P.L.2016, CHAPTER 86, ***approved January 9, 2017***
Senate, No. 976 ***(Second Reprint)***

AN ACT concerning bio-analytical and clinical laboratories and amending P.L.1953, c.420 and P.L.1975, c.166.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

[1]1. Section 2 of P.L.1953, c.420 (C.45:9-42.2) is amended to read as follows:

As used in this act, the following terms are defined as follows:

a. "Board" means the State Board of Medical Examiners which shall have authority to examine and license bio-analytical laboratory directors as set forth in this act. The board is authorized to make necessary rules to implement the provisions of this act.

b. "License" means a license granted and issued by the board under this act to any person who makes application therefor and fulfills the requirements set forth by this act. A license shall be either a plenary or specialty license issued pursuant to the provisions of section 7 of P.L.1953, c. 420 (C. 45:9-42.7).

c. A "Bio-analytical Laboratory" is any place, establishment or institution organized and operated primarily for the performance of chemical, microscopic, serological, parasitological, bacteriological or any other tests, by the practical application of one or more of the fundamental sciences, to material originating from the human body, for the purpose of obtaining scientific data which may be used as an aid to ascertain the state of health. The interpretation of cytologic and histologic criteria of disease is not considered to be within the scope of this definition of a bio-analytical laboratory.

d. A "Bio-analytical Laboratory Director" is any person licensed and qualified to <u>manage and</u> direct **[**and supervise**]** the technical work in a bio-analytical laboratory as defined in this act.

<u>e. [2]"[2]Point-of-care laboratory testing" means use of a laboratory testing instrument, kit, or test to which the following applies:

(1) The testing instrument, kit, or test is designed to be used at or near the site of the patient for whom the test or examination is being conducted;

(2) The testing instrument, kit, or test is used to perform testing outside the physical facilities of a certified clinical laboratory; and

(3) The testing instrument, kit, or test:</u>

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined <u>thus</u> is new matter
Matter enclosed in superscript numerals has been adopted as follows:
[1]Assembly floor amendments adopted June 30, 2016.
[2]Assembly floor amendments adopted September 15, 2016.

(a) is used to perform waived tests or moderate complexity clinical laboratory tests or examinations classified under the federal "Clinical Laboratory Improvement Amendments of 1988," Pub. L. 100-578 (42 U.S.C. s.263a) and any regulations adopted pursuant thereto;

(b) is used to perform tests or examinations on biological specimens that require no preparation after collection [2], except use of a reagent[2]; and

(c) is used to perform tests or examinations without the necessity for testing personnel to perform calibration or maintenance, except resetting pursuant to the manufacturer's instructions or basic cleaning or disinfecting; and

(4) For moderate complexity testing, the testing instrument, kit, or test is used in accordance with the patient test management system, the quality control program, and the comprehensive quality assurance program established and maintained by the laboratory pursuant to the standards established under the "Clinical Laboratory Improvement Amendments of 1988," Pub.L.100-578 (42 U.S.C. s.263a), any regulations adopted pursuant thereto, and any other procedures currently or subsequently approved by the federal Centers for Medicare & Medicaid Services and specified in Appendix C of the State Operations Manual.

f. "Waived test" means a test system, assay, or examination that is authorized as "waived" by the federal Food and Drug Administration or authorized as "waived" by the federal Department of Health and Human Services and currently or subsequently listed in 42 C.F.R. 493.15c.

g. "Certified clinical laboratory" means a clinical laboratory certified pursuant to the "Clinical Laboratory Improvement Amendments of 1988," Pub.L.100-578 (42 U.S.C.263a), but does not include a clinical laboratory possessing a certificate of waiver issued pursuant to 42 U.S.C.263a.(d)(2) and any regulations adopted pursuant thereto.[1]

(cf: P.L.1981, c.314, s.1)

[1][1.] 2.[1] Section 7 of P.L.1953, c.420 (C.45:9-42.7) is amended to read as follows:

7. a. Any person possessing the educational and experiential qualifications [hereinafter] set forth in federal regulations at 42 C.F.R. Part 493, subpart M, may apply for examination for a plenary license as a bio-analytical laboratory director. [The following qualifications as to education and experience are established as prerequisites for application for examination or licensure for a bio-analytical laboratory director's plenary license:

(1) A doctorate degree, plus not less than one year of experience, or

(2) A master's degree, plus not less than two years of experience, or

(3) A bachelor's degree, plus not less than three years of experience.

