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RWH/JA

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

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

3
4 **BE IT ENACTED** by the Senate and General Assembly of the State
5 of New Jersey:

6
7 ¹1. Section 2 of P.L.1953, c.420 (C.45:9-42.2) is amended to
8 read as follows:

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

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

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

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

28 d. A "Bio-analytical Laboratory Director" is any person
29 licensed and qualified to manage and direct **【and supervise】** the
30 technical work in a bio-analytical laboratory as defined in this act.

31 e. ²"Point-of-care laboratory testing" means use of a
32 laboratory testing instrument, kit, or test to which the following
33 applies:

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

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

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

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 thus is new matter

Matter enclosed in superscript numerals has been adopted as follows:

¹Assembly floor amendments adopted June 30, 2016.

²Assembly floor amendments adopted September 15, 2016.

1 (a) is used to perform waived tests or moderate complexity
2 clinical laboratory tests or examinations classified under the federal
3 “Clinical Laboratory Improvement Amendments of 1988,” Pub. L.
4 100-578 (42 U.S.C. s.263a) and any regulations adopted pursuant
5 thereto;

6 (b) is used to perform tests or examinations on biological
7 specimens that require no preparation after collection ², except use
8 of a reagent²; and

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

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

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

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

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

35
36 ¹**[1.]** 2.¹ Section 7 of P.L.1953, c.420 (C.45:9-42.7) is amended
37 to read as follows:

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

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

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

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

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

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

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

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

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

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

22 b. The board shall grant a plenary license to all applicants who
23 meet the qualifications for licensure and satisfactorily complete the
24 examination given by the board ¹, unless exempt from examination by
25 the board for those applicants licensed to practice medicine and
26 surgery who are certified in clinical pathology or anatomic pathology,
27 or who possess qualifications that are equivalent to those required for
28 such certifications¹.

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

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

1 The applicant for a specialty license ¹~~【must】~~ shall¹ offer proof to
2 the satisfaction of the State Board of Medical Examiners of one year's
3 experience in the specialty, which one year's experience ~~【must】~~ shall
4 be within three years next preceding the date of application for the
5 specialty license.

6 The specialty license shall authorize the licensee to perform and
7 supervise only those tests which are within the scope of the specialty.
8 (cf: P.L.1991, c.236, s.1)

9
10 ¹~~【2.】~~ 3.¹ Section 18 of P.L.1953, c.420 (C.45:9-42.18) is
11 amended to read as follows:

12 18. Each bio-analytical laboratory shall be under the ~~【direct and~~
13 constant supervision】 overall management and direction of either:

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

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

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

20
21 ¹~~【3.】~~ 4.¹ Section 20 of P.L.1953, c.420 (C.45:9-42.20) is
22 amended to read as follows:

23 20. The provisions of this act shall not affect:

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

28 b. Nonprofit research institutions.

29 c. Bio-analytical laboratories of hospitals, licensed by the ~~【New~~
30 Jersey Department of Institutions and Agencies】 Department of
31 Health, where the work is confined to regularly admitted patients or
32 registered clinic patients of the hospital.

33 d. Bio-analytical laboratories operated by the United States
34 Government, the ~~【State】~~ Department of Health, or any county or
35 municipality of the State.

36 e. ¹~~【Bio-analytical laboratories possessing a federal certificate of~~
37 waiver issued pursuant to the “Clinical Laboratory Improvement
38 Amendments of 1988” (Public Law 100-578) 42 U.S.C. s.263a and
39 any regulations adopted pursuant thereto that perform:

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

42 (2) waived tests authorized by the federal Department of Health
43 and Human Services and listed in 42 C.F.R. s.493.15(c)】 Facilities at
44 which the only testing that is conducted is point-of-care laboratory
45 testing¹ .

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

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

3 As used in this act:

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

15 b. "Department" means the **【State】** Department of Health.

16 c. "Commissioner" means the **【State】** Commissioner of Health or
17 his duly authorized agent.

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

23 e. "Clinical laboratory director" means a person who is
24 responsible for the administration of the technical and scientific
25 operation of a clinical laboratory, including, but not limited to,
26 supervision of procedures for testing and reporting of results. Nothing
27 in this act shall be deemed to exempt the director of a clinical
28 laboratory from the licensure requirements of P.L.1953, c. 420 (C.
29 45:9-42.1 et seq.), where such requirements would otherwise be
30 applicable.

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

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

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

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

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

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

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

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

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

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

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

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

19 j. “Waived test” means a test system, assay, or examination that
 20 is authorized as “waived” by the federal Food and Drug
 21 Administration or authorized as “waived” by the federal Department
 22 of Health and Human Services and currently or subsequently listed in
 23 42 C.F.R. 493.15c.

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

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

31

32 ¹**[4.] 6.¹** Section 8 of P.L.1975, c.166 (C.45:9-42.33) is amended
 33 to read as follows:

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

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

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

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

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

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

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

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

11 (2) waived tests authorized by the federal Department of Health
 12 and Human Services and listed in 42 C.F.R. s.493.15(c)] Facilities at
 13 which the only testing that is conducted is point-of-care laboratory
 14 testing¹.

