10) a misrepresentation with regard to the existence or category of license or other certification or professional qualification held in connection with any employment application.

Sec. 703.202. CIVIL PENALTY. (a) Provides that a person who violates this chapter or a rule adopted under this chapter is liable to this state for a civil penalty of not more than \$500 for each violation.

(b) Requires that the amount of the penalty be based on the seriousness of the violation, the history of previous violations, the amount necessary to deter a future violation, and any other matter that justice may require.

(c) Authorizes the attorney general to sue to collect a civil penalty under this section. Authorizes the attorney general to recover in the suit, on behalf of the state, the reasonable expenses incurred in obtaining the penalty, including investigation and court costs, reasonable attorney's fees, witness fees, and other expenses.

Sec. 703.203. HEARINGS; ADMINISTRATIVE PROCEDURE. (a) Provides that if DSHS proposes to deny a license or take disciplinary action against a license holder, the license holder is entitled to a hearing.

(b) Provides that the proceedings relating to a license denial and disciplinary action by DSHS under this chapter are governed by Chapter 2001 (Administrative Procedure), Government Code. Requires that a hearing under this chapter be conducted by the State Office of Administrative Hearings.

Sec. 703.204. ADMINISTRATIVE PENALTY. (a) Authorizes the commissioner to impose an administrative penalty on an individual licensed under this chapter who violates this chapter or a rule or order adopted under this chapter.

(b) Prohibits the amount of the penalty from exceeding \$500. Provides that each day a violation continues or occurs is a separate violation for the purpose of imposing a penalty. Requires that the amount be based on certain aspects of the violation.

(c) Authorizes the individual to stay enforcement during the time the order is under judicial review if the individual pays the penalty to the court clerk or files a supersedeas bond with the court in the amount of the penalty. Authorizes an individual who cannot afford to pay the penalty or file the bond to stay the enforcement by filing an affidavit in the manner required by the Texas Rules of Civil Procedure for a party who cannot afford to file a security for costs, except that DSHS is authorized to contest the affidavit as provide by those rules.

(d) Provides that a proceeding to impose an administrative penalty is subject to Chapter 2001, Government Code.

[Reserves Sections 703.205-70.250 for expansion.]

SUBCHAPTER F. TRANSITIONAL LICENSING

Sec. 703.251. TEMPORARY PROVISION; TRANSITIONAL LICENSING. (a) Provides that this subchapter expires September 1, 2015. Prohibits DSHS from issuing a transitional license under this subchapter after August 31, 2013.

(b) Requires DSHS to issue a transitional license to a qualified applicant under this subchapter who submits to DSHS the information required by rule, including, as applicable, the job description of the medical laboratory position the applicant most recently held and a sworn statement by the applicant's employer attesting to the applicant's job description; or proof that the applicant is certified by a nationally recognized agency approved by the executive commissioner, and pays the application and licensing fee.

Sec. 703.252. MEDICAL LABORATORY SCIENTIST. Requires an applicant, to qualify for a transitional license as a medical laboratory scientist, to:

(1) be currently certified as a medical laboratory scientist by a certification agency approved by the executive commissioner;

(2) have met the education requirements of Section 703.153 and have performed the duties of a medical laboratory scientist for at least three years during the five years preceding the date of the application;

(3) have been engaged in the full-time education of medical laboratory practitioners for at least two years during the five years preceding the date of application; or

(4) have performed the duties of a medical laboratory scientist for at least five years preceding the date of application.

Sec. 703.253. CATEGORICAL MEDICAL LABORATORY SCIENTIST. Requires an applicant, to qualify for a transitional license under this subchapter as a categorical medical laboratory scientist, to:

(1) be currently certified as a categorical medical laboratory scientist by a certification agency approved by the executive commissioner;

(2) have met the education requirements of Section 703.154 and have performed the duties of a categorical medical laboratory scientist for at least three years during the five years preceding the date of application;

(3) have been engaged in the full-time education of medical laboratory practitioners for at least two years during the five years preceding the date of application; or

(4) have performed the duties of a categorical medical laboratory scientist for at least five years preceding the date of the application.

Sec. 703.254. MEDICAL LABORATORY TECHNICIAN. Requires an applicant, to qualify for a transitional license under this subchapter as a medical laboratory technician, to:

(1) be currently certified as a medical laboratory technician by a certification agency approved by the executive commissioner;

(2) have met the education requirements of Section 703.155 and have performed the duties of a medical laboratory technician for at least three years during the five years preceding the date of application; or

(3) have performed the duties of a medical laboratory technician for at least five years preceding the date of application.

Sec. 703.255. EFFECT OF TRANSITIONAL LICENSE. Entitles the holder of a transitional license issued under this subchapter to practice to the same extent as the holder of a license under Subchapter D.

Sec. 703.256. RENEWAL. Provides that a transitional license issued under this subchapter expires on the second anniversary of the date of issuance. Authorizes the transitional license, notwithstanding the qualifications for an initial license under Section 703.153, 703.154, or 703.155, to be renewed under Section 703.158.

SECTION 2. Amends Section 411.110(a), Government Code, to entitle DSHS to obtain from the Department of Public Safety of the State of Texas (DPS) criminal history record information maintained by DPS that relates to certain persons including an applicant for a license or a license holder under Chapter 703, Occupations Code.

SECTION 3. Requires the executive commissioner, as soon as possible after the effective date of this Act, to appoint the members of the advisory committee in accordance with Chapter 703, Occupations Code, as added by this Act. Requires the executive commissioner, in making the initial appointments, to designate three members for terms expiring in February 1, 2013, three members for terms expiring in February 1, 2015, and three members for terms expiring in February 1, 2017.

SECTION 4. Requires the executive commissioner to adopt the rules, standards, procedures, and fees necessary to implement Chapter 703, Occupations Code, as added by this Act, not later than March 1, 2012.

SECTION 5. Provides that notwithstanding Chapter 703, Occupations Code, as added by this Act, an individual engaged in the practice of medical laboratory science is not required to hold a license under that chapter to engage in the practice of medical laboratory science before September 1, 2012.

SECTION 6. Effective date: September 1, 2011.