# GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2015

H HOUSE BILL 806

Short Title: Clinical Lab Science Practice Licensure. (Public)

Sponsors: Representatives Glazier and Lambeth (Primary Sponsors).

For a complete list of Sponsors, refer to the North Carolina General Assembly Web Site.

Referred to: Health, if favorable, Finance.

April 15, 2015 1 A BILL TO BE ENTITLED 2 AN ACT TO CREATE A LICENSING BOARD TO REGULATE CLINICAL 3 LABORATORY SCIENCE PRACTITIONERS. 4 The General Assembly of North Carolina enacts: **SECTION 1.** The General Statutes are amended by adding a new Chapter to read: 5 6 "Chapter 93F. 7 "North Carolina Clinical Laboratory Science Practice Board. 8 "§ 93F-1. Definitions. 9 The following definitions apply to this Chapter: 10 Board. – The North Carolina Clinical Laboratory Science Practice Board. (1) Clinical laboratory. – A facility in which services are performed to provide (2) 11 12 information or materials for use in the diagnosis, prevention, or treatment of 13 a disease or the identification or assessment of a medical or physical 14 condition. 15 Clinical laboratory science practitioner. – A health care professional who (3) performs clinical laboratory tests or who is engaged in management, 16 education, consulting, or research in clinical laboratory science. 17 Clinical laboratory scientist. – A person who performs clinical laboratory 18 <u>(4)</u> 19 testing pursuant to established protocols requiring the exercise of 20 independent judgment and responsibility. 21 Clinical laboratory test. – A procedure conducted by a laboratory or facility **(5)** 22 that provides information for the assessment of a medical condition or for the diagnosis, prevention, or treatment of a disease, including any related 23 24 oversight or interpretation or reporting of results. 25 "§ 93F-2. Board established; composition; terms. 26 There is hereby established the North Carolina Clinical Laboratory Science Practice 27 Board. The Board shall consist of five members. The composition of the Board shall be as 28 follows: 29 Two members shall be clinical laboratory science practitioners appointed by <u>(1)</u> the General Assembly upon the recommendation of the President Pro 30 Tempore of the Senate. 31 32 (2) Two members shall be clinical laboratory science practitioners appointed by



House of Representatives.

the General Assembly upon the recommendation of the Speaker of the

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One member shall be a member of the public who has never been a laboratory science practitioner and is in no way connected with the profession who shall be appointed by the Governor.

(b) Board members shall be appointed for four-year staggered terms. A Board member may not hold more than two consecutive terms. Each Board member shall hold office until July 1 of the year in which the Board member's respective term expires and shall serve until the Board member's successor is appointed and qualified. Appointments made by the General Assembly shall be made in accordance with G.S. 120-121.

The initial members of the Board shall be appointed on or before October 1, 2015. Of the Board members initially appointed, the Board member appointed by the Governor shall serve a two-year term, to expire July 1, 2017. The Board members appointed by the General Assembly upon the recommendation of the President Pro Tempore of the Senate shall serve three-year terms, to expire July 1, 2018. The Board members appointed by the Speaker of the House of Representatives shall serve four-year terms, to expire July 1, 2019.

Upon the expiration of the initial terms, Board members shall be appointed by the appointing authorities designated in subsection (a) of this section for a term of four years and shall serve until a successor is appointed and qualified.

- (c) All vacancies from unexpired terms shall be filled by the authority originally filling that position. Appointees to fill vacancies shall serve the remainder of the unexpired term and until a successor has been appointed and qualified.
- (d) The Board may remove any of its members for neglect of duty, incompetence, or unprofessional conduct.

#### "§ 93F-3. Meetings; election of officers; compensation.

The Board shall hold at least four meetings annually, and three members of the Board shall constitute a quorum for the transaction of business. Additional meetings may be held at other times within the State as may be necessary for the efficient transaction of the business of the Board. The Board may hold additional or special meetings at any time at the call of the chairman or on the call of any three members of the Board.

At the first scheduled meeting of the Board after October 1, 2015, and on July 1 of each odd-numbered year thereafter, the Board shall select from among its membership a chairman and a vice-chairman who shall serve for terms of two years or until their successors are elected.

Each member of the Board shall receive per diem and reimbursement for travel and subsistence as provided in G.S. 93B-5.

#### "§ 93F-4. Powers and duties of the Board.

The Board shall have the power and duty to do all of the following:

- (1) Administer the provisions of this Chapter.
- (2) Adopt rules as may be necessary to carry out the provisions of this Chapter.
- (3) Establish licensing criteria for applicants.
- (4) Approve clinical laboratory science training programs.
- (5) Establish continuing education and competency requirements for licensees.
- (6) Employ and discharge an executive director and other professional, clerical, and special personnel and to set the compensation and benefits for those persons.
- (7) Purchase or rent office space, equipment, and supplies necessary to carry out the provisions of this Chapter.
- (8) Adopt a seal by which it shall authenticate its proceedings, official documents, and licenses.
- (9) Conduct administrative hearings in accordance with Article 3A of Chapter 150B of the General Statutes.
- (10) Establish fees as allowed by this Chapter.
- (11) Issue, renew, deny, suspend, and revoke licenses pursuant to this Chapter.