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

16

17 ¹**["5.] 7.** Section 9 of P.L.1975, c.166 (C.45:9-42.34) is amended
 18 to read as follows:

19 9. The Public Health Council of the department shall promulgate
 20 rules and regulations for operation of clinical laboratories, including
 21 the use of quality control programs as described in subsection h. of this
 22 section, which shall be incorporated in and made a part of the State
 23 Sanitary Code. [Where feasible such] ¹**["The]** Notwithstanding the
 24 use of quality control programs as described in subsection h. of this
 25 section and the recognition of waived tests as described in subsection i.
 26 of this section, the¹ rules and regulations shall [equal or] ¹**["not**
 27 **exceed]** ¹**["minimum standards for laboratory certification contained in**
 28 **Federal] ¹at least equal¹ the standards set forth in federal** rules and
 29 regulations promulgated pursuant to the **["Clinical Laboratories**
 30 **Improvement Act of 1967" (Public Law 90-174) 42 U.S.C. 263a]**
 31 **"Clinical Laboratory Improvement Amendments of 1988" (Public Law**
 32 **100-578) 42 U.S.C. 263a. ¹Any rules or regulations promulgated after**
 33 **the effective date of P.L. , c. (C.) (pending before the**
 34 **Legislature as this bill) that exceed those federal standards shall only**
 35 **be promulgated after a rulemaking process that includes notice and**
 36 **comment and a public hearing.¹** The rules and regulations so
 37 promulgated shall include but shall not be limited to standards for:

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

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

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

1 personnel which the department may deem necessary for adequate
2 laboratory staffing] ¹and personnel essential to proper conduct and
3 operation of a clinical laboratory, including standards for education,
4 experience, and continuing education¹ .

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

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

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

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

22 h. The use of a quality control program by clinical laboratories
23 **1[that meets]** which shall not exceed¹ the standards set forth in federal
24 regulations promulgated pursuant to the "Clinical Laboratory
25 Improvement Amendments of 1988," (Public Law 100-578) 42 U.S.C.
26 263a, effective as of January 1, 2016¹, or as subsequently amended¹ ,
27 including the following alternative quality control testing procedures
28 approved by the federal Centers for Medicare and Medicaid Services:

29 (1) **1[until December 31, 2016, equivalent quality control**
30 **procedures as specified in Appendix C of the State Operations Manual**
31 **adopted by the Centers for Medicare and Medicaid Services;**

32 (2) starting on January 1, 2017, individualized quality control
33 plans] **Individualized Quality Control Plans¹ , as specified in**
34 Appendix C of the State Operations Manual; and

35 **1[(3)] (2)¹ any other equivalent quality control procedures**
36 **subsequently approved by the Centers for Medicare and Medicaid**
37 **Services and specified in Appendix C of the State Operations Manual.**

38 i. Recognition of ¹all waived tests and¹ waivers under the
39 "Clinical Laboratory Improvement Amendments of 1988" (Public Law
40 100-578) 42 U.S.C. 263a and all regulations adopted pursuant thereto
41 (42 C.F.R. Part 493).

42 j. **1[Personnel qualifications and proficiency testing standards**
43 **that do not exceed federal standards set forth in federal regulations at**
44 **42 C.F.R. Part 493, subpart M]** The use of waived tests by clinical
45 laboratories, which shall not exceed the standards set forth in the
46 federal rules and regulations promulgated pursuant to the "Clinical
47 Laboratory Improvement Amendments of 1988" (Public Law 100-

1 578) 42 U.S.C. 263a, effective as of January 1, 2016, or as
2 subsequently amended, unless expressly required under this Act or the
3 Public Health Council determines that it is necessary to exceed those
4 federal standards in order to protect the public health. Such
5 determinations shall detail the council's justification for exceeding
6 federal standards¹.

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

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

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

13 a. Prescribe minimum standards of performance in the
14 examination of specimens ¹**[, which standards shall not]** , and any
15 standards that would¹ exceed the standards established under federal
16 rules and regulations promulgated pursuant to the "Clinical
17 Laboratories Improvement Amendments of 1988" (Public Law 100-
18 578) 42 U.S.C. 263a ¹shall only be promulgated after a rulemaking
19 process that includes notice and comment and a public hearing¹;

20 b. Test the proficiency of clinical laboratories to determine if the
21 minimum standards of performance established pursuant to P.L. ,

22 c. (pending before the Legislature as this bill) are being met; and

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

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

36 e. Nothing contained in this section shall be construed to limit the
37 department's authority to rely upon the inspection and survey results
38 of any accreditation entity approved by the Centers for Medicare &
39 Medicaid Services pursuant to the "Clinical Laboratories
40 Improvement Amendments of 1988," Pub.L.100-578 (42 U.S.C.
41 263a), or conduct a complaint inspection of any laboratory at any
42 time.¹

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

44
45 ¹**[7.] 9.**¹ This act shall take effect immediately except that the
46 Public Health Council may take any anticipatory administrative
47 action in advance as shall be necessary for the implementation of
48 this act.

1

2

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

SENATE, No. 976

STATE OF NEW JERSEY 217th LEGISLATURE

INTRODUCED FEBRUARY 4, 2016

Sponsored by:

Senator ROBERT M. GORDON

District 38 (Bergen and Passaic)

Senator JENNIFER BECK

District 11 (Monmouth)

SYNOPSIS

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

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 2/12/2016)

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

3

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

6

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

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

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

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

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

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

28 b. The board shall grant a plenary license to all applicants who
29 meet the qualifications for licensure and satisfactorily complete the
30 examination given by the board.

