45:9-42.26 ET SEQ.

LEGISLATIVE HISTORY CHECKLIST

NJSA 45:9-42.26 to 45:9-42.45 ("Clinical Laboratory Improvement Act")

Laws of 1975 Chapter 166

Bill No. A2329

Sponsor(s) Deverin & Others

Date Introduced Nov. 25, 1974

Committee: Assembly Institutions, Health & Welfare

Senate Labor, Industry & Professions

Amended during passage Yes ~~No~~ Amendments during passage denoted by asterisks

Date of passage: Assembly February 27, 1975

Senate May 5, 1975

Date of approval July 23, 1975

Following statements are attached if available:

Sponsor statement		Yes	~~No~~
Committee Statement:	Assembly	Yes	~~No~~
	Senate	Yes	~~No~~
Fiscal Note		~~Yes~~	No
Veto message		~~Yes~~	No
Message on signing		Yes	~~No~~

Following were printed:

Reports	~~Yes~~	No
Hearings	~~Yes~~	No

ASSEMBLY, No. 2329

STATE OF NEW JERSEY

INTRODUCED NOVEMBER 25, 1974

By Assemblyman DEVERIN, Assemblywoman WILSON, Assemblymen GREGORIO, McCARTHY, BORNHEIMER, CALI and Assemblywoman BERMAN

Referred to Committee on Institutions, Health and Welfare

AN ACT concerning clinical laboratories, providing for the regulation thereof, amending section 22 and repealing sections 16, 17 and 19 of P. L. 1953, c. 420.

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

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

2. As used in this act:

a. "Clinical laboratory" means any facility used for the performance of chemical, bacteriologic, virologic, parasitologic, serologic, hematologic, immunohematologic, biophysical, cytologic or other examinations of materials derived from the human body for the purpose of yielding information for the diagnosis, prevention or treatment of disease or the assessment of medical condition. Anatomic pathology is not considered to be within the scope of this definition.

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

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

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

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.

3. 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.

4. 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.

5. 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.

6. 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.

7. No license issued under the provisions of this act shall be transferable.

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

a. Operated and maintained exclusively for research and teach

c. Specifically exempted from the provisions of this act by rules and regulations promulgated by the Public Health Council pursuant to section 9 of this act.

9. 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. 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 conditions within the clinical laboratory and its surroundings.

c. Clinical laboratory equipment and personnel essential to proper conduct and operation of a clinical laboratory.

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

e. Reporting by laboratories of diseases for the protection of the public health. The department shall furnish forms for this purpose. Such reports shall not be construed as constituting a diagnosis nor shall any clinical laboratory making such 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.

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

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

11. An advisory committee may be appointed by the commissioner and shall serve at his pleasure. 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, 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

a. Prescribe minimum standards of performance in the examination of specimens;

b. Test the proficiency of clinical laboratories to determine if minimum standards of performance are being met; and

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

13. 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.

14. 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.

15. 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

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.

16. 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

17. 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.

18. 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.).

19. 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.

20. If any provision of this act, or any application of any pro-

22. Section 22 of P. L. 1953, c. 420 (C. 45:9–42.22) is amended to read as follows:

22. The following shall be considered as unprofessional and unethical conduct within the meaning of said terms as set forth in section 13 (e) of this act:

a. The violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision of this act.

[b. Displaying or listing one's name in any city, commercial, telephone or public directory in a manner different or distinct from other listings therein or under a listing other than a bio-analytical laboratory. (Such as the use of display, bold face or block type.) It shall not be construed as unprofessional or unethical conduct to make use of two paid lines in the telephone directory in order to announce office hours or, if only a specialty is practiced, to so state in an additional line.

c. Displaying or listing prices or fees for laboratory services.