The above academic degrees shall be course-earned in the fields of chemistry, pharmacy or the biological sciences and awarded by an educational institution approved by the board. "Years of experience," as used in this section, means for plenary license applicants, years of general bio-analytical laboratory experience acceptable to the board.**]**

[1]The following qualifications as to education and experience are established as prerequisites for application for examination or licensure for a bio-analytical laboratory director's plenary license:

(1) A doctorate degree, plus not less than one year of experience, or

(2) A master's degree, plus not less than two years of experience, or

(3) A bachelor's degree, plus not less than three years of experience.

The above academic degrees shall be course-earned in the fields of chemistry, pharmacy or the biological sciences and awarded by an educational institution approved by the board. "Years of experience," as used in this section, means for plenary license applicants, years of general bio-analytical laboratory experience acceptable to the board.**[1]**

b. The board shall grant a plenary license to all applicants who meet the qualifications for licensure and satisfactorily complete the examination given by the board **[1]**, unless exempt from examination by the board for those applicants licensed to practice medicine and surgery who are certified in clinical pathology or anatomic pathology, or who possess qualifications that are equivalent to those required for such certifications**[1]**.

All examinations shall be written in the English language, but the board, in its discretion, may use supplementary oral and practical examinations of the whole class or of individual applicants. The scope of all examinations shall be such as to determine the competence of the applicant to perform and supervise **[**such**]** those tests which are within the scope of the director's plenary license and the clinical laboratory license under the "New Jersey Clinical Laboratory Improvement Act," P.L.1975, c.166 (C.45:9-42.26 et seq.).

c. The board shall grant a specialty license in one or more of the fields of toxicological chemistry, microbiology, cytogenetics, biochemical genetics, diagnostic laboratory immunology and clinical chemistry if the applicant is certified by a national accrediting board, which board requires a doctorate degree plus experience, such as but not limited to the American Board of Pathology, the American Osteopathic Board of Pathology, the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bio-analysis or the American Board of Medical Genetics, or any other national accrediting board recognized by the State Board of Medical Examiners.

The applicant for a specialty license [1]⟦must⟧ shall[1] offer proof to the satisfaction of the State Board of Medical Examiners of one year's experience in the specialty, which one year's experience ⟦must⟧ shall be within three years next preceding the date of application for the specialty license.

The specialty license shall authorize the licensee to perform and supervise only those tests which are within the scope of the specialty.

(cf: P.L.1991, c.236, s.1)

[1]⟦2.⟧ 3.[1] Section 18 of P.L.1953, c.420 (C.45:9-42.18) is amended to read as follows:

18. Each bio-analytical laboratory shall be under the ⟦direct and constant supervision⟧ overall management and direction of either:

(a) a person licensed to practice medicine and surgery in the State of New Jersey, or

(b) a licensed bio-analytical laboratory director, who shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed.

(cf: P.L.1953, c.420, s.18)

[1]⟦3.⟧ 4.[1] Section 20 of P.L.1953, c.420 (C.45:9-42.20) is amended to read as follows:

20. The provisions of this act shall not affect:

a. Physicians or members of other professions who, in their private practices perform bio-analytical laboratory tests in their own offices or laboratories for their own patients pursuant to licenses respectively granted to them according to law.

b. Nonprofit research institutions.

c. Bio-analytical laboratories of hospitals, licensed by the ⟦New Jersey Department of Institutions and Agencies⟧ Department of Health, where the work is confined to regularly admitted patients or registered clinic patients of the hospital.

d. Bio-analytical laboratories operated by the United States Government, the ⟦State⟧ Department of Health, or any county or municipality of the State.

e. [1]⟦Bio-analytical laboratories possessing a federal certificate of waiver issued pursuant to the "Clinical Laboratory Improvement Amendments of 1988" (Public Law 100-578) 42 U.S.C. s.263a and any regulations adopted pursuant thereto that perform:

(1) waived tests authorized by the federal Food and Drug Administration; or

(2) waived tests authorized by the federal Department of Health and Human Services and listed in 42 C.F.R. s.493.15(c)⟧ Facilities at which the only testing that is conducted is point-of-care laboratory testing[1] .