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

40 c. The board shall grant a specialty license in one or more of
41 the fields of toxicological chemistry, microbiology, cytogenetics,
42 biochemical genetics, diagnostic laboratory immunology and
43 clinical chemistry if the applicant is certified by a national
44 accrediting board, which board requires a doctorate degree plus
45 experience, such as but not limited to the American Board of
46 Pathology, the American Osteopathic Board of Pathology, the

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 thus is new matter.

1 American Board of Medical Microbiology, the American Board of
2 Clinical Chemistry, the American Board of Bio-analysis or the
3 American Board of Medical Genetics, or any other national
4 accrediting board recognized by the State Board of Medical
5 Examiners.

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

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

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

15

16 2. Section 18 of P.L.1953, c.420 (C.45:9-42.18) is amended to
17 read as follows:

18 18. Each bio-analytical laboratory shall be under the **[direct and**
19 **constant supervision]** overall management and direction of either:

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

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

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

26

27 3. Section 20 of P.L.1953, c.420 (C.45:9-42.20) is amended to
28 read as follows:

29 20. The provisions of this act shall not affect:

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

34 b. Nonprofit research institutions.

35 c. Bio-analytical laboratories of hospitals, licensed by the
36 **[New Jersey Department of Institutions and Agencies]** Department
37 of Health, where the work is confined to regularly admitted patients
38 or registered clinic patients of the hospital.

39 d. Bio-analytical laboratories operated by the United States
40 Government, the **[State]** Department of Health, or any county or
41 municipality of the State.

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

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

1 (2) waived tests authorized by the federal Department of Health
2 and Human Services and listed in 42 C.F.R. s.493.15(c).

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

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

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

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

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

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

18 d. Clinical laboratories which are operated by the Department
19 of Corrections, any county jail, any county probation department, or
20 any drug or alcohol treatment center providing services to persons
21 under the jurisdiction of any of these agencies or in a program of
22 supervisory treatment pursuant to the provisions of N.J.S.2C:43-13
23 and which perform only urinalysis for screening purposes to detect
24 the presence of alcohol or illegal substances. The Attorney General
25 shall approve procedures, methods, and devices used by these
26 agencies or centers in screening for alcohol or illegal substances; or

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

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

33 (2) waived tests authorized by the federal Department of Health
34 and Human Services and listed in 42 C.F.R. s.493.15(c).

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

36
37 5. Section 9 of P.L.1975, c.166 (C.45:9-42.34) is amended to
38 read as follows:

39 9. The Public Health Council of the department shall
40 promulgate rules and regulations for operation of clinical
41 laboratories, including the use of quality control programs as
42 described in subsection h. of this section, which shall be
43 incorporated in and made a part of the State Sanitary Code. **【Where**
44 **feasible such】** The rules and regulations shall **【equal or】** not exceed
45 **【minimum standards for laboratory certification contained in**
46 **Federal】** the standards set forth in federal rules and regulations
47 promulgated pursuant to the **【"Clinical Laboratories Improvement**
48 **Act of 1967" (Public Law 90-174) 42 U.S.C. 263a】** "Clinical

1 Laboratory Improvement Amendments of 1988" (Public Law 100-
2 578) 42 U.S.C. 263a. The rules and regulations so promulgated
3 shall include but shall not be limited to standards for:
4 a. Construction of new, or modification of existing clinical
5 laboratories.
6 b. Sanitary and safe conditions within the clinical laboratory
7 and its surroundings, including adequate working space, lighting,
8 fire prevention, and safety measures.
9 c. Clinical laboratory equipment **[,]** and maintenance
10 procedures for **[such]** the equipment **[and** personnel essential to
11 proper conduct and operation of a clinical laboratory, including
12 standards for education, experience, continuing education, and
13 periodic proficiency testing for laboratory directors, supervisors,
14 technicians, and other personnel which the department may deem
15 necessary for adequate laboratory staffing**]**.
16 d. The acceptance, collection, transportation, identification,
17 and examination of clinical laboratory specimens and reporting of
18 results by clinical laboratories.
19 e. Reporting by laboratories of diseases for the protection of
20 the public health. The department shall furnish forms for this
21 purpose. **[Such]** The reports shall not be construed as constituting
22 a diagnosis nor shall any clinical laboratory making **[such]** a report
23 be held liable under the laws of this State for having violated a trust
24 or confidential relationship.
25 f. Submitting such reports concerning clinical laboratory
26 operations as may be necessary to administer this act. Each
27 laboratory shall maintain a manual of procedures followed in that
28 laboratory, which shall be reviewed and updated annually. **[Such]**
29 The manual shall also include, but not be limited to, a list of
30 equipment used for each procedure.
31 g. Exemptions of specific types of clinical laboratories from
32 the provisions of section 7 of P.L.1971, c.136 (C.26:2H-7).
33 h. The use of a quality control program by clinical laboratories
34 that meets the standards set forth in federal regulations promulgated
35 pursuant to the "Clinical Laboratory Improvement Amendments of
36 1988," (Public Law 100-578) 42 U.S.C. 263a, effective as of
37 January 1, 2016, including the following alternative quality control
38 testing procedures approved by the federal Centers for Medicare
39 and Medicaid Services:
40 (1) until December 31, 2016, equivalent quality control
41 procedures as specified in Appendix C of the State Operations
42 Manual adopted by the Centers for Medicare and Medicaid
43 Services;
44 (2) starting on January 1, 2017, individualized quality control
45 plans, as specified in Appendix C of the State Operations Manual;
46 and

