[redacted]

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Documents (28)

1. *§ 45:9-42.26. Short title*
   Client/Matter: -None-
2. *§ 45:9-42.27. Definitions.*
   Client/Matter: -None-
3. *§ 45:9-42.28. License; necessity; categories*
   Client/Matter: -None-
4. *§ 45:9-42.29. License; application; form; contents; fee; annual renewal*
   Client/Matter: -None-
5. *§ 45:9-42.30. Annual issuance and expiration; renewal; fees; display*
   Client/Matter: -None-
6. *§ 45:9-42.31. Owner and director; joint and separate responsibility for compliance*
   Client/Matter: -None-
7. *§ 45:9-42.32. Transfer of license; prohibition; change in ownership or direction; notice and reapplication*
   Client/Matter: -None-
8. *§ 45:9-42.33. Provisions not applicable.*
   Client/Matter: -None-
9. *§ 45:9-42.34. Rules, regulations; standards for operation of clinical laboratories.*
   Client/Matter: -None-
10. *§ 45:9-42.34a. Calculation of glomerular filtration rate when testing to diagnose kidney disease*
    Client/Matter: -None-
11. *§ 45:9-42.35. Rules and regulations; license application, issuance, renewal and expiration*
    Client/Matter: -None-
12. *§ 45:9-42.36. Advisory committee*
    Client/Matter: -None-
13. *§ 45:9-42.37. Clinical laboratory evaluation program.*
    Client/Matter: -None-
14. *§ 45:9-42.38. Right of entry and inspection*
    Client/Matter: -None-
15. *§ 45:9-42.39. Confidentiality of information, examination upon application to court*
    Client/Matter: -None-
16. *§ 45:9-42.40. Denial, revocation, suspension, limitation, annulment or denial of renewal; grounds*
    Client/Matter: -None-
17. *§ 45:9-42.41. Refusal to grant, suspension, limitation or revocation of license; notice; hearing; service of order; summary suspension*
    Client/Matter: -None-

18. *§ 45:9-42.41a. Clinical laboratory bills, presentation*
Client/Matter: -None-
19. *§ 45:9-42.41b. Schedule of fees, charges, provided annually*
Client/Matter: -None-
20. *§ 45:9-42.41c. Interpretation charges permitted*
Client/Matter: -None-
21. *§ 45:9-42.42. Prohibited activities*
Client/Matter: -None-
22. *§ 45:9-42.43. Violations, penalty*
Client/Matter: -None-
23. *§ 45:9-42.44. Injunction of violation or threatened violation*
Client/Matter: -None-
24. *§ 45:9-42.45. Severability*
Client/Matter: -None-
25. *§ 45:9-42.46. Recording of race, ethnicity, sexual orientation, gender identity of patients, procedure*
Client/Matter: -None-
26. *§ 45:9-42.47. Recorded gender identity, sexual orientation, racial, ethnic information necessary for storing demographic information; compliance; penalties*
Client/Matter: -None-
27. *§ 45:9-42.48. Prohibiting compelling patient to disclose demographic information*
Client/Matter: -None-
28. *§ 45:9-42.49. Evidence-based cultural competency training program, tools; content of training*
Client/Matter: -None-

N.J. Stat. § 45:9-42.26

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

LexisNexis® New Jersey Annotated Statutes > Title 45. Professions and Occupations (Subts. 1 — 2) > Subtitle 1. Professions and Occupations Subject to State Boards of Registration and Examination (Chs. 1 — 16B) > Chapter 9. Physicians and Surgeons (Arts. 1 — 5) > Article 3B. New Jersey Clinical Laboratory Improvement Act (§§ 45:9-42.26 — 45:9-42.49)

§ 45:9-42.26. Short title

This act shall be known and may be cited as the “New Jersey Clinical Laboratory Improvement Act.”

History

L. 1975, c. 166, 1, eff. Aug. 1, 1975.

Annotations

Research References & Practice Aids

Cross References:

Blood samples; collection, testing, see *26:2-137.5*.

Laboratory director’s license; qualifications; examination; specialities, see *45:9-42.7*.

Calculation of glomerular filtration rate when testing to diagnose kidney disease, see *45:9-42.34a*.

Definitions relative to pharmacists, see *45:14-41*.

Administrative Code:

N.J.A.C. 13:35-6.27 (2013), CHAPTER BOARD OF MEDICAL EXAMINERS, Standards for collaborative practice for drug therapy management with licensed pharmacists.

N.J.A.C. 13:39-13.7 (2013), CHAPTER STATE BOARD OF PHARMACY, Scope of collaborative drug therapy management.

N.J.A.C. 6A:16-4.4 (2013), CHAPTER PROGRAMS TO SUPPORT STUDENT DEVELOPMENT, Voluntary policy for random testing of student alcohol or other drug use.

N.J.A.C. 8:20-1.1 (2013), CHAPTER BIRTH DEFECTS REGISTRY, Definitions.

N.J.A.C. 8:44-2.1 (2013), CHAPTER CHAPTER IV OF THE STATE SANITARY CODE, Definitions.