(cf: P.L.1953, c.420, s.20)

[1]5. Section 2 of P.L.1975, c.166 (C.45:9-42.27) is amended to read as follows:

As used in this act:

a. "Clinical laboratory" , except as used in subsection k. of this section, means any facility used for the performance of chemical, bacteriologic, virologic, parasitologic, serologic, hematologic, immunohematologic, biophysical, cytologic or other examinations of materials derived from the human body for the purpose of yielding information for the diagnosis, prevention or treatment of disease or the assessment of medical condition. ⟦Anatomic pathology is not considered to be within the scope of this definition.⟧ Any facility used for the collection, processing and transmission of specimens to another facility for the performance of clinical tests falls within the purview of this act.

b. "Department" means the ⟦State⟧ Department of Health.

c. "Commissioner" means the ⟦State⟧ Commissioner of Health or his duly authorized agent.

d. "Clinical laboratory owner" means a person or agency in whom is vested the rights of control, possession, and dominion of a clinical laboratory and for the purposes of this act shall include a county, municipality, or any other owner of an institution operating a clinical laboratory.

e. "Clinical laboratory director" means a person who is responsible for the administration of the technical and scientific operation of a clinical laboratory, including, but not limited to, supervision of procedures for testing and reporting of results. Nothing in this act shall be deemed to exempt the director of a clinical laboratory from the licensure requirements of P.L.1953, c. 420 (C. 45:9-42.1 et seq.), where such requirements would otherwise be applicable.

f. "Clinical laboratory evaluation program" means a program of evaluating the proficiency of clinical laboratories by the department.

g. "Anatomic pathology" means the gross or microscopic examination of tissues by a physician specifically trained to interpret and diagnose disease by such examination.

h. "Person" means any individual, partnership, limited partnership, corporation or other legal entity.

i. Point-of-care laboratory testing" means use of a laboratory testing instrument, kit, or test to which the following applies:

(1) The testing instrument, kit, or test is designed to be used at or near the site of the patient for whom the test or examination is being conducted;

(2) The testing instrument, kit, or test is used to perform testing outside the physical facilities of a certified clinical laboratory; and

(3) The testing instrument, kit, or test:

(a) is used to perform waived tests or moderate complexity clinical laboratory tests or examinations classified under the federal "Clinical

Laboratory Improvement Amendments of 1988," Pub. L. 100-578 (42 U.S.C. s.263a) and any regulations adopted pursuant thereto;

(b) is used to perform tests or examinations on biological specimens that require no preparation after collection; and

(c) is used to perform tests or examinations without the necessity for testing personnel to perform calibration or maintenance, except resetting pursuant to the manufacturer's instructions or basic cleaning or disinfecting; and

(4) For moderate complexity testing, the testing instrument, kit, or test is used in accordance with the patient test management system, the quality control program, and the comprehensive quality assurance program established and maintained by the laboratory pursuant to the standards established under the "Clinical Laboratory Improvement Amendments of 1988," Pub.L.100-578 (42 U.S.C. s.263a), any regulations adopted pursuant thereto, and any other procedures currently or subsequently approved by the federal Centers for Medicare & Medicaid Services and specified in Appendix C of the State Operations Manual.

j. "Waived test" means a test system, assay, or examination that is authorized as "waived" by the federal Food and Drug Administration or authorized as "waived" by the federal Department of Health and Human Services and currently or subsequently listed in 42 C.F.R. 493.15c.

k. "Certified clinical laboratory" means a clinical laboratory certified pursuant to the "Clinical Laboratory Improvement Amendments of 1988," Pub.L.100-578 (42 U.S.C.263a), but does not include a clinical laboratory possessing a certificate of waiver issued pursuant to 42 U.S.C.263a.(d)(2) and any regulations adopted pursuant thereto.[1]