1 federal law. Additionally, the bill provides that the provisions of
2 P.L.1953, c.420 (C.45:9-42.1 et seq.), the "Bio-analytical
3 Laboratory and Laboratory Directors Act (1953)," and P.L.1975,
4 c.166 (C.45:9-42.26 et seq.), the "New Jersey Clinical Laboratory
5 Improvement Act," do not apply to bio-analytical and clinical
6 laboratories that: (1) possess a federal certificate of waiver issued
7 pursuant to the "Clinical Laboratory Improvement Amendments of
8 1988" (CLIA); and (2) perform waived tests authorized by the
9 federal Food and Drug Administration or the federal Department of
10 Health and Human Services. The bill additionally clarifies that the
11 rules and regulations promulgated by the Public Health Council are
12 to include standards for the recognition of waivers under CLIA and
13 personnel qualifications and proficiency testing standards that do
14 not exceed federal requirements.

15 The bill revises the requirements concerning supervision of bio-
16 analytical laboratories to require that the laboratory be under the
17 overall management and direction of either a licensed physician or a
18 licensed bio-analytical laboratory director who is accessible to the
19 laboratory to provide onsite, telephone, or electronic consultation as
20 needed. The bill additionally removes certain provisions in current
21 law concerning the requirements for licensure as a bio-analytical
22 laboratory director which do not conform to current federal
23 requirements.

ASSEMBLY HEALTH AND SENIOR SERVICES COMMITTEE

STATEMENT TO

SENATE, No. 976

STATE OF NEW JERSEY

DATED: FEBRUARY 22, 2016

The Assembly Health and Senior Services Committee reports favorably Senate Bill No. 976.

This bill requires the Public Health Council to promulgate rules and regulations for the use of quality control programs in bio-analytical and clinical laboratories. Pursuant to current law, the council has promulgated and incorporated in the State Sanitary Code rules and regulations for the operation of bio-analytical and clinical laboratories; however, the council is not currently required to promulgate rules and regulations establishing standards for the use of quality control programs.

The bill requires the council to include standards for the use of quality control programs in the State Sanitary Code, and provides that these standards are not to exceed the standards mandated under federal law. Additionally, the bill provides that the provisions of P.L.1953, c.420 (C.45:9-42.1 et seq.), the "Bio-analytical Laboratory and Laboratory Directors Act (1953)," and P.L.1975, c.166 (C.45:9-42.26 et seq.), the "New Jersey Clinical Laboratory Improvement Act," do not apply to bio-analytical and clinical laboratories that: (1) possess a federal certificate of waiver issued pursuant to the "Clinical Laboratory Improvement Amendments of 1988" (CLIA); and (2) perform waived tests authorized by the federal Food and Drug Administration or the federal Department of Health and Human Services. The bill additionally clarifies that the rules and regulations promulgated by the Public Health Council are to include standards for the recognition of waivers under CLIA and personnel qualifications and proficiency testing standards that do not exceed federal requirements.

The bill revises the requirements concerning supervision of bio-analytical laboratories to require that the laboratory be under the overall management and direction of either a licensed physician or a licensed bio-analytical laboratory director who is accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed. The bill additionally removes certain provisions in current law concerning the requirements for licensure as a bio-analytical laboratory director which do not conform to current federal requirements.

As reported by the committee, this bill is identical to Assembly Bill No. 2332(1R), which the committee also reported on this date.

SENATE HEALTH, HUMAN SERVICES AND SENIOR
CITIZENS COMMITTEE

STATEMENT TO

SENATE, No. 976

STATE OF NEW JERSEY

DATED: FEBRUARY 4, 2016

The Senate Health, Human Services and Senior Citizens Committee reports favorably Senate Bill No. 976.

This bill requires the Public Health Council to promulgate rules and regulations for the use of quality control programs in bio-analytical and clinical laboratories. Pursuant to current law, the council has promulgated and incorporated in the State Sanitary Code rules and regulations for the operation of bio-analytical and clinical laboratories; however, the council is not currently required to promulgate rules and regulations establishing standards for the use of quality control programs.

The bill requires the council to include standards for the use of quality control programs in the State Sanitary Code, and provides that these standards are not to exceed the standards mandated under federal law. Additionally, the bill provides that the provisions of P.L.1953, c.420 (C.45:9-42.1 et seq.), the "Bio-analytical Laboratory and Laboratory Directors Act (1953)," and P.L.1975, c.166 (C.45:9-42.26 et seq.), the "New Jersey Clinical Laboratory Improvement Act," do not apply to bio-analytical and clinical laboratories that: (1) possess a federal certificate of waiver issued pursuant to the "Clinical Laboratory Improvement Amendments of 1988" (CLIA); and (2) perform waived tests authorized by the federal Food and Drug Administration or the federal Department of Health and Human Services. The bill additionally clarifies that the rules and regulations promulgated by the Public Health Council are to include standards for the recognition of waivers under CLIA and personnel qualifications and proficiency testing standards that do not exceed federal requirements.

The bill revises the requirements concerning supervision of bio-analytical laboratories to require that the laboratory be under the overall management and direction of either a licensed physician or a licensed bio-analytical laboratory director who is accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed. The bill additionally removes certain provisions in current law concerning the requirements for licensure as a bio-analytical laboratory director which do not conform to current federal requirements.