d. Advertising by a bio-analytical laboratory director of the prices or charges to be made, the character or accuracy of his work, or advertising that he would perform laboratory services free of charge, or on credit or installments, or at reduced or special fees, or anything similar to the foregoing, by means of circulars, cards, signs, posters or pictures, or by advertising in newspapers, magazines, or other publications or by projections by means of light, rays, electronics, crier, radio broadcasting, television or by use of advertising solicitor or publicity agent, or any other advertising media, or using his name or permitting the use of his name as a bio-analytical laboratory director, directly or indirectly, in the sale of advertising to the public of bio-analytical laboratory products or work. The foregoing portion of this section shall not be construed as prohibiting personal and direct announcements to a licensed practitioner of any of the healing arts of the services rendered by a bio-analytical laboratory, or such other pertinent, scientific material as may be of interest to such practitioner; provided, however, that no statements concerning the performance of laboratory services free of charge, or on credit or installments, or at reduced or special fees, or anything similar to the foregoing be made, or

card containing such announcement, together with his name, profession, title, degree, laboratory location, office hours, telephone number, and residence address and telephone number, if desired, and may insert such announcement (2 inches by two columns) in a newspaper for a period not exceeding 1 month; provided, further, that a licensee may display his name or the laboratory name, or both, on the premises where the laboratory is located and upon the windows or doors thereof, and by one doorplate, and upon a name or office directory where the information is limited to that of a business card, but no licensee shall use more than a total of three signs visible from the street, and such signs shall be separated from each other and each sign shall not exceed an overall area of 360 square inches or 30 inches in width, but when such sign is above second-floor level, it shall not exceed an overall area of 504 square inches or 42 inches in width, nor shall the lettering of such signs be larger than 5 inches in height. Any announcement, permitted by the provisions of this paragraph, which is false or misleading shall also be considered unethical and unprofessional conduct.]

[e.] *b.* Using, displaying or listing the name of a deceased bio-analytical laboratory director of this State by a registered bio-analytical laboratory in connection with its practice for a period of more than 1 year after the death of a bio-analytical laboratory director.

[f.] *c.* Using, displaying, or listing the name of a bio-analytical laboratory director who has retired from active practice, or who has sold his practice, or has moved to another state and is in practice in that state, by a registered bio-analytical laboratory director in connection with his practice for a period of more than 1 year after such retirement, sale or removal.

[g.] *d.* Practices involving rebates and discounts, or other financial inducements for the obtaining of referrals, either direct or indirect, shall be considered unprofessional and unethical practice.

[h.] *e.* Conduct, which, in the opinion of the board, disqualifies a licensee to practice with safety to the public.

The foregoing paragraphs are not intended as a complete definition of that which constitutes unprofessional or unethical conduct.

24. This act shall take effect the first day of the month following enactment, but all actions necessary and appropriate to enable this act to become effective on said date may be taken as though this act were effective immediately.

STATEMENT

Clinical laboratories provide essential health services of assistance to the medical practitioner by furnishing information invaluable to the diagnosis and treatment of disease. Unreliable and inaccurate laboratory results may lead to an erroneous diagnosis, contribute to the selection of an inappropriate method of treatment, cause unnecessary anxiety, suffering, financial burdens and may even contribute directly to death. The protection of the people of this State requires affirmative action to insure that the highest level of competency, reliability and accuracy is attained by clinical laboratories in this State.

It is the purpose of this act to promote the public health, safety, and welfare by requiring the annual licensure of all clinical laboratories in the State based on their demonstrated ability to meet minimum standards of performance of services offered which are accepted and approved by the Department of Health and to initiate and develop a program of education and training to foster the improvement of clinical laboratory services in the State.

ASSEMBLY INSTITUTIONS, HEALTH AND WELFARE COMMITTEE

STATEMENT TO

ASSEMBLY, No. 2329

STATE OF NEW JERSEY

DATED: FEBRUARY 13, 1975

This bill was amended by the Committee to provide for expanded regulatory control of clinical laboratories through the inclusion of facilities "used for the collection, processing and transmission of specimens to another facility." Further amendments allowed licenses to be obtained for one or more laboratory specialty categories and subcategories, such as, microbiology, serology, hematology and clinical chemistry.

In addition, amendments provided that rules and regulations promulgated by the Public Health Council would, where feasible, equal or exceed standards promulgated by the Federal "Clinical Laboratory Improvement Act," and that such rules and regulations would include standards for education, experience, continuing education, and periodic proficiency testing for different levels of laboratory personnel.

ASSEMBLY COMMITTEE AMENDMENTS TO

ASSEMBLY, No. 2329

STATE OF NEW JERSEY

ADOPTED FEBRUARY 13, 1975

Amend page 1, section 2, line 9, after "definition.", insert "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.".

Amend page 2, section 3, line 5, after "location.", insert "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.".