N.J.A.C. 8:52-12.4 (2013), CHAPTER PUBLIC HEALTH PRACTICE STANDARDS OF PERFORMANCE FOR LOCAL BOARDS OF HEALTH IN NEW JERSEY, Technical capacities.

N.J.A.C. 13:35-6.16 (2013), CHAPTER BOARD OF MEDICAL EXAMINERS, Professional practice structure.

End of Document

N.J. Stat. § 45:9-42.27

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.27. Definitions.

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. 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 Department of Health.

c. "Commissioner" means the 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. § 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. § 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. 493.15(c)*.

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.

History

L. 1975, c. 166, 2, eff. Aug. 1, 1975; amended by *2016, c. 86*, § 5, effective January 9, 2017.

Annotations

Notes

Effective Dates

Section 9 of L. *2016, c. 86* provides: “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.” Chapter 86, L. 2016, was approved on Jan. 9, 2017.

Amendment Notes

2016 amendment, by Chapter 86, “in a., inserted the comma following "Clinical laboratory" and "except as used in subsection k. of this section" in the first sentence and deleted the former second sentence, which read: “Anatomic pathology is not considered to be within the scope of this definition”; substituted "Department of Health" for "State Department of Health" in b.; substituted "Commissioner of Health" for "State Commissioner of Health" in c.; and added i., j., and k.

Research References & Practice Aids

Administrative Code:

N.J.A.C. 13:35-2.6 (2013), CHAPTER BOARD OF MEDICAL EXAMINERS, Medical standards governing screening and diagnostic medical testing offices; determinations with respect to the validity of certain diagnostic tests.

N.J.A.C. 8:57-1.3 (2013), CHAPTER COMMUNICABLE DISEASES, Definitions.

End of Document

N.J. Stat. § 45:9-42.28

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

LexisNexis® New Jersey Annotated Statutes > Title 45. Professions and Occupations (Subts. 1 — 2) > Subtitle 1. Professions and Occupations Subject to State Boards of Registration and Examination (Chs. 1 — 16B) > Chapter 9. Physicians and Surgeons (Arts. 1 — 5) > Article 3B. New Jersey Clinical Laboratory Improvement Act (§§ 45:9-42.26 — 45:9-42.49)

§ 45:9-42.28. License; necessity; categories

No person shall conduct, maintain, or operate a clinical laboratory or solicit or accept specimens for laboratory examination unless a license therefor has been obtained from the department pursuant to the terms of this act. A separate license shall be obtained for each location. A clinical laboratory license shall be obtained for all or any designated part of any one or more of the following categories, or other categories as may be included in rules and regulations promulgated pursuant to this act:

a. Microbiology, including the subcategories of bacteriology, virology, mycology, and parasitology;

b. Serology, including syphilis serology, nonsyphilis serology;

c. Hematology, including immunohematology; and,

d. Clinical chemistry, including urinalysis, chemical toxicology, and in vitro radioisotope technic.

History

L. 1975, c. 166, 3, eff. Aug. 1, 1975.

End of Document

N.J. Stat. § 45:9-42.29

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

LexisNexis® New Jersey Annotated Statutes > Title 45. Professions and Occupations (Subts. 1 — 2) > Subtitle 1. Professions and Occupations Subject to State Boards of Registration and Examination (Chs. 1 — 16B) > Chapter 9. Physicians and Surgeons (Arts. 1 — 5) > Article 3B. New Jersey Clinical Laboratory Improvement Act (§§ 45:9-42.26 — 45:9-42.49)

§ 45:9-42.29. License; application; form; contents; fee; annual renewal

All clinical laboratories operating prior to the effective date of this act shall be issued a license upon submission of a properly completed application form and payment of the requisite fee. Said license shall thereafter be renewable, on a calendar year basis, subject to all provisions of this act. The license application form shall include, but need not be limited to the following information:

a. The name and address of the clinical laboratory owner and his authorized agent and such information regarding the owner and agent as may be required;

b. The name and address of the clinical laboratory director;

c. The name and address of the clinical laboratory for which the license is requested and a description and plan of the premises to be occupied for the operation of said laboratory;

d. A list of the major laboratory equipment to be utilized; and,

e. The tests to be performed in the clinical laboratory.

History

L. 1975, c. 166, 4, eff. Aug. 1, 1975.

End of Document

N.J. Stat. § 45:9-42.30

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

LexisNexis® New Jersey Annotated Statutes > Title 45. Professions and Occupations (Subts. 1 — 2) > Subtitle 1. Professions and Occupations Subject to State Boards of Registration and Examination (Chs. 1 — 16B) > Chapter 9. Physicians and Surgeons (Arts. 1 — 5) > Article 3B. New Jersey Clinical Laboratory Improvement Act (§§ 45:9-42.26 — 45:9-42.49)

§ 45:9-42.30. Annual issuance and expiration; renewal; fees; display

All clinical laboratory licenses shall be issued on or before January 1 in each calendar year and shall expire on December 31 in each calendar year. Application for renewal therefor shall be made at such time and in such manner as shall be prescribed by the department. The commissioner shall charge for a license or renewal such reasonable fees as he shall prescribe by rule or regulation. The license shall be conspicuously displayed by the licensee on the premises of a clinical laboratory.

