

MAINE STATE LEGISLATURE

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ONE HUNDRED AND THIRD LEGISLATURE

Legislative Document

No. 1208

S. P. 475

In Senate, March 1, 1967

Referred to the Committee on Legal Affairs. Sent down for concurrence and ordered printed.

JERROLD B. SPEERS, Secretary

Presented by Senator Berry of Cumberland.

STATE OF MAINE

IN THE YEAR OF OUR LORD NINETEEN HUNDRED
SIXTY-SEVEN

AN ACT Establishing the Maine Medical Laboratory Act.

Be it enacted by the People of the State of Maine, as follows:

R. S., T. 22, c. 411, additional. Title 22 of the Revised Statutes is amended by adding a new chapter 411, as follows:

CHAPTER 411

MAINE MEDICAL LABORATORY ACT

ARTICLE I. TITLE, INTENT AND APPLICATION

§ 2011. Short title

This Act may be cited as the State of Maine Medical Laboratory Act.

§ 2012. Purpose

The proper operation of medical laboratories within the State of Maine is a matter of vital concern, since they provide essential health services by aiding other medical practitioners in the diagnosis and treatment of disease. It is the purpose of this Act to develop, establish and enforce minimum standards for the licensure of medical laboratories and to provide for qualifications for the director of such laboratories. This Act shall be liberally construed to carry out these objectives and purposes.

§ 2013. Exampntions

This Act applies to medical laboratories, owners and directors of medical laboratories except that this does not apply to:

1. **Governmental.** Medical laboratories operated by the United States Government, the State of Maine or municipalities of the State of Maine;
2. **Hospitals.** Laboratory facilities and laboratory services operated in a hospital licensed by the State of Maine;
3. **Physicians.** Physicians registered in the State of Maine who operate a medical laboratory exclusively for the examination of their own patients, provided if referred work is received in the laboratory all provisions of this Act shall apply;
4. **Schools and industrial plants.** Medical laboratories in a school, college, university or industrial plant which are under the direct supervision of and which services are used exclusively by a duly licensed physician;
5. **Research and teaching.** Laboratories operated and maintained for research and teaching purposes which are recognized by the advisory commission or involve no patient or public health service.

ARTICLE 2. DEFINITIONS

§ 2014. Definitions

For the purposes of this Act, the following words and phrases have the meanings ascribed to them unless the context otherwise requires.

1. **Advisory commission.** "Advisory commission" shall be a group of consultants to the department on matters relating to this Act.
2. **Department.** "Department" means the Department of Health and Welfare of the State of Maine.
3. **Director of medical laboratory.** "Director of medical laboratory" means an individual who is responsible for the professional, technical and scientific operation of a medical laboratory, including the reporting of the findings of medical laboratory tests. The director of a medical laboratory may not be merely nominal, but must be responsible for its operation to such extent as may be necessary to assure compliance with the objects and purposes of this Act.
4. **Medical laboratory.** "Medical laboratory" or "laboratory" means any institution, building or place which provides through its ownership or operation an organization which employs methods and instruments for the examination of tissues, secretions and excretions of the human body or any function of the human body in order to diagnose disease, follow the course of disease, aid in the treatment of such disease, or which produce information used as a basis for health advice or which purports to offer such examinations.
5. **Person.** "Person" means any individual, partnership or association.

ARTICLE 3. APPLICATION FOR AND ISSUANCE OF LICENCES AND RENEWALS

§ 2015. License

The department with the approval of the advisory commission shall issue a medical laboratory license to any medical laboratory which has applied for said

license on forms provided by the department and which is found to be in compliance with this Act.

No medical laboratory licensed under this Act shall send specimens to any laboratory within the State unless such laboratory is in compliance with this Act. When the specimen has been referred for examination to an out-of-state laboratory, the report shall bear or be accompanied by a clear statement that such findings were obtained in such other laboratory, which shall be identified.

§ 2016. Application

Application shall be made on a form prescribed by the department. All applications shall be accompanied by a license application fee of \$100. The application shall be notarized and shall contain the following information:

1. Name and location. The name and location of the medical laboratory;
2. Director and owners. The name of the director of the laboratory and the name of the owner or owners, if different;
3. Services. A description of the services provided by such medical laboratory; and
4. Other information. Such other information as the department may deem necessary or expedient in carrying out its powers and duties under this Act.