Amend page 2, section 4, line 5, after "act.", insert "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.".

Amend page 2, section 7, line 2, after "transferable.", insert "A change in ownership or direction of a licensed laboratory shall require notification to the department within 14 calendar days and reapplication for licensure.".

Amend page 3, section 9, line 3, after "Code.", insert "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.".

Amend page 3, section 9, line 8, after "Sanitary", insert "and safe".

Amend page 3, section 9, line 9, after "surroundings", insert ", including adequate working space, lighting, fire prevention and safety measures".

Amend page 3, section 9, line 10, after "equipment", insert ", maintenance procedures for such equipment,".

Amend page 3, section 9, line 11, after "laboratory", insert ", 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".

Amend page 3, section 9, line 12, after "collection,", insert "transportation,".

Amend page 3, section 9, line 22, after "act.", insert "Each laboratory shall maintain a manual of procedures followed in that laboratory, which shall be reviewed and updated annually. Such manual shall also include, but not be limited to, a list of equipment used for each procedure.".

Amend page 3, section 11, line 1, omit "may" and insert "shall".

Amend page 3, section 11, line 2, omit "at his pleasure" and insert "for a term of 2 years, with no member serving for more than two consecutive terms".

Amend page 3, section 11, line 6, after "laboratories", insert "who are not pathologists".

Amend page 8, section 22, line 61, omit "b." and insert "e.".

Amend page 8, section 22, line 66, omit "c." and insert "f.".

Amend page 8, section 22, line 72, omit "d." and insert "g.".

Amend page 8, section 22, line 76, omit "e." and insert "h.".

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ASSEMBLY, No. 2329

STATE OF NEW JERSEY

INTRODUCED NOVEMBER 25, 1974

By Assemblyman DEVERIN, Assemblywoman WILSON, Assemblymen GREGORIO, McCARTHY, BORNHEIMER, CALI and Assemblywoman BERMAN

Referred to Committee on Institutions, Health and Welfare

AN ACT concerning clinical laboratories, providing for the regulation thereof, amending section 22 and repealing sections 16, 17 and 19 of P. L. 1953, c. 420.

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

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

2. As used in this act:

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

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

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

d. "Clinical laboratory owner" means a person or agency in whom is vested the rights of control, possession, and dominion of

sible 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.

3. 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.**

4. 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;

5. 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.

6. 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.

7. 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.***

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

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

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

c. Specifically exempted from the provisions of this act by rules and regulations promulgated by the Public Health Council pursuant to section 9 of this act.

9. 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:

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

b. Sanitary **and safe** conditions within the clinical laboratory

tion, 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.

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

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

f. Submitting such reports concerning clinical laboratory operations as may be necessary to administer this act. **Each laboratory shall maintain a manual of procedures followed in that laboratory, which shall be reviewed and updated annually. Such 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).

11. An advisory committee *[may]* **shall*** be appointed by the commissioner and shall serve *[at his pleasure]* **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.

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

a. Prescribe minimum standards of performance in the examination of specimens;

improving the quality of performance of clinical laboratories licensed by this act.

13. 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.

14. 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.

15. 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. Having professional connection with or lending the

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.

16. 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 or 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.

17. 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

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.

18. 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.).

19. 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.

20. 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.

21. Sections 16, 17 and 19 of P. L. 1953, c. 420 [C. 45:9-42.16, 45:9-42.17, and 45:9-42.19] are hereby repealed.

22. Section 22 of P. L. 1953, c. 420 (C. 45:9-42.22) is amended to read as follows:

22. The following shall be considered as unprofessional and unethical conduct within the meaning of said terms as set forth in section 13 (e) of this act:

[b. Displaying or listing one's name in any city, commercial, telephone or public directory in a manner different or distinct from other listings therein or under a listing other than a bio-analytical laboratory. (Such as the use of display, bold face or block type.) It shall not be construed as unprofessional or unethical conduct to make use of two paid lines in the telephone directory in order to announce office hours or, if only a specialty is practiced, to so state in an additional line.

c. Displaying or listing prices or fees for laboratory services.