History

L. 1975, c. 166, 5, eff. Aug. 1, 1975.

Annotations

Research References & Practice Aids

Administrative Code:

N.J.A.C. 8:44 (2013), CHAPTER CHAPTER IV OF THE STATE SANITARY CODE, 8, Chapter 44 — Chapter Notes.

N.J.A.C. 8:45 (2013), CHAPTER CLINICAL LABORATORY SERVICES, 8, Chapter 45 — Chapter Notes.

End of Document

N.J. Stat. § 45:9-42.31

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.31. Owner and director; joint and separate responsibility for compliance

The owner and director of a clinical laboratory shall be jointly and separately responsible for its compliance with this act and regulations as may be promulgated hereunder.

History

L. 1975, c. 166, 6, eff. Aug. 1, 1975.

End of Document

N.J. Stat. § 45:9-42.32

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.32. Transfer of license; prohibition; change in ownership or direction; notice and reapplication

No license issued under the provisions of this act shall be transferable. A change in ownership or direction of a licensed laboratory shall require notification to the department within 14 calendar days and reapplication for licensure.

History

L. 1975, c. 166, 7, eff. Aug. 1, 1975.

End of Document

N.J. Stat. § 45:9-42.33

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

LexisNexis® New Jersey Annotated Statutes > Title 45. Professions and Occupations (Subts. 1 — 2) > Subtitle 1. Professions and Occupations Subject to State Boards of Registration and Examination (Chs. 1 — 16B) > Chapter 9. Physicians and Surgeons (Arts. 1 — 5) > Article 3B. New Jersey Clinical Laboratory Improvement Act (§§ 45:9-42.26 — 45:9-42.49)

§ 45:9-42.33. Provisions not applicable.

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*);

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. Facilities at which the only testing that is conducted is point-of-care laboratory testing.

History

L. 1975, c. 166, § 8; amended *1991, c. 26*, § 1; *2016, c. 86*, § 6, effective January 9, 2017.

Annotations

Notes

Effective Dates

Section 9 of L. *2016, c. 86* provides: “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.” Chapter 86, L. 2016, was approved on Jan. 9, 2017.

Amendment Notes

2016 amendment, by Chapter 86, added e; and made related changes.

End of Document

N.J. Stat. § 45:9-42.34

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.34. Rules, regulations; standards for operation of clinical laboratories.

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. 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 rules and regulations shall at least equal the standards set forth in federal rules and regulations promulgated pursuant to the "Clinical Laboratory Improvement Amendments of 1988," *Pub.L.100-578* (*42 U.S.C. § 263a*). Any rules or regulations promulgated after the effective date [Jan. 9, 2017] of *P.L.2016, c.86* that exceed those federal standards shall only be promulgated after a rulemaking process that includes notice and comment and a public hearing. 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 the equipment and personnel essential to proper conduct and operation of a clinical laboratory, including standards for education, experience, and continuing education.

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. The reports shall not be construed as constituting a diagnosis nor shall any clinical laboratory making 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. 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 which shall not exceed the standards set forth in federal regulations promulgated pursuant to the "Clinical Laboratory Improvement Amendments of 1988," *Pub.L.100-578* (*42 U.S.C. § 263a*), effective as of January 1, 2016, or as subsequently amended, including the following alternative quality control testing procedures approved by the federal Centers for Medicare and Medicaid Services:

(1) Individualized Quality Control Plans , as specified in Appendix C of the State Operations Manual; and

(2) 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 all waived tests and waivers under the "Clinical Laboratory Improvement Amendments of 1988," *Pub.L.100-578* (*42 U.S.C. § 263a*) and all regulations adopted pursuant thereto (42 C.F.R. Part 493).

j. 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," *Pub.L.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.

History

L. 1975, c. 166, 9, eff. Aug. 1, 1975; amended by *2016, c. 86*, § 7, effective January 9, 2017.

Annotations

Notes

Effective Dates

Section 9 of L. *2016, c. 86* provides: "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." Chapter 86, L. 2016, was approved on Jan. 9, 2017.

Amendment Notes

2016 amendment, by Chapter 86, rewrote the introductory paragraph, which formerly read: "The Public Health Council of the department shall promulgate rules and regulations for operation of clinical laboratories which shall be incorporated in and made a part of the State Sanitary Code. Where feasible such rules and regulations shall equal or exceed minimum standards for laboratory certification contained in Federal rules and regulations promulgated pursuant to the "Clinical Laboratories Improvement Act of 1967" (Public Law 90-174) 42 U.S.C. 263a. The rules and regulations so promulgated shall include but shall not be limited to standards for"; rewrote c., which formerly read: "Clinical laboratory equipment, maintenance procedures for such 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"; in e., substituted "The reports" for "Such reports" and "a report" for "such report"; substituted "The manual" for "Such manual" in f.; added h., i., and j.; and made a stylistic change.

Research References & Practice Aids

Cross References:

Provisions not applicable, see *45:9-42.33*.

