

By: Lucio

S.B. No. 1662

A BILL TO BE ENTITLED

AN ACT

relating to requiring the registration of medical laboratory science professionals; providing an administrative penalty; imposing fees.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subtitle M, Title 3, Occupations Code, is amended by adding Chapter 703 to read as follows:

CHAPTER 703. MEDICAL LABORATORY SCIENCE PROFESSIONALS REGISTRY

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 703.001. SHORT TITLE. This chapter may be cited as the Medical Laboratory Science Professionals Registry Act.

Sec. 703.002. PUBLIC POLICY; LEGISLATIVE PURPOSE. (a) The legislature declares as a policy of this state that medical laboratory science professionals provide essential services to health care professionals by furnishing vital information that may be used in the diagnosis and treatment of diseases.

(b) The purpose of this chapter is to ensure better protection of the public by:

(1) requiring certain laboratory professionals to be registered by this state;

(2) ensuring that updated information about registered laboratory professionals is available to state agencies and other interested parties; and

(3) enabling the collection of workforce data that

does not currently exist.

Sec. 703.003. DEFINITIONS. In this chapter:

(1) "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. Part 493).

(2) "Commissioner" means the commissioner of state health services.

(3) "Department" means the Department of State Health Services.

(4) "Executive commissioner" means the executive commissioner of the Health and Human Services Commission.

(5) "Medical laboratory test" means a microbiological, serological, chemical, biological, hematological, immunological, immuno-hematological, immunoassay, cytochemical, or genetic test or procedure performed on material derived from or existing in a human body that provides information for the diagnosis, prevention, or monitoring of a disease or impairment or assessment of a medical condition. The term includes the pre-analytic, analytic, and post-analytic phases of testing.

(6) "Practice of medical laboratory science" means practice by an individual who manages, supervises, educates, consults, researches, or performs medical laboratory testing or technical procedures in a medical laboratory. The term does not include the practice of medicine or the activities of a person performing only clerical duties or other duties not directly related to the performance of medical laboratory testing.

Sec. 703.004. EXEMPTIONS. This chapter does not apply to:

(1) a physician licensed to practice medicine in this

1 state;

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

5 (3) an individual engaged in the employ of the federal
6 government or a federal bureau, division, or agency and in the
7 discharge of the employee's official duties;

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

12 (5) an intern, student, or trainee participating in a
13 medical laboratory science program, provided that:

14 (A) the activities constitute a part of a planned
15 course in the program; and

16 (B) the individual is designated by title as an
17 intern, student, or trainee;

18 (6) an individual solely performing
19 provider-performed microscopy tests under CLIA;

20 (7) an individual who performs non-testing
21 pre-analytical duties, including processing specimens,
22 accessioning, loading specimens into analyzers, or preparing
23 specimens for referral testing;

24 (8) an individual solely performing waived tests under
25 CLIA;

26 (9) an individual solely performing point-of-care
27 testing;

1 (10) an individual solely performing histopathology
2 testing;

3 (11) an individual solely performing cytologic
4 testing;

5 (12) an individual solely performing or interpreting
6 histocompatibility testing for transplantation services;

7 (13) an individual solely performing analytical
8 chemical procedures, including mass spectrometry; or

9 (14) an individual solely performing testing on blood
10 products for pharmaceutical use under guidelines of the United
11 States Food and Drug Administration.

12 Sec. 703.005. RULES. The executive commissioner shall
13 adopt rules to implement this chapter.

14 SUBCHAPTER B. REGISTRATION

15 Sec. 703.051. REGISTRATION REQUIRED. A person is required
16 to register with the department under Section 703.052 if the person
17 performs a medical laboratory test in a medical laboratory that is
18 certified by CLIA or is granted deemed status under rules adopted by
19 CLIA.

20 Sec. 703.052. MEDICAL LABORATORY SCIENCE PROFESSIONALS
21 REGISTRY. (a) The department shall maintain a registry of persons
22 described by Section 703.051. The executive commissioner shall
23 adopt rules prescribing the information a person must provide to
24 register. The department shall issue a registration to a person who
25 submits the required information.

26 (b) Information collected under this section must be:

27 (1) collected electronically on a standardized form;

1 (2) aggregated into a database; and
2 (3) made available to the public, provided that
3 confidential information is protected.

4 (c) A registration under this chapter expires on the second
5 anniversary of the date the registration is issued and may be
6 renewed as provided by rules adopted under this chapter.

7 (d) The department may charge a fee for a registration under
8 this chapter in an amount sufficient to cover the costs of
9 administering this chapter.

10 SUBCHAPTER C. ENFORCEMENT

11 Sec. 703.101. ADMINISTRATIVE PENALTY. (a) The
12 commissioner may impose an administrative penalty on the owner of a
13 medical laboratory who employs an individual who:

14 (1) is required by Section 703.051 to register with
15 the department under this chapter; and

16 (2) is not registered with the department.

17 (b) The amount of the penalty may not exceed an amount set by
18 the commissioner. Each day a violation continues or occurs is a
19 separate violation for the purpose of imposing a penalty. The
20 amount shall be based on:

21 (1) the seriousness of the violation, including the
22 nature, circumstances, extent, and gravity of the violation;

23 (2) any economic harm caused by the violation;

24 (3) the history of previous violations;

25 (4) the amount necessary to deter a future violation;

26 (5) efforts to correct the violation; and

27 (6) any other matter that justice may require.

1 (c) The owner of the medical laboratory may stay enforcement
2 during the time the order is under judicial review if the person
3 pays the penalty to the court clerk or files a supersedeas bond with
4 the court in the amount of the penalty. A person who cannot afford
5 to pay the penalty or file the bond may stay enforcement by filing
6 an affidavit in the manner required by the Texas Rules of Civil
7 Procedure for a party that cannot afford to file security for costs,
8 except that the department may contest the affidavit as provided by
9 those rules.

10 (d) A proceeding to impose an administrative penalty is
11 subject to Chapter 2001, Government Code.

12 SECTION 2. (a) A person is not required to submit the
13 information required by Section 703.052, Occupations Code, as added
14 by this Act, before September 1, 2016.

15 (b) A person is not required to register under Section
16 703.051, Occupations Code, as added by this Act, and the
17 commissioner of state health services may not impose an
18 administrative penalty under Section 703.101, Occupations Code, as
19 added by this Act, before December 1, 2016.

20 SECTION 3. (a) Except as provided by Subsection (b) of
21 this section, this Act takes effect September 1, 2015.

22 (b) Sections 703.051 and 703.101, Occupations Code, as
23 added by this Act, take effect December 1, 2016.