§ 2017. Renewal

A license shall expire 3 years after the date of issuance unless renewed. Licenses may be renewed in the same manner and subject to the same conditions as the issuance of the original license and upon payment of a renewal application fee of \$50.

§ 2018. Terms

A license to conduct a medical laboratory where the owner is not the director shall be issued jointly to the owner and the director for the premises stated in the application, and they shall be severally and jointly responsible to the department for the maintenance and conduct thereof and for any violations of this Act and regulations pertaining thereto. A separate license must be obtained for each location. A license shall be valid only in the hands of the persons to whom it is issued and shall not be the subject of sale, assignment or transfer, voluntary or involuntary, nor shall a license be valid for any premises other than those for which issued. A new license may be secured for the new location, director or owner prior to the actual change, provided that the contemplated change is in compliance with this Act and regulations pertaining thereto.

§ 2019. Display

Any person maintaining, conducting or operating a medical laboratory shall display in a prominent place in the medical laboratory the license issued to him by the department. A medical laboratory shall not in any advertisement, announcement, letter, circular, poster, sign or in any other manner include any statement expressly or by implication to the effect that it is approved or endorsed by the department.

§ 2020. Fees

Fees required under this Act may not be returned to the applicant or licensee under any circumstances.

§ 2021. Use

All fees charged and collected by the department shall be deposited by it in the State Treasury to the credit of the department. All such moneys are appropriated to be used by the department in carrying out this Act. The expenditures of the department and advisory commission may be paid from such moneys.

§ 2022. Duplicate

A licensee may obtain a duplicate copy of the license upon payment of \$2 to the department.

ARTICLE 4. POWERS AND DUTIES OF THE DEPARTMENT**§ 2023. Rules and regulations**

The department with the approval of the advisory commission shall prescribe and publish rules and regulations for medical laboratories. These rules and regulations shall relate to:

1. Qualifications of directors. The qualifications of directors of medical laboratories;

2. Location and construction of laboratory. The location and construction of the laboratory including plumbing, heating, lighting, ventilation, electrical services and similar conditions which shall insure the conduct and operation of the laboratory in a manner which will protect the public health;

3. Sanitary conditions. All sanitary conditions within the laboratory and its surroundings, including water supply, sewage, handling of specimens and general hygiene which shall insure the protection of the public health; and

4. Equipment. Equipment essential in the opinion of the advisory commission to proper conduct and operation of a medical laboratory.

§ 2024. Inspection

The department is authorized to inspect the premises and operations of all medical laboratories subject to licensure under this Act.

§ 2025. Evaluation

The department may require the demonstration of proficiency in the performance of the tests offered by the laboratory through some type of evaluation program. The individual or individuals directing such evaluation programs shall have at least the minimum qualifications of a director.

ARTICLE 5. ADVISORY COMMISSION**§ 2026. Membership**

The advisory commission shall consist of 7 members. The Commissioner of Health and Welfare or a person appointed by him shall be a member and is

designated as chairman. The Maine Osteopathic Society may appoint one member. The Maine Medical Society may appoint one member. The rest of the members shall be appointed by the Governor, and at least 3 of these shall be certified by the American Board of Pathology, and at least one of these shall be certified by the American Osteopathic Board of Pathology. If no such qualified persons are available, then he shall substitute a person whom he deems qualified.

Each member shall hold office for a term of 3 years, except that the members first appointed by the Governor under this Act shall be appointed for the following terms: One for one year, one for 2 years, and one for 3 years as designated by the Governor at the time of appointment unless sooner removed by the Governor. No member shall be eligible for more than 3 consecutive terms, except the Commissioner of Health and Welfare or the person he designates, and any appointment to fill a vacancy shall be for the unexpired portion of the term. The Governor may remove any member for cause after notice and hearing at any time prior to expiration of his term.

§ 2027. Expenses

Members of the advisory commission shall serve without pay, but they shall receive reimbursement for actual and necessary expenses incurred in the performance of their duties.

§ 2028. Consultation and meetings

The advisory commission shall consult with the department and the board on matters of policy affecting the administration of this Act and in the development revision and enforcement of the rules and regulations promulgated. The advisory commission shall meet as frequently as the department deems necessary. Upon request of 3 members it shall be the duty of the chairman to call a meeting of the advisory commission.