End of Document

N.J. Stat. § 45:9-42.34a

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§ 45:9-42.34a. Calculation of glomerular filtration rate when testing to diagnose kidney disease

The director of a clinical laboratory licensed in this State pursuant to P.L. 1975, c. 166 (*C. 45:9-42.26* et seq.) shall provide that when the laboratory tests a specimen to determine a patient's serum creatinine level, as ordered or prescribed by a health care professional authorized to make such an order or prescription, the laboratory shall calculate the patient's glomerular filtration rate using such information as is provided by the health care professional or patient, as applicable. The laboratory shall include the patient's glomerular filtration rate with its report to the health care professional.

History

L. *2005, c. 236*, § 1, eff. Nov. 25, 2005.

Annotations

Notes

Effective Dates:

Section 2 of L. *2005, c. 236* provides: "This act shall take effect on the 60th day after enactment." Chapter 236, L. 2005, was approved on September 26, 2005.

End of Document

N.J. Stat. § 45:9-42.35

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.35. Rules and regulations; license application, issuance, renewal and expiration

The commissioner shall establish reasonable rules and regulations for license application, issuance, renewal and expiration.

History

L. 1975, c. 166, 10, eff. Aug. 1, 1975.

End of Document

N.J. Stat. § 45:9-42.36

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.36. Advisory committee

An advisory committee shall be appointed by the commissioner and shall serve for a term of 2 years, with no member serving for more than two consecutive terms. Members of the advisory committee shall serve in a voluntary capacity to advise the department on all matters relating to this act and shall consist of two persons who are diplomates of the American Board of Pathology, two directors of private clinical laboratories who are not pathologists, one physician who is not a pathologist, one medical technologist, one private citizen not directly related to the practice of medicine or the operation of a clinical laboratory and such additional members as the commissioner may in his discretion appoint. Members shall serve without compensation but shall receive actual and necessary expenses.

History

L. 1975, c. 166, 11, eff. Aug. 1, 1975.

End of Document

N.J. Stat. § 45:9-42.37

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.37. Clinical laboratory evaluation program.

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

a. Prescribe minimum standards of performance in the examination of specimens, and any standards that would exceed the standards established under federal rules and regulations promulgated pursuant to the "Clinical Laboratories Improvement Amendments of 1988," *Pub.L.100-578* (*42 U.S.C. § 263a*) shall only be promulgated after a rulemaking process that includes notice and comment and a public hearing;

b. Test the proficiency of clinical laboratories to determine if the minimum standards of performance established pursuant to *P.L.2016, c.86* are being met;

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;

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," *Pub.L.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; and

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.

History

L. 1975, c. 166, 12, eff. Aug. 1, 1975; amended by *2016, c. 86*, § 8, effective January 9, 2017.

Annotations

Notes

Effective Dates

Section 9 of L. *2016, c. 86* provides: “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.” Chapter 86, L. 2016, was approved on Jan. 9, 2017.

Amendment Notes

2016 amendment, by Chapter 86, rewrote a., which formerly read: "Prescribe minimum standards of performance in the examination of specimens, which standards shall not"; in b., inserted "the" and "established pursuant to P.L.2016, c.86 are being met"; and added d. and e.

End of Document

N.J. Stat. § 45:9-42.38

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LexisNexis® New Jersey Annotated Statutes > Title 45. Professions and Occupations (Subts. 1 — 2) > Subtitle 1. Professions and Occupations Subject to State Boards of Registration and Examination (Chs. 1 — 16B) > Chapter 9. Physicians and Surgeons (Arts. 1 — 5) > Article 3B. New Jersey Clinical Laboratory Improvement Act (§§ 45:9-42.26 — 45:9-42.49)

§ 45:9-42.38. Right of entry and inspection

The department and any officers or employees thereof in the performance of any duty imposed by this act shall have the power and authority to enter at any time and inspect any clinical laboratory for the purpose of studying and evaluating the operation, supervision, records, and procedures of such facilities and to determine their effect upon the health and safety of the people of this State.

History

L. 1975, c. 166, 13, eff. Aug. 1, 1975.

End of Document

N.J. Stat. § 45:9-42.39

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.39. Confidentiality of information, examination upon application to court

All reports submitted under the provisions of this act and any information obtained in the course of inspections shall be deemed confidential and may be examined only upon application to a court of competent jurisdiction in association with proceedings related to suspension, limitation, or revocation of a license under this act. This provision shall in no way interfere with the department's powers to summarize, analyze and publish information obtained during the course of carrying out provisions of this act so long as the specific identity of individual laboratories is not disclosed, nor shall it be considered to limit the department's powers in disclosing results of an action in suspending, limiting or revoking a license of a specific laboratory under the provisions of this act.