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(12) Call upon the Attorney General to provide legal counsel and representation to the Board or, upon the approval of the Attorney General, hire another attorney to represent the Board, provided that the cost of legal representation is borne by the Board.

## "§ 93F-5. License required.

On and after January 1, 2016, no person shall engage in the practice of clinical laboratory science or hold out to the public that the person is a clinical laboratory science practitioner in this State unless the person is licensed pursuant to this Chapter.

### "§ 93F-6. Exemptions.

The provisions of this Chapter shall not apply to any of the following:

- (1) A person licensed to practice medicine pursuant to Chapter 90 of the General Statutes.
- (2) A clinical laboratory science practitioner employed by the United States or any bureau, division, or agency of the United States while in the discharge of the employee's official duties.
- (3) A clinical laboratory science practitioner engaged in teaching or research, provided that the results of any test performed are not used in health maintenance, diagnosis, or treatment of disease.
- (4) Students or trainees enrolled in a clinical laboratory science education or training program; provided that all of the following apply:
  - a. The activities performed are part of a planned curriculum of a clinical laboratory science program.
  - b. The persons work directly under the supervision of a person licensed to practice clinical laboratory science pursuant to this Chapter.
- (5) A person performing only waived tests pursuant to the federal laboratory requirements regulations adopted under 42 U.S.C. § 263a(d)(2).

#### "§ 93F-7. Requirements for licensure.

- (a) The Board shall have the authority to establish, classify, and issue licenses for clinical laboratory science practitioners. The Board shall establish rules to determine the minimum educational requirements, experience, and competency for each class of license issued.
- (b) Applicants shall make written application in the form and manner prescribed by the Board. Upon receipt of the application and payment of an application fee in an amount to be established by the Board, the Board shall issue a license for an applicant who meets the requirements established pursuant to subsection (a) of this section.

#### "§ 93F-8. Expiration and renewal of license; reinstatement.

- (a) All licenses issued by the Board pursuant to this Chapter shall expire two years after the date of issuance. A license may be renewed 45 days prior to its expiration by submitting (i) an application in a form prescribed by the Board, (ii) evidence of compliance with continuing education and competency standards as established by the Board, and (iii) a renewal fee in an amount to be established by the Board.
- (b) An expired license may be reinstated by submitting the application as provided in subsection (a) of this section along with a reinstatement fee in an amount established by the Board. The Board may, in its discretion, consider licensees who fail to renew licensure within six months of expiration as not having been previously licensed and subject to the provisions of this Chapter and the rules of the Board relating to the issuance of an original license.

### "§ 93F-9. Disciplinary action by the Board; injunctions.

(a) The Board shall have the authority to take disciplinary action. Upon its own initiative or upon the complaint of any person, the Board may investigate the actions of any person or entity licensed or registered under this Chapter, or any other person or entity who shall assume to act in such capacity. If the Board finds probable cause that a licensee has

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violated any of the provisions of this Chapter, the Board may hold a hearing on the allegations 1 2 of misconduct under Article 3A of Chapter 150B of the General Statutes. 3 The Board may suspend or revoke a license issued pursuant to this Chapter or 4 reprimand a licensee if, following a hearing, the Board adjudges the licensee to be guilty of any 5 of the following: 6 Making any willful or negligent misrepresentation or any willful or negligent <u>(1)</u> 7 omission of material fact on an application or other submission to the Board. 8 Engaging in gross negligence or gross incompetence as a clinical laboratory (2) 9 science practitioner. 10 Engaging in any act for which an active clinical laboratory science <u>(3)</u> 11 practitioner license is required with an expired or inactive license. 12 Demonstrating incompetence in the performance of clinical laboratory <u>(4)</u> 13 testing or procedures or erroneous reporting of results. 14 Performing a test or issuing a report to a person not authorized by law to <u>(5)</u> 15

receive such services.

(6) Reporting a test result when no laboratory test was performed on a clinical specimen.

(7) Having been convicted of or entered a plea of guilty or nolo contendere to any felony charge or to any misdemeanor charge involving moral turpitude.

(8) <u>Having a license revoked, suspended, or denied by the licensing authority of another jurisdiction.</u>

(9) Any other conduct which constitutes improper, fraudulent, or dishonest dealing.

(10) Violating any rule adopted by the Board or any provision of this Chapter or aiding and abetting any person or entity in such a violation.

(c) The Board may appear in its own name in superior court in actions for injunctive relief, a restraining order, or other appropriate action to prevent any person or entity from violating the provisions of this Chapter or rules adopted by the Board. The superior court shall have the power to grant injunctive relief even if criminal prosecution has been or may be instituted as a result of the violations, regardless of whether the person or entity is a registrant or licensee of the Board."

**SECTION 2.** This act is effective when it becomes law.

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