d. Advertising by a bio-analytical laboratory director of the prices or charges to be made, the character or accuracy of his work, or advertising that he would perform laboratory services free of charge, or on credit or installments, or at reduced or special fees, or anything similar to the foregoing, by means of circulars, cards, signs, posters or pictures, or by advertising in newspapers, magazines, or other publications or by projections by means of light, rays, electronics, crier, radio broadcasting, television or by use of advertising solicitor or publicity agent, or any other advertising media, or using his name or permitting the use of his name as a bio-analytical laboratory director, directly or indirectly, in the sale of advertising to the public of bio-analytical laboratory products or work. The foregoing portion of this section shall not be construed as prohibiting personal and direct announcements to a licensed practitioner of any of the healing arts of the services rendered by a bio-analytical laboratory, or such other pertinent, scientific material as may be of interest to such practitioner; provided, however, that no statements concerning the performance of laboratory services free of charge, or on credit or installments, or at reduced or special fees, or anything similar to the foregoing be made, or from which the foregoing may be inferred. A licensee may, however, announce the opening of a bio-analytical laboratory, his affiliation or association with a bio-analytical laboratory, his change of affiliation or removal of said laboratory, or his absence from or return to said laboratory by way of a professional announcement card containing such announcement, together with his name, profession, title, degree, laboratory location, office hours, telephone number, and residence address and telephone number, if desired,

or office directory where the information is limited to that of a business card, but no licensee shall use more than a total of three signs visible from the street, and such signs shall be separated from each other and each sign shall not exceed an overall area of 360 square inches or 30 inches in width, but when such sign is above second-floor level, it shall not exceed an overall area of 504 square inches or 42 inches in width, nor shall the lettering of such signs be larger than 5 inches in height. Any announcement, permitted by the provisions of this paragraph, which is false or misleading shall also be considered unethical and unprofessional conduct.]

[e.] *[*b.*]* **e.* Using, displaying or listing the name of a deceased bio-analytical laboratory director of this State by a registered bio-analytical laboratory in connection with its practice for a period of more than 1 year after the death of a bio-analytical laboratory director.

[f.] *[*c.*]* **f.* Using, displaying, or listing the name of a bio-analytical laboratory director who has retired from active practice, or who has sold his practice, or has moved to another state and is in practice in that state, by a registered bio-analytical laboratory director in connection with his practice for a period of more than 1 year after such retirement, sale or removal.

[g.] *[*d.*]* **g.* Practices involving rebates and discounts, or other financial inducements for the obtaining of referrals, either direct or indirect, shall be considered unprofessional and unethical practice.

[h.] *[*e.*]* **h.* Conduct, which, in the opinion of the board, disqualifies a licensee to practice with safety to the public.

The foregoing paragraphs are not intended as a complete definition of that which constitutes unprofessional or unethical conduct. The board may, by rule, establish additional standards of professional and ethical conduct.

23. There is hereby appropriated the sum of $150,000.00 to the State Department of Health for implementation of the provisions of this act.

24. This act shall take effect the first day of the month following enactment, but all actions necessary and appropriate to enable this act to become effective on said date may be taken as though this

ASSEMBLY AMENDMENTS TO

ASSEMBLY, No. 2329

[OFFICIAL COPY REPRINT]

STATE OF NEW JERSEY

ADOPTED FEBRUARY 24, 1975

Amend page 7, section 21, line 2, after "42.19]",, insert "(C. 45:9-42.16, 45:9-42.17, and 45:9-42.19)".

Amend page 9, section 23, lines 1-3, omit entirely.

Amend page 9, section 24, line 1, renumber section 24 as 23.

sible 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.

3. 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.**

4. 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;

5. 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.

6. 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.

7. 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.***

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

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

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

c. Specifically exempted from the provisions of this act by rules and regulations promulgated by the Public Health Council pursuant to section 9 of this act.

9. 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:

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**.

tion, 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.

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

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

f. Submitting such reports concerning clinical laboratory operations as may be necessary to administer this act. **Each laboratory shall maintain a manual of procedures followed in that laboratory, which shall be reviewed and updated annually. Such 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).

11. An advisory committee *[may]* **shall** be appointed by the commissioner and shall serve *[at his pleasure]* **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.

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

a. Prescribe minimum standards of performance in the examination of specimens;

improving the quality of performance of clinical laboratories licensed by this act.

13. 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.

14. 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.

15. 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

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.

16. 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 or 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.