History

L. 1975, c. 166, 14, eff. Aug. 1, 1975.

End of Document

N.J. Stat. § 45:9-42.40

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.40. Denial, revocation, suspension, limitation, annulment or denial of renewal; grounds

A clinical laboratory license may be denied, revoked, suspended, limited, annulled, or renewal thereof may be denied by the commissioner for good cause, including but not limited to:

a. Making false statements on an application for a clinical laboratory license or any other documents required by the department.

b. A reasonable finding by the department that the quality of performance of clinical laboratory tests is below those set by the department and that remedial measures such as consultation and training are not accepted or do not result in improvement to a level of proficiency acceptable to the department.

c. Reporting of fictitious results not based on test performance.

d. Performing a test and rendering a report thereon to a person not authorized by law to receive such services.

e. Referring a specimen for examination to an unlicensed clinical laboratory that is required to be licensed under this act.

f. Knowingly having professional connection with or lending the use of the name of the licensed clinical laboratory to an unlicensed clinical laboratory.

g. Violating or aiding and abetting in the violation of any provision of this act or the provisions of the State Sanitary Code.

h. Failing to file any report required by the provisions of this act or the provisions of the State Sanitary Code.

i. Representing that the laboratory is entitled to perform any laboratory procedure or category of procedures not authorized in its license.

History

L. 1975, c. 166, 15, eff. Aug. 1, 1975.

Annotations

Research References & Practice Aids

Administrative Code:

N.J.A.C. 8:57-1.15 (2013), CHAPTER COMMUNICABLE DISEASES, Enforcement.

End of Document

N.J. Stat. § 45:9-42.41

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.41. Refusal to grant, suspension, limitation or revocation of license; notice; hearing; service of order; summary suspension

The commissioner, before refusing to grant a license or before suspending, limiting or revoking a license previously granted shall give notice to the applicant or licensee personally, or by mail addressed to him at his last known address, and afford him an opportunity to be heard with respect thereto at a time and place specified in such notice. Such applicant or licensee shall have the right to be heard in person or through an attorney, and to offer evidence pertinent to the subject of the hearing. A duly certified copy of the order of the commissioner issued as a result of such hearing shall be served on the applicant or the licensee by mail personally addressed to him at his last known address, except if such applicant or licensee be a corporation then the order shall be served in the same manner upon any officer or registered agent of the corporation.

If the commissioner shall have reason to believe that a condition exists or has occurred at a laboratory, in violation of the provisions of this act or the rules and regulations promulgated hereunder, which condition poses an imminent threat to the public health, safety or welfare, he may summarily suspend the license of the laboratory without a hearing and may order immediate correction of such violation as a prerequisite of reinstatement of licensure. If a licensee that is subjected to summary suspension shall deny that a violation exists or has occurred, he shall have the right to apply to the commissioner for a hearing. Such hearing shall be held and a decision rendered within 48 hours of receipt of said request. If the commissioner shall rule against the licensee, the licensee shall have the right to apply for injunctive relief against the commissioner's order. Jurisdiction of such injunctive relief shall be in the Superior Court of New Jersey.

History

L. 1975, c. 166, 16, eff. Aug. 1, 1975.

End of Document

N.J. Stat. § 45:9-42.41a

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.41a. Clinical laboratory bills, presentation

A clinical laboratory shall present or cause to be presented a claim, bill or demand for payment for clinical laboratory services directly to the recipient of the services, except that the claim, bill or demand for payment may be presented to any of the following:

a. An immediate family member of the recipient of the services or other person legally responsible for the debts or care of the recipient of the services;

b. A third party payer including a health insurer, a health, hospital or medical services corporation, a State approved or federally qualified health maintenance organization in which the recipient of the services is enrolled, a governmental agency or its specified agent which provides health care benefits on behalf of the recipient of the services, and an employer of the recipient of the services who is responsible for payment of the services, provided that billing these payers is consistent with the terms of any applicable contract between the payer and the recipient of the services;

c. A hospital or skilled nursing facility in which the recipient of the services is or has been an inpatient or outpatient;

d. A substance abuse program in which the recipient of the services is or has been a participant; and

e. A nonprofit clinic or other health care provider whose purpose is the promotion of public health, from which the recipient of the services has received health care.

Upon the request of the health care provider who requested the clinical laboratory services, a clinical laboratory shall notify the health care provider of the amount of the claim, bill or demand for payment that was presented to the recipient or the recipient's responsible third party pursuant to this section.

Notwithstanding the provisions of this section to the contrary, in the case of a clinical laboratory which performs services at the request of another clinical laboratory, the clinical laboratory may present the claim, bill or demand for payment to the requesting clinical laboratory.

Notwithstanding the provisions of this section to the contrary, nothing in this section shall affect a contractual agreement between a clinical laboratory and a third party payer regarding presentation of a claim, bill or demand for payment directly to that third party payer.

History

L. *1997, c. 156*, § 1.

Annotations

Research References & Practice Aids

Cross References:

Prohibited activities, see *45:9-42.42*.

Violations, penalty, see *45:9-42.43*.

End of Document

N.J. Stat. § 45:9-42.41b

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§ 45:9-42.41b. Schedule of fees, charges, provided annually

A clinical laboratory shall annually provide a health care provider with a list of its schedule of fees and charges for laboratory services rendered to the health care provider's patients. The clinical laboratory shall promptly provide the health care provider with an updated list of its schedule of fees and charges whenever any changes are made to the list. The clinical laboratory shall include with the list a form to be used by the health care provider to request billing information pursuant to section 1 of this act.