STATEMENT TO
SENATE, No. 976

with Assembly Floor Amendments
(Proposed by Assemblyman BENSON)

ADOPTED: JUNE 30, 2016

These floor amendments clarify that the rules and regulations promulgated by the council must include standards for the recognition of all waived tests and waivers under CLIA and federal regulations. Under the bill, rules and regulations concerning the use of waived tests by clinical laboratories must not exceed federal CLIA standards, unless expressly required or the council determines that it is necessary to exceed those standards in order to protect the public health. Under such circumstances, the council must detail its justification for exceeding federal standards. For all other rules or regulations promulgated after the enactment of this bill, if the rule or regulation would exceed federal CLIA standards, the council must provide for notice and comment rulemaking, including a public hearing.

The amendments provide that the provisions of P.L.1953, c.420 (C.45:9-42.1 et seq.), the “Bio-analytical Laboratory and Laboratory Directors Act (1953),” and P.L.1975, c.166 (C.45:9-42.26 et seq.), the “New Jersey Clinical Laboratory Improvement Act,” do not apply to the use of point-of-care testing. As such, point-of-care laboratory testing used at or near the site of a patient is not within the scope of the definition of “clinical laboratory.” For example, there are several types of facilities, like nursing homes, urgent care centers, and clinics, that typically conduct only point-of-care testing. Such facilities would not be considered “clinical laboratories” and would be exempt from the requirements of this bill. For facilities that perform both point-of-care testing and clinical laboratory testing, only the facilities’ point-of-care testing used at or near the site of the patient would be exempt.

The amendments also provide that in lieu of routine on-site survey and inspection of any clinical laboratory, the State Department of Health may 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 federal CLIA, provided the department determines that the standards of the accreditation entity are equivalent to the department’s standards for on-site survey and inspection.

STATEMENT TO

[First Reprint]

SENATE, No. 976

with Assembly Floor Amendments
(Proposed by Assemblyman BENSON)

ADOPTED: SEPTEMBER 15, 2016

These floor amendments clarify that the use of a reagent is permitted in preparing certain biological specimens for laboratory testing, and make a technical correction.

ASSEMBLY, No. 2332

STATE OF NEW JERSEY 217th LEGISLATURE

INTRODUCED FEBRUARY 4, 2016

Sponsored by:

Assemblyman DANIEL R. BENSON
District 14 (Mercer and Middlesex)

SYNOPSIS

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

CURRENT VERSION OF TEXT

As introduced.



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

3

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

6

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

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

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

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

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

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

28 b. The board shall grant a plenary license to all applicants who
29 meet the qualifications for licensure and satisfactorily complete the
30 examination given by the board.

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

40 c. The board shall grant a specialty license in one or more of
41 the fields of toxicological chemistry, microbiology, cytogenetics,
42 biochemical genetics, diagnostic laboratory immunology and
43 clinical chemistry if the applicant is certified by a national
44 accrediting board, which board requires a doctorate degree plus
45 experience, such as but not limited to the American Board of
46 Pathology, the American Osteopathic Board of Pathology, the

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 thus is new matter.

1 American Board of Medical Microbiology, the American Board of
2 Clinical Chemistry, the American Board of Bio-analysis or the
3 American Board of Medical Genetics, or any other national
4 accrediting board recognized by the State Board of Medical
5 Examiners.

6 The applicant for a specialty license must offer proof to the
7 satisfaction of the State Board of Medical Examiners of one year's
8 experience in the specialty, which one year's experience **【must】**
9 shall be within three years next preceding the date of application for
10 the specialty license.

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

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

15

16 2. Section 18 of P.L.1953, c.420 (C.45:9-42.18) is amended to
17 read as follows:

18 18. Each bio-analytical laboratory shall be under the **【direct and**
19 **constant supervision】** overall management and direction of either:

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

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

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

26

27 3. Section 20 of P.L.1953, c.420 (C.45:9-42.20) is amended to
28 read as follows:

29 20. The provisions of this act shall not affect:

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

34 b. Nonprofit research institutions.

35 c. Bio-analytical laboratories of hospitals, licensed by the
36 **【New Jersey Department of Institutions and Agencies】** Department
37 of Health, where the work is confined to regularly admitted patients
38 or registered clinic patients of the hospital.

39 d. Bio-analytical laboratories operated by the United States
40 Government, the **【State】** Department of Health, or any county or
41 municipality of the State.

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

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

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4

1 (2) waived tests authorized by the federal Department of Health
2 and Human Services and listed in 42 C.F.R. s.493.15(c).

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

4

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

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

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

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

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

18 d. Clinical laboratories which are operated by the Department
19 of Corrections, any county jail, any county probation department, or
20 any drug or alcohol treatment center providing services to persons
21 under the jurisdiction of any of these agencies or in a program of
22 supervisory treatment pursuant to the provisions of N.J.S.2C:43-13
23 and which perform only urinalysis for screening purposes to detect
24 the presence of alcohol or illegal substances. The Attorney General
25 shall approve procedures, methods, and devices used by these
26 agencies or centers in screening for alcohol or illegal substances; or

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

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

33 (2) waived tests authorized by the federal Department of Health
34 and Human Services and listed in 42 C.F.R. s.493.15(c).