(cf: P.L.1975, c.166, s.2)

[1]**[**4.**]** 6.[1] Section 8 of P.L.1975, c.166 (C.45:9-42.33) is amended to read as follows:

8. The provisions of this act shall not apply to:

a. Clinical laboratories operated and maintained exclusively for research and teaching purposes, involving no patient or public health services whatsoever;

b. Clinical laboratories operated by the United States Government, or blood banks licensed under P.L.1963, c.33 (C.26:2A-2 et seq.);

c. Clinical laboratories specifically exempted from the provisions of this act by rules and regulations promulgated by the Public Health Council pursuant to section 9 of P.L.1975, c.166 (C.45:9-42.34); **[**or**]**

d. Clinical laboratories which are operated by the Department of Corrections, any county jail, any county probation department, or any drug or alcohol treatment center providing services to persons under the jurisdiction of any of these agencies or in a program of supervisory treatment pursuant to the provisions of N.J.S.2C:43-13 and which

perform only urinalysis for screening purposes to detect the presence of alcohol or illegal substances. The Attorney General shall approve procedures, methods, and devices used by these agencies or centers in screening for alcohol or illegal substances; or

e. [1][Clinical laboratories possessing a federal certificate of waiver issued pursuant to the "Clinical Laboratory Improvement Amendments of 1988" (Public Law 100-578) 42 U.S.C. s.263a and any regulations adopted pursuant thereto that perform:

(1) waived tests authorized by the federal Food and Drug Administration; or

(2) waived tests authorized by the federal Department of Health and Human Services and listed in 42 C.F.R. s.493.15(c)] Facilities at which the only testing that is conducted is point-of-care laboratory testing[1] .

(cf: P.L.1991, c.26, s.1)

[1][5.] 7.[1] Section 9 of P.L.1975, c.166 (C.45:9-42.34) is amended to read as follows:

9. The Public Health Council of the department shall promulgate rules and regulations for operation of clinical laboratories, including the use of quality control programs as described in subsection h. of this section, which shall be incorporated in and made a part of the State Sanitary Code. [Where feasible such] [1][The] Notwithstanding the use of quality control programs as described in subsection h. of this section and the recognition of waived tests as described in subsection i. of this section, the[1] rules and regulations shall [equal or] [1][not exceed][1] [minimum standards for laboratory certification contained in Federal] [1]at least equal[1] the standards set forth in federal rules and regulations promulgated pursuant to the ["Clinical Laboratories Improvement Act of 1967" (Public Law 90-174) 42 U.S.C. 263a] "Clinical Laboratory Improvement Amendments of 1988" (Public Law 100-578) 42 U.S.C. 263a. [1]Any rules or regulations promulgated after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill) that exceed those federal standards shall only be promulgated after a rulemaking process that includes notice and comment and a public hearing.[1] The rules and regulations so promulgated shall include but shall not be limited to standards for:

a. Construction of new, or modification of existing clinical laboratories.

b. Sanitary and safe conditions within the clinical laboratory and its surroundings, including adequate working space, lighting, fire prevention, and safety measures.

c. Clinical laboratory equipment [,] and maintenance procedures for [such] the equipment [and personnel essential to proper conduct and operation of a clinical laboratory, including standards for education, experience, continuing education, and periodic proficiency testing for laboratory directors, supervisors, technicians, and other

personnel which the department may deem necessary for adequate laboratory staffing**]** [1]and personnel essential to proper conduct and operation of a clinical laboratory, including standards for education, experience, and continuing education[1] .

d. The acceptance, collection, transportation, identification, and examination of clinical laboratory specimens and reporting of results by clinical laboratories.

e. Reporting by laboratories of diseases for the protection of the public health. The department shall furnish forms for this purpose. **[**Such**]** The reports shall not be construed as constituting a diagnosis nor shall any clinical laboratory making **[**such**]** a report be held liable under the laws of this State for having violated a trust or confidential relationship.

f. Submitting such reports concerning clinical laboratory operations as may be necessary to administer this act. Each laboratory shall maintain a manual of procedures followed in that laboratory, which shall be reviewed and updated annually. **[**Such**]** The manual shall also include, but not be limited to, a list of equipment used for each procedure.

