

BILL ANALYSIS

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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 no statewide database of current laboratory testing personnel that could be used to determine whether shortages exist and identify certain needs of communities throughout the state. There is also no statewide means to contact laboratory personnel to perform critical microbiological testing in the event of an act of bioterrorism as occurred in 2001. Additionally, there is no method to identify individuals who have been involved in unethical conduct or malpractice while performing their duties as a clinical laboratory scientist or technician.

As proposed, S.B. 775 amends current law relating to the licensing and regulation of clinical 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, 703.151, 703.159, and 703.161, Occupations Code) and SECTIONS 3 of this bill.

SECTION BY SECTION ANALYSIS

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

CHAPTER 703. CLINICAL LABORATORY SCIENCE PROFESSIONALS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 703.001. **SHORT TITLE.** Authorizes this chapter to be cited as the Clinical 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 clinical 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 clinical laboratories and clinical 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 impairment 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 clinical laboratory science professionals and ensuring that clinical 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 "advisory board," "categorical clinical laboratory scientist," "clinical laboratory," "clinical laboratory science professional," "clinical laboratory scientist," "clinical laboratory scientist services," "clinical laboratory specialist

in cytogenetics," "clinical laboratory specialist in histocompatibility," "clinical laboratory specialist in molecular biology," "clinical laboratory technician," "clinical laboratory technician services," "clinical laboratory test," "commissioner," "department," "executive commissioner," "point-of-care testing," "practice of clinical laboratory science," "trainee," and "waived test."

Sec. 703.004. EXEMPTIONS. Exempts certain individuals from application of this chapter.

Sec. 703.005. APPLICATION OF SUNSET ACT. Provides that the Clinical Laboratory Science Advisory Board (board) is subject to Chapter 325, Government Code (Texas Sunset Act). Provides that the board, unless continued in existence as provided by that chapter, is abolished and this chapter expires September 1, 2021.

[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 the qualifications for licensure under each category of clinical laboratory science professional; the renewal of licensure; standards of professional conduct for each category of clinical laboratory science professional; authorization or approval of nationally recognized, validated, criterion-based certification examinations for clinical laboratory science professionals; and criteria for the continuing education of clinical laboratory science professionals as required for license renewal.

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

Sec. 703.052. FEES. Requires the commissioner of state health services (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 the Department of State Health Services (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, guilty plea, or deferred adjudication 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 that DSHS 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 in the preceding year.

(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. CLINICAL LABORATORY SCIENCE ADVISORY BOARD

Sec. 703.101. **ADVISORY BOARD.** (a) Provides that the board is an advisory body to DSHS and the executive commissioner.

(b) Sets forth the composition of the board.

(c) Authorizes the governor to make appointments to the board from lists submitted by certain organizations.

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

Sec. 703.102. **TERMS; VACANCIES.** (a) Provides that members serve staggered three-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 an officer, director, or employee of an individual regulated under this chapter, an individual required to register as a lobbyist under Chapter 305 (Registration of Lobbyists), Government Code, or 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 board serves without compensation. Entitles a board member, if authorized by the commissioner, to reimbursement for actual and necessary expenses incurred in performing the functions of the board, subject to the General Appropriations Act.

Sec. 703.105. **MEETINGS.** Requires the board to meet twice annually and authorizes the board to meet at other times at the call of the commissioner.

Sec. 703.106. **ADVISORY BOARD DUTIES.** Requires the board to provide advice and recommendations to DSHS and the 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.** (a) Prohibits an individual, except as provided by Section 703.004, from performing or offering to perform clinical laboratory tests or representing that the individual is a clinical laboratory science professional unless the individual holds an appropriate license issued under this chapter.

(b) Authorizes the executive commissioner by rule to establish the qualifications and licensing requirements for additional categories of clinical laboratory license professionals as the executive commissioner determines necessary to protect the public health and safety.

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; submit to DSHS any other information required by DSHS rule; demonstrate to the satisfaction of the commissioner the qualifications required by this chapter and DSHS 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 DSHS 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.