17. No person shall:

a. Operate, maintain, direct, or engage in the business of operating a clinical laboratory, as herein defined, unless he has obtained

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.

18. 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.).

19. 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.

20. 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.

21. Sections 16, 17 and 19 of P. L. 1953, c. 420 [C. 45:9–42.16, 45:9–42.17, and 45:9–42.19] **(C. 45:9–42.16, 45:9–42.17, and 45:9–42.19)** are hereby repealed.

22. Section 22 of P. L. 1953, c. 420 (C. 45:9–42.22) is amended to read as follows:

22. The following shall be considered as unprofessional and unethical conduct within the meaning of said terms as set forth in

[b. Displaying or listing one's name in any city, commercial, telephone or public directory in a manner different or distinct from other listings therein or under a listing other than a bio-analytical laboratory. (Such as the use of display, bold face or block type.) It shall not be construed as unprofessional or unethical conduct to make use of two paid lines in the telephone directory in order to announce office hours or, if only a specialty is practiced, to so state in an additional line.

c. Displaying or listing prices or fees for laboratory services.

d. Advertising by a bio-analytical laboratory director of the prices or charges to be made, the character or accuracy of his work, or advertising that he would perform laboratory services free of charge, or on credit or installments, or at reduced or special fees, or anything similar to the foregoing, by means of circulars, cards, signs, posters or pictures, or by advertising in newspapers, magazines, or other publications or by projections by means of light, rays, electronics, crier, radio broadcasting, television or by use of advertising solicitor or publicity agent, or any other advertising media, or using his name or permitting the use of his name as a bio-analytical laboratory director, directly or indirectly, in the sale of advertising to the public of bio-analytical laboratory products or work. The foregoing portion of this section shall not be construed as prohibiting personal and direct announcements to a licensed practitioner of any of the healing arts of the services rendered by a bio-analytical laboratory, or such other pertinent, scientific material as may be of interest to such practitioner; provided, however, that no statements concerning the performance of laboratory services free of charge, or on credit or installments, or at reduced or special fees, or anything similar to the foregoing be made, or from which the foregoing may be inferred. A licensee may, however, announce the opening of a bio-analytical laboratory, his affiliation or association with a bio-analytical laboratory, his change of affiliation or removal of said laboratory, or his absence from or return to said laboratory by way of a professional announcement card containing such announcement, together with his name, profession, title, degree, laboratory location, office hours, telephone number, and residence address and telephone number, if desired,

or office directory where the information is limited to that of a business card, but no licensee shall use more than a total of three signs visible from the street, and such signs shall be separated from each other and each sign shall not exceed an overall area of 360 square inches or 30 inches in width, but when such sign is above second-floor level, it shall not exceed an overall area of 504 square inches or 42 inches in width, nor shall the lettering of such signs be larger than 5 inches in height. Any announcement, permitted by the provisions of this paragraph, which is false or misleading shall also be considered unethical and unprofessional conduct.]

[e.] *[*b.*]* **e.** Using, displaying or listing the name of a deceased bio-analytical laboratory director of this State by a registered bio-analytical laboratory in connection with its practice for a period of more than 1 year after the death of a bio-analytical laboratory director.

[f.] *[*c.*]* **f.** Using, displaying, or listing the name of a bio-analytical laboratory director who has retired from active practice, or who has sold his practice, or has moved to another state and is in practice in that state, by a registered bio-analytical laboratory director in connection with his practice for a period of more than 1 year after such retirement, sale or removal.

[g.] *[*d.*]* **g.** Practices involving rebates and discounts, or other financial inducements for the obtaining of referrals, either direct or indirect, shall be considered unprofessional and unethical practice.

[h.] *[*e.*]* **h.** Conduct, which, in the opinion of the board, disqualifies a licensee to practice with safety to the public.

The foregoing paragraphs are not intended as a complete definition of that which constitutes unprofessional or unethical conduct. The board may, by rule, establish additional standards of professional and ethical conduct.

[23. There is hereby appropriated the sum of $150,000.00 to the State Department of Health for implementation of the provisions of this act.]

[24.] ***23.*** This act shall take effect the first day of the month following enactment, but all actions necessary and appropriate to enable this act to become effective on said date may be taken as though this act were effective immediately.