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

36

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

39 9. The Public Health Council of the department shall
40 promulgate rules and regulations for operation of clinical
41 laboratories, including the use of quality control programs as
42 described in subsection h. of this section, which shall be
43 incorporated in and made a part of the State Sanitary Code. **【Where**
44 **feasible such】** The rules and regulations shall **【equal or】** not exceed
45 **【minimum standards for laboratory certification contained in**
46 **Federal】** the standards set forth in federal rules and regulations
47 promulgated pursuant to the **【"Clinical Laboratories Improvement**
48 **Act of 1967" (Public Law 90-174) 42 U.S.C. 263a】** "Clinical

- 1 Laboratory Improvement Amendments of 1988" (Public Law 100-
2 578) 42 U.S.C. 263a. The rules and regulations so promulgated
3 shall include but shall not be limited to standards for:
- 4 a. Construction of new, or modification of existing clinical
5 laboratories.
- 6 b. Sanitary and safe conditions within the clinical laboratory
7 and its surroundings, including adequate working space, lighting,
8 fire prevention, and safety measures.
- 9 c. Clinical laboratory equipment **[,]** and maintenance
10 procedures for **[such]** the equipment **[and** personnel essential to
11 proper conduct and operation of a clinical laboratory, including
12 standards for education, experience, continuing education, and
13 periodic proficiency testing for laboratory directors, supervisors,
14 technicians, and other personnel which the department may deem
15 necessary for adequate laboratory staffing**]**.
- 16 d. The acceptance, collection, transportation, identification,
17 and examination of clinical laboratory specimens and reporting of
18 results by clinical laboratories.
- 19 e. Reporting by laboratories of diseases for the protection of
20 the public health. The department shall furnish forms for this
21 purpose. **[Such]** The reports shall not be construed as constituting
22 a diagnosis nor shall any clinical laboratory making **[such]** a report
23 be held liable under the laws of this State for having violated a trust
24 or confidential relationship.
- 25 f. Submitting such reports concerning clinical laboratory
26 operations as may be necessary to administer this act. Each
27 laboratory shall maintain a manual of procedures followed in that
28 laboratory, which shall be reviewed and updated annually. **[Such]**
29 The manual shall also include, but not be limited to, a list of
30 equipment used for each procedure.
- 31 g. Exemptions of specific types of clinical laboratories from
32 the provisions of section 7 of P.L.1971, c.136 (C.26:2H-7).
- 33 h. The use of a quality control program by clinical laboratories
34 that meets the standards set forth in federal regulations promulgated
35 pursuant to the "Clinical Laboratory Improvement Amendments of
36 1988," (Public Law 100-578) 42 U.S.C. 263a, effective as of
37 January 1, 2014, including the following alternative quality control
38 testing procedures approved by the federal Centers for Medicare
39 and Medicaid Services:
- 40 (1) until December 31, 2015, equivalent quality control
41 procedures as specified in Appendix C of the State Operations
42 Manual adopted by the Centers for Medicare and Medicaid
43 Services;
- 44 (2) starting on January 1, 2016, individualized quality control
45 plans, as specified in Appendix C of the State Operations Manual;
46 and

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

4 i. Recognition of waivers under the “Clinical Laboratory
5 Improvement Amendments of 1988” (Public Law 100-578) 42
6 U.S.C. 263a and all regulations adopted pursuant thereto (42 C.F.R.
7 Part 493).

8 j. Personnel qualifications and proficiency testing standards
9 that do not exceed federal standards set forth in federal regulations
10 at 42 C.F.R. Part 493, subpart M.

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

12

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

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

17 a. Prescribe minimum standards of performance in the
18 examination of specimens, which standards shall not exceed the
19 standards established under federal rules and regulations
20 promulgated pursuant to the “Clinical Laboratories Improvement
21 Amendments of 1988” (Public Law 100-578) 42 U.S.C. 263a;

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

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

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

31

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

35

36

37

STATEMENT

38

39 This bill requires the Public Health Council to promulgate rules
40 and regulations for the use of quality control programs in bio-
41 analytical and clinical laboratories. Pursuant to current law, the
42 council has promulgated and incorporated in the State Sanitary
43 Code rules and regulations for the operation of bio-analytical and
44 clinical laboratories; however, the council is not currently required
45 to promulgate rules and regulations establishing standards for the
46 use of quality control programs.

47 The bill requires the council to include standards for the use of
48 quality control programs in the State Sanitary Code, and provides

1 that these standards are not to exceed the standards mandated under
2 federal law. Additionally, the bill provides that the provisions of
3 P.L.1953, c.420 (C.45:9-42.1 et seq.), the "Bio-analytical
4 Laboratory and Laboratory Directors Act (1953)," and P.L.1975,
5 c.166 (C.45:9-42.26 et seq.), the "New Jersey Clinical Laboratory
6 Improvement Act," do not apply to bio-analytical and clinical
7 laboratories that: (1) possess a federal certificate of waiver issued
8 pursuant to the "Clinical Laboratory Improvement Amendments of
9 1988" (CLIA); and (2) perform waived tests authorized by the
10 federal Food and Drug Administration or the federal Department of
11 Health and Human Services. The bill additionally clarifies that the
12 rules and regulations promulgated by the Public Health Council are
13 to include standards for the recognition of waivers under CLIA and
14 personnel qualifications and proficiency testing standards that do
15 not exceed federal requirements.