History

L. *1997, c. 156*, § 4.

End of Document

N.J. Stat. § 45:9-42.41c

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.41c. Interpretation charges permitted

Nothing in this act shall be construed to prevent a health care provider from including a charge for the interpretation of a laboratory test as part of the health care provider's office visit fee.

History

L. *1997, c. 156*, § 5.

End of Document

N.J. Stat. § 45:9-42.42

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.42. Prohibited activities

No person shall:

a. Operate, maintain, direct, or engage in the business of operating a clinical laboratory, as herein defined, unless he has obtained a clinical laboratory license from the department, or is exempt under the provisions of this act.

b. Collect or receive specimens for analysis by an unlicensed laboratory.

c. Accept specimens for tests from and make reports to persons who are not legally qualified or authorized to submit specimens to clinical laboratories and to receive such reports, but this shall not prohibit the referral of specimens from one licensed clinical laboratory to another similarly licensed under the laws of the state in which it is located, providing the report indicates clearly the clinical laboratory performing the test and the name of the director of such clinical laboratory.

d. Either personally, or through an agent, solicit referral of specimens to his or any other clinical laboratory or contract to perform clinical laboratory examinations of specimens in a manner which offers or implies an offer of rebates to a person or persons submitting specimens, other fee-splitting inducements, participation in any fee-splitting arrangements or other unearned remuneration.

e. Obstruct or interfere with the department or any officer or employee thereof in the performance of any duty imposed by this act.

f. Collect any amounts that were billed in violation of section 1 of *P.L.1997, c. 156* (*C. 45:9-42.41a*).

History

L. 1975, c. 166, § 17; amended *1997, c. 156*, § 2.

Annotations

CASE NOTES

Evidence: Scientific Evidence: Blood Alcohol

Under the provisions of former N.J. Stat. Ann. § *45:9-42.19* (now *N.J. Stat. Ann. § 45:9-42.42*), blood tests are authorized to be made by bio-analytical laboratories at the request of local boards of health; because those boards usually include a majority of nonmedical members, there is no requirement under *N.J. Stat. Ann. § 45:9-42.1* et seq. that such tests be performed at the request of a licensed physician. *State v. McMaster, 118 N.J. Super. 476, 288 A.2d 583, 1972 N.J. Super. LEXIS 568 (App.Div. 1972)*.

End of Document

N.J. Stat. § 45:9-42.43

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.43. Violations, penalty

a. Any person convicted of violating any provision of this act or of any rule or regulation adopted hereunder shall be subject to a penalty of not less than $100.00 nor more than $1,000.00 for each violation. The penalty shall be collected, and enforced in summary proceedings under the penalty enforcement law (*N.J.S.2A:58-1* et seq.).

b. A person who collects any amounts that were billed in violation of section 1 of *P.L.1997, c. 156* (*C. 45:9-42.41a*), is liable for, and shall refund on a timely basis to the person who was billed, any amounts so collected.

History

L. 1975, c. 166, § 18; amended *1997, c. 156*, § 3.

End of Document

N.J. Stat. § 45:9-42.44

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.44. Injunction of violation or threatened violation

Any violation or threatened violation of any provision of this act or of any rule or regulation adopted hereunder may be restrained by the Superior Court in an action brought for such purpose by the Attorney General on behalf of the department.

History

L. 1975, c. 166, 19, eff. Aug. 1, 1975.

End of Document

N.J. Stat. § 45:9-42.45

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.45. Severability

If any provision of this act, or any application of any provision, is held invalid, the invalidity shall not affect other applications of the provision, or other provisions of the act, which reasonably can be given effect despite the invalidity. To this end, the provisions of this act are hereby declared severable.

History

L. 1975, c. 166, 20, eff. Aug. 1, 1975.

End of Document

N.J. Stat. § 45:9-42.46

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.46. Recording of race, ethnicity, sexual orientation, gender identity of patients, procedure

a.

(1) A clinical laboratory shall electronically record the race, ethnicity, sexual orientation, and gender identity of each patient who presents with a non-electronic order for testing at a clinical laboratory patient service center. If a clinical laboratory processes a specimen without the presence of a patient, the clinical laboratory shall not be responsible for recording and reporting the patient's gender identity, sexual orientation, and racial and ethnic information and may record "not provided" in lieu of the other selections provided under paragraphs (2) through (4) of this subsection.

(2) Race and ethnicity selections shall include: Alaska Native or American Indian, non-Hispanic; Asian, non-Hispanic; Black or African American, non-Hispanic; Hispanic or Latino; Multiracial, non-Hispanic; Native Hawaiian or other Pacific Islander, non-Hispanic; other race, non-Hispanic; White, non-Hispanic; does not wish to disclose; and not provided.

(3) Sexual orientation selections shall include: bisexual; straight; gay or lesbian; something else; does not wish to disclose; and not provided.