Sec. 703.153. CLINICAL LABORATORY SCIENTIST. Requires an applicant for a clinical laboratory scientist license to hold a baccalaureate degree from a regionally accredited college or university, have successfully completed the clinical laboratory experience or training required by DSHS 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 DSHS rule.

Sec. 703.154. CATEGORICAL CLINICAL LABORATORY SCIENTIST. Requires an applicant for a categorical clinical laboratory scientist license to meet certain requirements detailed under Section 703.153.

Sec. 703.155. CLINICAL LABORATORY TECHNICIAN. Requires an applicant for a clinical laboratory technician license to meet certain requirements detailed under Section 703.153.

Sec. 703.156. CLINICAL LABORATORY SPECIALIST IN MOLECULAR BIOLOGY. Requires an applicant for a clinical laboratory specialist in molecular biology license to meet certain requirements detailed under Section 703.153.

Sec. 703.157. CLINICAL LABORATORY SPECIALIST IN CYTOGENETICS. Requires an applicant for a clinical laboratory specialist in cytogenetics license to meet certain requirements detailed under Section 703.153.

Sec. 703.158. CLINICAL LABORATORY SPECIALIST IN HISTOCOMPATIBILITY. Requires an applicant for a clinical laboratory specialist in histocompatibility license to meet certain requirements detailed under Section 703.153.

Sec. 703.159. TEMPORARY LICENSE. (a) Authorizes the executive commissioner, by rule, to establish a procedure for issuance of temporary licenses to individuals otherwise qualified under this chapter who intend to engage in the practice of clinical laboratory science in this state for a limited period not to exceed one year.

(b) Provides that a temporary license, unless otherwise noted on the license, is valid until the first anniversary of the date of issuance and may be renewed once at the discretion of the commissioner.

Sec. 703.160. 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 DSHS rule.

Sec. 703.161. LICENSE RENEWAL. (a) Provides that a license issued under this chapter expires on the second anniversary of the date of issuance.

(b) Authorizes a license holder to renew the license by paying the required renewal fee and completing certain programs or recertification.

(c) Authorizes the executive commissioner by rule to require additional evidence of competency to practice clinical 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 703.162-703.200 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, that DSHS considers appropriate for certain infractions.

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, in the suit, to recover, 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) Entitles a license holder, if DSHS proposes to deny a license or take disciplinary action against a license holder, 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. Authorizes a hearing under this chapter to be conducted by a hearings officer designated by the Health and Human Services Commission.

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 the seriousness of the violation, including the nature, circumstances, extent, and gravity of the violation, the economic harm caused by the violation, the history of previous violations, the amount necessary to deter a future violation, efforts to correct the violation, and any other matter that justice may require.

(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 superseded 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 enforcement by filing an affidavit in the manner required by the Texas Rules of Civil Procedure for a party who cannot afford to file security for costs, except that DSHS may contest the affidavit as provided by those rules.

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

SECTION 2. Requires the governor, as soon as possible after the effective date of this Act, to appoint the members of the board in accordance with Chapter 703, Occupations Code, as added by this Act. Requires the governor, in making the initial appointments, to designate certain members with terms with varying term expirations.

SECTION 3. Requires the executive commissioner, as soon as possible after the effective date of this Act, to adopt the rules, standards, procedures, and fees necessary to implement Chapter 703, Occupations Code, as added by this Act, and Section 5 of this Act.

SECTION 4. Exempts an individual engaged in the practice of clinical laboratory science, notwithstanding Chapter 703, Occupations Code, as added by this Act, from being required to hold a license under that chapter to engage in the practice of clinical laboratory science before September 1, 2011.

SECTION 5. Requires DSHS to, notwithstanding Chapter 703, Occupations Code, as added by this Act, issue a license to a qualified applicant under this section who applies for a license under this section not later than September 1, 2011, submits to DSHS the information required by DSHS rule, submits to DSHS the job description of the position the applicant most recently performed and a sworn statement by the applicant's employer attesting to the applicant's job description, has at least three years of acceptable experience, in the preceding five years, in the applicable practice of clinical laboratory science, is certified by or eligible for certification by a nationally recognized certification agency approved by DSHS, and pays the application and licensing fee.

SECTION 6. Effective date: September 1, 2009.