16 The bill revises the requirements concerning supervision of bio-
17 analytical laboratories to require that the laboratory be under the
18 overall management and direction of either a licensed physician or a
19 licensed bio-analytical laboratory director who is accessible to the
20 laboratory to provide onsite, telephone, or electronic consultation as
21 needed. The bill additionally removes certain provisions in current
22 law concerning the requirements for licensure as a bio-analytical
23 laboratory director which do not conform to current federal
24 requirements.

ASSEMBLY HEALTH AND SENIOR SERVICES COMMITTEE

STATEMENT TO

ASSEMBLY, No. 2332

with committee amendments

STATE OF NEW JERSEY

DATED: FEBRUARY 22, 2016

The Assembly Health and Senior Services Committee reports favorably and with committee amendments Assembly Bill No. 2332.

As amended, this bill requires the Public Health Council to promulgate rules and regulations for the use of quality control programs in bio-analytical and clinical laboratories. Pursuant to current law, the council has promulgated and incorporated in the State Sanitary Code rules and regulations for the operation of bio-analytical and clinical laboratories; however, the council is not currently required to promulgate rules and regulations establishing standards for the use of quality control programs.

The bill requires the council to include standards for the use of quality control programs in the State Sanitary Code, and provides that these standards are not to exceed the standards mandated under federal law. Additionally, the bill provides that the provisions of P.L.1953, c.420 (C.45:9-42.1 et seq.), the "Bio-analytical Laboratory and Laboratory Directors Act (1953)," and P.L.1975, c.166 (C.45:9-42.26 et seq.), the "New Jersey Clinical Laboratory Improvement Act," do not apply to bio-analytical and clinical laboratories that: (1) possess a federal certificate of waiver issued pursuant to the "Clinical Laboratory Improvement Amendments of 1988" (CLIA); and (2) perform waived tests authorized by the federal Food and Drug Administration or the federal Department of Health and Human Services. The bill additionally clarifies that the rules and regulations promulgated by the Public Health Council are to include standards for the recognition of waivers under CLIA and personnel qualifications and proficiency testing standards that do not exceed federal requirements.

The bill revises the requirements concerning supervision of bio-analytical laboratories to require that the laboratory be under the overall management and direction of either a licensed physician or a licensed bio-analytical laboratory director who is accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed. The bill additionally removes certain provisions in current law concerning the requirements for licensure as a bio-analytical laboratory director which do not conform to current federal requirements.

As amended, this bill is identical to Senate Bill No. 976, which the committee also reported on this date.

COMMITTEE AMENDMENTS:

The committee amendments update the dates on which various requirements in the bill will take effect and make a technical correction to the synopsis.

STATEMENT TO
[First Reprint]
ASSEMBLY, No. 2332

with Assembly Floor Amendments
(Proposed by Assemblyman BENSON)

ADOPTED: JUNE 30, 2016

These floor amendments clarify that the rules and regulations promulgated by the council must include standards for the recognition of all waived tests and waivers under CLIA and federal regulations. Under the bill, rules and regulations concerning the use of waived tests by clinical laboratories must not exceed federal CLIA standards, unless expressly required or the council determines that it is necessary to exceed those standards in order to protect the public health. Under such circumstances, the council must detail its justification for exceeding federal standards. For all other rules or regulations promulgated after the enactment of this bill, if the rule or regulation would exceed federal CLIA standards, the council must provide for notice and comment rulemaking, including a public hearing.

The amendments provide that the provisions of P.L.1953, c.420 (C.45:9-42.1 et seq.), the “Bio-analytical Laboratory and Laboratory Directors Act (1953),” and P.L.1975, c.166 (C.45:9-42.26 et seq.), the “New Jersey Clinical Laboratory Improvement Act,” do not apply to the use of point-of-care testing. As such, point-of-care laboratory testing used at or near the site of a patient is not within the scope of the definition of “clinical laboratory.” For example, there are several types of facilities, like nursing homes, urgent care centers, and clinics, that typically conduct only point-of-care testing. Such facilities would not be considered “clinical laboratories” and would be exempt from the requirements of this bill. For facilities that perform both point-of-care testing and clinical laboratory testing, only the facilities’ point-of-care testing used at or near the site of the patient would be exempt.

The amendments also provide that in lieu of routine on-site survey and inspection of any clinical laboratory, the State Department of Health may 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 federal CLIA, provided the department determines that the standards of the accreditation entity are equivalent to the department’s standards for on-site survey and inspection.

STATEMENT TO
[Second Reprint]
ASSEMBLY, No. 2332

with Assembly Floor Amendments
(Proposed by Assemblyman BENSON)

ADOPTED: SEPTEMBER 15, 2016

These floor amendments clarify that the use of a reagent is permitted in preparing certain biological specimens for laboratory testing, and make a technical correction.

Governor Chris Christie Signs Legislation Enhancing Protections For Domestic Violence Survivors

Monday, January 9, 2017 Tags: [Bill Action](#)



Trenton, NJ - Governor Chris Christie today signed legislation to enhance protections for survivors of domestic violence.

This new law will deter domestic violence, partly by increasing criminal penalties for offences including maximums for repeat offenders, as urged in Governor Christie's conditional vetoes of earlier versions of this legislation.