(4) Gender identity selections shall include: male, female, gender nonconforming, transgender male-to-female, transgender female-to-male, does not wish to disclose, and not provided.

b. Any healthcare-related data that is required under State law to be reported by a clinical laboratory to the Department of Health shall include any corresponding gender identity, sexual orientation, and racial and ethnic data recorded pursuant to this section, and shall be incorporated into the appropriate disease surveillance reporting system. The Commissioner of Health shall issue guidance concerning the healthcare-related data that is subject to the requirements of this subsection.

c. A non-electronic specimen collection and analysis requisition form distributed by a clinical laboratory shall contain a section for the manual entry of the patient's racial, ethnic, sexual orientation, and gender identity information on the form.

d. Race and ethnicity, sexual orientation, and gender identity information that is required to be recorded or reported pursuant to this section shall be recorded or reported using a

program that is compatible with the State's disease surveillance reporting system using such data fields as may be available or necessary in the version of Health Level Seven International recording and reporting standards or equivalent standards adopted by the laboratory, or using any other program or standard as may be designated by the Commissioner of Health that produces superior data collection and related benefits or that is otherwise in accordance with best practice.

e. The Commissioner of Health may modify, by regulation, the race, ethnicity, sexual orientation, and gender identity selections provided in subsection a. of this section as appropriate or pursuant to federal requirements.

History

L. *2021, c. 454*, § 2, effective July 17, 2022; *2022, c. 44*, § 2, eff. June 30, 2022, retroactive to Jan. 18, 2022.

Annotations

Notes

Editor's Notes

Section 6 of L. *2021, c. 454*, as amended by section 5 of L. *2022, c. 44*, provides: "The Commissioner of Health shall adopt rules and regulations as are necessary to effectuate the provisions of this act, which rules and regulations shall be effective immediately upon filing with the Office of Administrative Law for a period not to exceed 18 months, and shall, thereafter, be amended, adopted, or readopted in accordance with the provisions of the 'Administrative Procedure Act,' P.L.1968, c.410 (*C.52:14B-1* et seq.)."

Effective Dates

Section 7 of L. *2021, c. 454*, as amended by section 6 of L. *2022, c. 44*, provides: "This act shall take effect 12 months after the date of enactment except that paragraphs (3) and (4) of subsection a. of section 2 of this act shall take effect 18 months after the date of enactment." Chapter 454, L. 2021, was approved on Jan. 18, 2022, and Chapter 44, L. 2022 was approved on June 30, 2022, retroactive to Jan. 18, 2022.

Section 7 of L. *2022, c. 44* provides: "This act shall take effect immediately and shall be retroactive to January 18, 2022." Chapter 44, L. 2022, was approved on June 30, 2022.

N.J. Stat. § 45:9-42.47

Current through New Jersey 220th First Annual Session, L. 2022, c. 119 and J.R. 8

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§ 45:9-42.47. Recorded gender identity, sexual orientation, racial, ethnic information necessary for storing demographic information; compliance; penalties

Any electronic medical records or laboratory information management systems used by acute care hospitals and licensed clinical laboratories in this State or sold by a vendor of such systems in this State for use by acute care hospitals and licensed clinical laboratories, on or after the effective date of this act [*C.26:2H-5.36* et al.], shall be configured in a manner that prevents an authorized user from saving or storing a patient's demographic information into the electronic medical records or laboratory information management systems unless a selection for a patient's gender identity, sexual orientation, and racial and ethnic information is recorded. Nothing in this act shall prohibit a clinical laboratory from receiving, processing, or saving data related to specimens that are ordered or received from outside of this State. The gender identity, sexual orientation, and racial and ethnic information of a patient shall be included in laboratory orders generated by electronic medical record systems. The Department of Health may impose necessary corrective actions to achieve compliance with the provisions of this section, which may include, but need not be limited to, an attestation to be completed by an acute care hospital or a licensed clinical laboratory that: indicates specific steps that will be taken to achieve compliance within 120 days following the date of attestation; acknowledges legal obligations and penalties under this section; and provides relevant vendor information. A vendor of electronic medical records or laboratory information management systems that fails to comply with the provisions of this section shall be liable to a civil penalty of up to $1,000 for each day during which the vendor's system is out of compliance. A civil penalty assessed pursuant to this section shall be collected by and in the name of the Department of Health in summary proceedings before a court of competent jurisdiction pursuant to the provisions of the "Penalty Enforcement Law of 1999," *P.L.1999, c.174* (*C.2A:58-10* et seq.).

History

L. *2021, c. 454*, § 3, effective July 17, 2022; *2022, c. 44*, § 3, eff. June 30, 2022, retroactive to Jan. 18, 2022.

Annotations

Notes

Publisher's Notes

The bracketed material was added by the Publisher to provide a reference.

Editor's Notes

Section 6 of L. *2021, c. 454*, as amended by section 5 of L. *2022, c. 44*, provides: “The Commissioner of Health shall adopt rules and regulations as are necessary to effectuate the provisions of this act, which rules and regulations shall be effective immediately upon filing with the Office of Administrative Law for a period not to exceed 18 months, and shall, thereafter, be amended, adopted, or readopted in accordance with the provisions of the ‘Administrative Procedure Act,’ P.L.1968, c.410 (*C.52:14B-1* et seq.).”