SENATE COMMITTEE AMENDMENT TO

ASSEMBLY, No. 2329

[CORRECTED COPY]

[SECOND OFFICIAL COPY REPRINT]

STATE OF NEW JERSEY

ADOPTED APRIL 21, 1975

Amend page 9, section 22, line 60, after line 60 insert:

"b. Deleted by amendment.

c. Deleted by amendment.

d. Deleted by amendment.".

[SENATE REPRINT]

ASSEMBLY, No. 2329

[SECOND OFFICIAL COPY REPRINT]

with Senate committee amendment adopted April 21, 1975

STATE OF NEW JERSEY

INTRODUCED NOVEMBER 25, 1974

By Assemblyman DEVERIN, Assemblywoman WILSON, Assemblymen GREGORIO, McCARTHY, BORNHEIMER, CALI and Assemblywoman BERMAN

Referred to Committee on Institutions, Health and Welfare

AN ACT concerning clinical laboratories, providing for the regulation thereof, amending section 22 and repealing sections 16, 17 and 19 of P. L. 1953, c. 420.

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

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

2. As used in this act:

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

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

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

d. "Clinical laboratory owner" means a person or agency in whom is vested the rights of control, possession, and dominion of

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.

3. 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.**

4. 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

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

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

5. 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.

6. 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.

7. 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.**

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

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

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

c. Specifically exempted from the provisions of this act by rules and regulations promulgated by the Public Health Council pursuant to section 9 of this act.

9. The Publc 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:

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

b. Sanitary **and safe** conditions within the clinical laboratory

c. 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**.

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

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

f. Submitting such reports concerning clinical laboratory operations as may be necessary to administer this act. **Each laboratory shall maintain a manual of procedures followed in that laboratory, which shall be reviewed and updated annually. Such 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).

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

11. An advisory committee *[may]* **shall** be appointed by the commissioner and shall serve *[at his pleasure]* **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

a. Prescribe minimum standards of pe
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c. Develop and organize appropriat
activities in clinical laboratory proc
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13. The department and any officer
performance of any duty imposed by this act shall ha
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.

14. 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.

15. 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.

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.

16. 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

17. 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.

18. 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.).

19. 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.

20. 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.

22. Section 22 of P. L. 1953, c. 420 (C. 45:9–42.22) is amended to read as follows:

22. The following shall be considered as unprofessional and unethical conduct within the meaning of said terms as set forth in section 13 (e) of this act:

a. The violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision of this act.

[b. Displaying or listing one's name in any city, commercial, telephone or public directory in a manner different or distinct from other listings therein or under a listing other than a bio-analytical laboratory. (Such as the use of display, bold face or block type.) It shall not be construed as unprofessional or unethical conduct to make use of two paid lines in the telephone directory in order to announce office hours or, if only a specialty is practiced, to so state in an additional line.

c. Displaying or listing prices or fees for laboratory services.

d. Advertising by a bio-analytical laboratory director of the prices or charges to be made, the character or accuracy of his work, or advertising that he would perform laboratory services free of charge, or on credit or installments, or at reduced or special fees, or anything similar to the foregoing, by means of circulars, cards, signs, posters or pictures, or by advertising in newspapers, magazines, or other publications or by projections by means of light, rays, electronics, crier, radio broadcasting, television or by use of advertising solicitor or publicity agent, or any other advertising media, or using his name or permitting the use of his name as a bio-analytical laboratory director, directly or indirectly, in the sale of advertising to the public of bio-analytical laboratory products or work. The foregoing portion of this section shall not be construed as prohibiting personal and direct announcements to a licensed practitioner of any of the healing arts of the services rendered by a bio-analytical laboratory, or such other pertinent, scientific material as may be of interest to such practitioner; provided, however, that no statements concerning the performance of laboratory services free of charge, or on credit or installments, or at reduced or special fees, or anything similar to the foregoing be made, or

card containing such announcement, together with his name, profession, title, degree, laboratory location, office hours, telephone number, and residence address and telephone number, if desired, and may insert such announcement (2 inches by two columns) in a newspaper for a period not exceeding 1 month; provided, further, that a licensee may display his name or the laboratory name, or both, on the premises where the laboratory is located and upon the windows or doors thereof, and by one doorplate, and upon a name or office directory where the information is limited to that of a business card, but no licensee shall use more than a total of three signs visible from the street, and such signs shall be separated from each other and each sign shall not exceed an overall area of 360 square inches or 30 inches in width, but when such sign is above second-floor level, it shall not exceed an overall area of 504 square inches or 42 inches in width, nor shall the lettering of such signs be larger than 5 inches in height. Any announcement, permitted by the provisions of this paragraph, which is false or misleading shall also be considered unethical and unprofessional conduct.]