"This new law will help prevent domestic violence in New Jersey by enhancing criminal penalties and ensuring immediate compliance with stronger protective orders," Governor Christie said. "Survivors of domestic violence will be safer than ever before. I am proud we came together to enact this model legislation that is much more than just symbolic and is real reform that fulfills our primary responsibility of improving public safety in New Jersey."

This new law reinforces existing laws by creating a more in-depth process to ensure domestic violence offenders' firearms, identification cards and permits are confiscated as required while they are subject to restraining orders. It forces offenders to immediately upon sentencing – rather than after several days – arrange for the surrender of their firearms, identification cards and permits to a law enforcement officer. It also requires an order for a temporary or final restraining order to include notice to the defendant of the penalties for a violation of any provision of the order, including but not limited to the penalties for contempt of court and unlawful possession of a firearm or other weapon.

In addition to signing S-2483/A-4126 (Weinberg, Beck/Mosquera, Greenwald, Downey, Houghtaling, Munoz, Sumter, Benson, Lampitt, Wimberly) into law, the Governor also took action today on the following legislation:

BILL SIGNINGS:

S-909/A-2688 (Rice/Spencer, Pintor Marin) - Exempts person who remediates property in environmental opportunity zone from remediation funding source requirement

S-976/A-2332 (Gordon, Beck/Benson, Downey, Eustace) - Requires Public Health Council to promulgate rules and regulations for use of quality control programs in bio-analytical and clinical laboratories

S-981/A-2375 (Smith, Bateman, Greenstein/McKeon, Gusciora, Spencer) - Revises "Electronic Waste Management Act"

S-1489/A-1465 (Cruz-Perez, Cunningham/Lampitt, Mosquera, Wimberly, Downey, McKnight) - Ensures equal rights and opportunities for pregnant students in institutions of higher education

S-2098/A-3549 (Sacco, Pennacchio/Johnson, Zwicker, Wisniewski, Benson) - Exempts hydrogen fuel cell-powered vehicles from certain labeling requirements

S-2463/A-3892 (Vitale, Rice, Allen/Vainieri Huttie, Lampitt, Mukherji) - Changes the time when child placement review hearings are initiated from 45 days to 60 days

S-2526/A-4105 (Diegnan, Thompson/Dancer, DeCroce, Clifton, Pinkin, Mukherji) - Designates portion of Interstate Highway Route 195 in Upper Freehold Township as "State Trooper Anthony A. Raspa Memorial Highway"

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More Information

- [SENATE BILL NO. 790](#)
- [ASSEMBLY BILL NO. 312](#)

S-2601/A-4207 (Pou, Beck/Vainieri Huttie, Holley, Downey, Mukherji, Muoio, Jasey) - Modifies scope of "Sexual Assault Survivor Protection Act of 2015" and enforcement of protective orders under that act

S-2708/A-4064 (Codey/Jasey, McKeon, Mukherji) - Authorizes State Treasurer to convey surplus real property known as Millburn Regional Day School in Millburn Township, Essex County, to Millburn Township Board of Education or to Millburn Township for \$3,550,000

SJR-29/AJR-58 (Weinberg/Vainieri Huttie, Jasey, Jones, McKnight, Phoebus, Wimberly) - Designates one night in November of each year as a "Night of Conversation" about drug and alcohol addiction

A-793/S-316 (Andrzejczak, Land, Taliaferro/Van Drew, Connors) - Requires Dept. of Agriculture and DEP to work with US Army Corps of Engineers to establish joint permit application process for aquaculture projects

A-794/S-317 (Andrzejczak, Land, Taliaferro, Van Drew, Connors) - Requires Dept. of Agriculture and DEP to adopt coordinated permit application and review program for aquaculture projects

A-1424/S-1050 (Johnson, Wimberly, Sumter/Weinberg, Stack) - Authorizes Victims of Crime Compensation Office to make payment for relocation expenses of certain witnesses of crimes

A-2106/S-2351 (Mukherji, Chaparro, Holley, Jimenez, Pintor Marin, Sumter, Wimberly/Ruiz, Madden) - Permits homeless to receive certified copy of birth certificate without fee

A-2107/S-2350 (Mukherji, Holley, Gusciora, Pintor Marin, Wimberly/Ruiz, Madden) - Exempts homeless from fee for non-driver identification cards

A-2158/S-2241 (Coughlin, Wolfe, Holley, McKnight/Diegnan) - Authorizes use of emergency reserve fund or proceeds from bonds issued by EDA to finance school security improvements

A-2763/S-1933 (Mazzeo, Mosquera, Mukherji, Andrzejczak, Land, Houghtaling/Sweeney, Stack) - Enters NJ in Interstate Wildlife Violator Compact

A-3534/S-2086 (A.M. Bucco, Singleton, Webber, Benson, Moriarty/A.R. Bucco, Van Drew) - Permits authorities and local units operating water supply or sewerage facilities to waive, reduce, or defer sewerage and water service fees for deployed military personnel

BILLS VETOED:

S-790/A-3256 (Sarlo, O'Toole/Lagana, Benson, Sumter) – CONDITIONAL - Requires Police Training Commission to develop accelerated training course for certain county corrections officers

A-312/S-2557 (Singleton, Lampitt, Quijano, Pintor Marin, Wimberly, Downey/Cruz-Perez, Stack) – CONDITIONAL - Requires Division of Local Government Services to include certain property tax information on division's web page

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