g. Exemptions of specific types of clinical laboratories from the provisions of section 7 of P.L.1971, c.136 (C.26:2H-7).

h. The use of a quality control program by clinical laboratories [1]**[**that meets**]** which shall not exceed[1] the standards set forth in federal regulations promulgated pursuant to the "Clinical Laboratory Improvement Amendments of 1988," (Public Law 100-578) 42 U.S.C. 263a, effective as of January 1, 2016 [1], or as subsequently amended[1] , including the following alternative quality control testing procedures approved by the federal Centers for Medicare and Medicaid Services:

(1) [1]**[**until December 31, 2016, equivalent quality control procedures as specified in Appendix C of the State Operations Manual adopted by the Centers for Medicare and Medicaid Services;

(2) starting on January 1, 2017, individualized quality control plans**]** Individualized Quality Control Plans[1] , as specified in Appendix C of the State Operations Manual; and

[1]**[**(3)**]** (2)[1] any other equivalent quality control procedures subsequently approved by the Centers for Medicare and Medicaid Services and specified in Appendix C of the State Operations Manual.

i. Recognition of [1]all waived tests and[1] waivers under the "Clinical Laboratory Improvement Amendments of 1988" (Public Law 100-578) 42 U.S.C. 263a and all regulations adopted pursuant thereto (42 C.F.R. Part 493).

j. [1]**[**Personnel qualifications and proficiency testing standards that do not exceed federal standards set forth in federal regulations at 42 C.F.R. Part 493, subpart M**]** The use of waived tests by clinical laboratories, which shall not exceed the standards set forth in the federal rules and regulations promulgated pursuant to the "Clinical Laboratory Improvement Amendments of 1988" (Public Law 100-

578) 42 U.S.C. 263a, effective as of January 1, 2016, or as subsequently amended, unless expressly required under this Act or the Public Health Council determines that it is necessary to exceed those federal standards in order to protect the public health. Such determinations shall detail the council's justification for exceeding federal standards[1].

(cf: P.L.1975, c.166, s.9)

[1][6.] 8.[1] Section 12 of P.L.1975, c.166 (C.45:9-42.37) is amended to read as follows:

12. The department shall establish and conduct a clinical laboratory evaluation program to:

a. Prescribe minimum standards of performance in the examination of specimens [1][, which standards shall not] , and any standards that would[1] exceed the standards established under federal rules and regulations promulgated pursuant to the "Clinical Laboratories Improvement Amendments of 1988" (Public Law 100-578) 42 U.S.C. 263a [1]shall only be promulgated after a rulemaking process that includes notice and comment and a public hearing[1];

b. Test the proficiency of clinical laboratories to determine if the minimum standards of performance established pursuant to P.L. , c. (pending before the Legislature as this bill) are being met; and

c. Develop and organize appropriate consultation and training activities in clinical laboratory procedures with the purpose of improving the quality of performance of clinical laboratories licensed by this act.

[1]d. In lieu of routine on-site survey and inspection of any clinical laboratory to determine compliance with this Act, the department may instead formally recognize and rely upon the routine survey and inspection of clinical laboratories by any accreditation entity approved by the Centers for Medicare and Medicaid Services pursuant to the "Clinical Laboratories Improvement Amendments of 1988" (Public Law 100-578) 42 U.S.C. 263a, provided the department determines that the standards of the accreditation entity are equivalent to the department's standards for on-site survey and inspection.

e. Nothing contained in this section shall be construed to limit the department's authority to rely upon the inspection and survey results of any accreditation entity approved by the Centers for Medicare & Medicaid Services pursuant to the "Clinical Laboratories Improvement Amendments of 1988," Pub.L.100-578 (42 U.S.C. 263a), or conduct a complaint inspection of any laboratory at any time.[1]

(cf: P.L.1975, c.166, s.12)

[1][7.] 9.[1] This act shall take effect immediately except that the Public Health Council may take any anticipatory administrative action in advance as shall be necessary for the implementation of this act.

Requires Public Health Council to promulgate rules and regulations for use of quality control programs in bio-analytical and clinical laboratories.