***b. Deleted by amendment.*

c. Deleted by amendment.

d. Deleted by amendment.***

[e.] *[*b.*]* **e.** Using, displaying or listing the name of a deceased bio-analytical laboratory director of this State by a registered bio-analytical laboratory in connection with its practice for a period of more than 1 year after the death of a bio-analytical laboratory director.

[f.] *[*c.*]* **f.** Using, displaying, or listing the name of a bio-analytical laboratory director who has retired from active practice, or who has sold his practice, or has moved to another state and is in practice in that state, by a registered bio-analytical laboratory director in connection with his practice for a period of more than 1 year after such retirement, sale or removal.

[g.] *[*d.*]* **g.** Practices involving rebates and discounts, or other financial inducements for the obtaining of referrals, either direct or indirect, shall be considered unprofessional and unethical practice.

[h.] *[*e.*]* **h.** Conduct, which, in the opinion of the board, disqualifies a licensee to practice with safety to the public.

The foregoing paragraphs are not intended as a complete definition of that which constitutes unprofessional or unethical conduct. The board may, by rule, establish additional standards of profes-

[23. There is hereby appropriated the sum of $150,000.00 to the State Department of Health for implementation of the provisions of this act.]

[24.] ***23.*** This act shall take effect the first day of the month following enactment, but all actions necessary and appropriate to enable this act to become effective on said date may be taken as though this act were effective immediately.

CHAPTER 166 LAWS OF N. J. 1975
APPROVED 7-23-75
[THIRD OFFICIAL COPY REPRINT]

ASSEMBLY, No. 2329

STATE OF NEW JERSEY

INTRODUCED NOVEMBER 25, 1974

By Assemblyman DEVERIN, Assemblywoman WILSON, Assemblymen GREGORIO, McCARTHY, BORNHEIMER, CALI and Assemblywoman BERMAN

Referred to Committee on Institutions, Health and Welfare

AN ACT concerning clinical laboratories, providing for the regulation thereof, amending section 22 and repealing sections 16, 17 and 19 of P. L. 1953, c. 420.

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

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

2. As used in this act:

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

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

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

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

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.

3. 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.**

4. 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

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

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

5. 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.

6. 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.

7. 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.**

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

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

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

c. Specifically exempted from the provisions of this act by rules and regulations promulgated by the Public Health Council pursuant to section 9 of this act.

9. 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:

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

b. Sanitary **and safe** conditions within the clinical laboratory

c. 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**.

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

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

f. Submitting such reports concerning clinical laboratory operations as may be necessary to administer this act. **Each laboratory shall maintain a manual of procedures followed in that laboratory, which shall be reviewed and updated annually. Such 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).

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

11. An advisory committee *[may]* **shall** be appointed by the commissioner and shall serve *[at his pleasure]* **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

a. Prescribe minimum standards of performance in the examination of specimens;

b. Test the proficiency of clinical laboratories to determine if minimum standards of performance are being met; and

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

13. 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.

14. 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.

15. 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.

[illegible] of falsifying results not based on test performance

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.

16. 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 or receipt of said

17. 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.

18. 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.).

19. 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.

20. 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

22. Section 22 of P. L. 1953, c. 420 (C. 45:9–42.22) is amended to read as follows:

22. The following shall be considered as unprofessional and unethical conduct within the meaning of said terms as set forth in section 13 (e) of this act:

a. The violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision of this act.