Effective Dates

Section 7 of L. *2021, c. 454*, as amended by section 6 of L. *2022, c. 44*, provides: “This act shall take effect 12 months after the date of enactment except that paragraphs (3) and (4) of subsection a. of section 2 of this act shall take effect 18 months after the date of enactment.” Chapter 454, L. 2021, was approved on Jan. 18, 2022, and Chapter 44, L. 2022 was approved on June 30, 2022, retroactive to Jan. 18, 2022.

Section 7 of L. *2022, c. 44* provides: “This act shall take effect immediately and shall be retroactive to January 18, 2022.” Chapter 44, L. 2022, was approved on June 30, 2022.

End of Document

N.J. Stat. § 45:9-42.48

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§ 45:9-42.48. Prohibiting compelling patient to disclose demographic information

> Nothing in this act [C.26:2H-5.36 et al.] shall be construed to compel a patient to disclose the patient's race, ethnicity, sexual orientation, or gender identity to a clinical laboratory, health care provider, or any other entity.

History

L. 2021, c. 454, § 4, effective July 17, 2022.

Annotations

Notes

Publisher's Notes

The bracketed material was added by the Publisher to provide a reference.

Editor's Notes

Section 6 of L. 2021, c. 454, as amended by section 5 of L. 2022, c. 44, provides: "The Commissioner of Health shall adopt rules and regulations as are necessary to effectuate the provisions of this act, which rules and regulations shall be effective immediately upon filing with the Office of Administrative Law for a period not to exceed 18 months, and shall, thereafter, be amended, adopted, or readopted in accordance with the provisions of the 'Administrative Procedure Act,' P.L.1968, c.410 (C.52:14B-1 et seq.)."

Effective Dates

Section 7 of L. 2021, c. 454, as amended by section 6 of L. 2022, c. 44, provides: "This act shall take effect 12 months after the date of enactment except that paragraphs (3) and (4) of subsection a. of section 2 of this act shall take effect 18 months after the date of enactment."

Chapter 454, L. 2021, was approved on Jan. 18, 2022, and Chapter 44, L. 2022 was approved on June 30, 2022, retroactive to Jan. 18, 2022.

Section 7 of L. *2022, c. 44* provides: “This act shall take effect immediately and shall be retroactive to January 18, 2022.” Chapter 44, L. 2022, was approved on June 30, 2022.

End of Document

N.J. Stat. § 45:9-42.49

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§ 45:9-42.49. Evidence-based cultural competency training program, tools; content of training

a. Each clinical laboratory shall implement an evidence-based cultural competency training program for all staff members employed by or working under the supervision of the clinical laboratory who have direct contact with patients and are responsible for collecting race and ethnicity, sexual orientation, and gender identity information from patients.

b. Each cultural competency training program implemented pursuant to subsection a. of this section shall include training on how to collect race, ethnicity, sexual orientation, and gender identity in a culturally competent and sensitive manner. This may include the following topics:

(1) common terminology for race and ethnicity, sexual orientation, and gender identity data;

(2) information on the relationship between patient health and collecting race and ethnicity, sexual orientation, and gender identity data;

(3) information on how race and ethnicity, sexual orientation, and gender identity data will be used;

(4) information on how to navigate discomfort in patients and staff when asking patients for their race and ethnicity, sexual orientation, and gender identity information; and

(5) information on how to create an inclusive and affirming environment for all patients.

c. Each staff member who is employed by or working under the supervision of the clinical laboratory, has direct contact with patients, and is responsible for collecting race and ethnicity, sexual orientation, and gender identity information from patients, shall:

(1) complete the cultural competency training program implemented pursuant to subsection a. of this section at such times and intervals as the clinical laboratory shall require; and

(2) complete a cultural competency refresher course at least once biennially if completion of the course is deemed necessary by the clinical laboratory.

History

L. *2021, c. 454*, § 5, effective May 18, 2022; *2022, c. 44*, § 4, eff. June 30, 2022, retroactive to Jan. 18, 2022.

Annotations

Notes

Editor's Notes

Section 6 of L. *2021, c. 454*, as amended by section 5 of L. *2022, c. 44*, provides: “The Commissioner of Health shall adopt rules and regulations as are necessary to effectuate the provisions of this act, which rules and regulations shall be effective immediately upon filing with the Office of Administrative Law for a period not to exceed 18 months, and shall, thereafter, be amended, adopted, or readopted in accordance with the provisions of the ‘Administrative Procedure Act,’ P.L.1968, c.410 (*C.52:14B-1* et seq.).”

Effective Dates

Section 7 of L. *2021, c. 454*, as amended by section 6 of L. *2022, c. 44*, provides: “This act shall take effect 12 months after the date of enactment except that paragraphs (3) and (4) of subsection a. of section 2 of this act shall take effect 18 months after the date of enactment.” Chapter 454, L. 2021, was approved on Jan. 18, 2022, and Chapter 44, L. 2022 was approved on June 30, 2022, retroactive to Jan. 18, 2022.

Section 7 of L. *2022, c. 44* provides: “This act shall take effect immediately and shall be retroactive to January 18, 2022.” Chapter 44, L. 2022, was approved on June 30, 2022.

End of Document