[b. Displaying or listing one's name in any city, commercial, telephone or public directory in a manner different or distinct from other listings therein or under a listing other than a bio-analytical laboratory. (Such as the use of display, bold face or block type.) It shall not be construed as unprofessional or unethical conduct to make use of two paid lines in the telephone directory in order to announce office hours or, if only a specialty is practiced, to so state in an additional line.

c. Displaying or listing prices or fees for laboratory services.

d. Advertising by a bio-analytical laboratory director of the prices or charges to be made, the character or accuracy of his work, or advertising that he would perform laboratory services free of charge, or on credit or installments, or at reduced or special fees, or anything similar to the foregoing, by means of circulars, cards, signs, posters or pictures, or by advertising in newspapers, magazines, or other publications or by projections by means of light, rays, electronics, crier, radio broadcasting, television or by use of advertising solicitor or publicity agent, or any other advertising media, or using his name or permitting the use of his name as a bio-analytical laboratory director, directly or indirectly, in the sale of advertising to the public of bio-analytical laboratory products or work. The foregoing portion of this section shall not be construed as prohibiting personal and direct announcements to a licensed practitioner of any of the healing arts of the services rendered by a bio-analytical laboratory, or such other pertinent, scientific material as may be of interest to such practitioner; provided, however, that no statements concerning the performance of laboratory services free of charge, or on credit or installments, or at reduced or special fees, or anything similar to the foregoing be made, or

card containing such announcement, together with his name, profession, title, degree, laboratory location, office hours, telephone number, and residence address and telephone number, if desired, and may insert such announcement (2 inches by two columns) in a newspaper for a period not exceeding 1 month; provided, further, that a licensee may display his name or the laboratory name, or both, on the premises where the laboratory is located and upon the windows or doors thereof, and by one doorplate, and upon a name or office directory where the information is limited to that of a business card, but no licensee shall use more than a total of three signs visible from the street, and such signs shall be separated from each other and each sign shall not exceed an overall area of 360 square inches or 30 inches in width, but when such sign is above second-floor level, it shall not exceed an overall area of 504 square inches or 42 inches in width, nor shall the lettering of such signs be larger than 5 inches in height. Any announcement, permitted by the provisions of this paragraph, which is false or misleading shall also be considered unethical and unprofessional conduct.]

60A ***b. Deleted by amendment.*

60B *c. Deleted by amendment.*

60C *d. Deleted by amendment.****

[e.] *[*b.*]* **e.** Using, displaying or listing the name of a deceased bio-analytical laboratory director of this State by a registered bio-analytical laboratory in connection with its practice for a period of more than 1 year after the death of a bio-analytical laboratory director.

[f.] *[*c.*]* **f.** Using, displaying, or listing the name of a bio-analytical laboratory director who has retired from active practice, or who has sold his practice, or has moved to another state and is in practice in that state, by a registered bio-analytical laboratory director in connection with his practice for a period of more than 1 year after such retirement, sale or removal.

[g.] *[*d.*]* **g.** Practices involving rebates and discounts, or other financial inducements for the obtaining of referrals, either direct or indirect, shall be considered unprofessional and unethical practice.

[h.] *[*e.*]* **h.** Conduct, which, in the opinion of the board, disqualifies a licensee to practice with safety to the public.

FROM THE OFFICE OF THE GOVERNOR

JULY 23, 1975

FOR IMMEDIATE RELEASE

FOR FURTHER INFORMATION

DICK CAMPBELL

Governor Brendan Byrne signed into law Wednesday a bill to provide state regulation of clinical laboratories.

The bill, A-2329, sponsored by Assemblyman Thomas J. Deverin, D-Middlesex, provides for the licensing and regulation of clinical laboratories by the State Department of Health.

"For the first time, the Department will be able to establish performance standards in an area which has been subject to abuse in New Jersey," said Byrne. "There has been continuing evidence over the past several years that some laboratories are inadequate and that these inadequacies have jeopardized the health of our citizens."

The measure provides that the standards set by the Department shall be equal to or higher than the standards in effect in the federal law to regulate clinical laboratories which deal in interstate commerce.

The bill also calls on the Department to test the proficiency of clinical laboratories to determine if the standards are being met, and to develop consultation and training programs to improve the quality of performance at laboratories.

The measure empowers the State Health Commission to suspend or revoke a license for violations of the law.

A-1659

Byrne also signed into law a bill which authorizes municipal plumbing inspectors to inspect and approve or disapprove the installation of propane gas equipment into residential buildings.

The measure, sponsored by Assemblyman Daniel F. Newman, D-Ocean, provides that the municipal inspector may make the inspections according to the standards established by the Department of Labor and Industry and the State Police.

The Governor said that with the increased use of propane gas because of