ARTICLE 6. QUALIFICATIONS OF THE DIRECTOR
AND OWNER OF A MEDICAL LABORATORY

§ 2029. Director and owner

Every medical laboratory shall have a director who is a legal resident of the State of Maine except under certain conditions which may be designated by the advisory commission and department. He shall also possess one of the following qualifications:

1. Certification. He is a physician licensed to practice medicine in the State of Maine, certified by the American Board of Pathology or the American Osteopathic Board of Pathology, or who possesses qualifications acceptable to the board and equivalent to such certification; or
2. Special qualifications. He is a physician licensed to practice medicine with special qualifications acceptable to the board; or
3. Current director. He is an individual who has acted as the director of a medical laboratory within the State for one year prior to the effective date of this Act. He may continue to direct that laboratory only except that the department,

upon recommendation of the advisory commission, may, as a condition precedent to the issuance of a license, require such individual to pass an examination in the event that it deems such an examination necessary to determine the competence of the individual as a director.

No medical laboratory shall perform examinations in the field of pathologic anatomy including exfoliative cytology unless the director is a diplomate of the American Board of Pathology certified in pathologic anatomy or the American Osteopathic Board of Pathology certified in pathologic anatomy, or unless he is a physician licensed to practice medicine in the State of Maine who possesses special qualifications acceptable to the board, or unless he is a dentist licensed in Maine and is certified by the American Board of Oral Pathology.

An owner must have the same qualification as a director except for certain exceptions to be designated by the advisory board.

ARTICLE 7. ACCEPTANCE, COLLECTION, IDENTIFICATION AND EXAMINATION OF SPECIMENS AND REPORTS OF FINDINGS

§ 2030. Requested

Except as otherwise provided, a medical laboratory shall examine specimens only at the request of a licensed physician or other person authorized by law to use the findings of laboratory examinations.

§ 2031. Tests reported

The result of a test shall be reported directly to the licensed physician or other person authorized by law who requested it. A report of results issued from a medical laboratory shall clearly identify that medical laboratory and the director.

§ 2032. Specimens

No person other than a licensed physician or one authorized by law shall manipulate a person for the collection of specimens or process or submit or act as an agent for the transmittal of specimens, except that technical personnel of a licensed medical laboratory may collect blood or remove stomach contents or collect material for smears and cultures under the direction or upon the request of a physician or dentist.

§ 2033. Rebates or fee splitting prohibited

The owner or director of a laboratory licensed under this Act, either personally or through an agent, shall not practice in any manner which offers or implies to offer rebates to persons submitting specimens or other fee splitting inducements, or participate in any fee splitting arrangement. This applies to contents of fee schedules, billing methods or personal solicitation. The contractual provision of laboratory services for a fixed fee independent of the number of specimens submitted for such services is declared to be a violation of this section. Fees for services shall be rendered directly to patients or their agents including insurance companies, and not to the referring physician.

§ 2034. Records

Records involving laboratory services and copies of reports of laboratory tests shall be kept in a manner satisfactory to the department and shall be available at all times for inspection by its representative.

ARTICLE 8. REVOCATION AND SUSPENSION OF LICENSES**§ 2035. Denial; revocation**

A license may be denied or revoked or the renewal of a license may be denied for any of the following reasons:

1. Violation of Act. Violation of any of the provisions of this Act or the rules and regulations promulgated by the department hereunder;
2. Assignment from unauthorized person. Knowingly accepting an assignment for medical laboratory tests or specimens from and the rendering a report thereon to persons not authorized by law to submit such specimens;
3. Conviction. A conviction of a felony or of any crime involving moral turpitude under the laws of any state or of the United States arising out of or in connection with the operation of a medical laboratory. The record of conviction or a certified copy thereof shall be conclusive evidence of such conviction;
4. Lending name. Knowingly lending the use of the name of a licensed medical laboratory or its director to an unlicensed medical laboratory.

§ 2036. Hearing

Before suspension or revocation of its license, if requested, a hearing shall be held before a meeting of the advisory commission to show cause why a license should not be suspended or revoked.

ARTICLE 9. OFFENSES AND PENALTIES**§ 2037. Offenses**

It is unlawful for any person to:

1. Unlicensed. Operate, maintain, direct, or engage in the business of operating a medical laboratory, as defined, unless he has obtained a medical laboratory license from the department;
2. Unsupervised. Conduct, maintain or operate a medical laboratory unless such medical laboratory is under the direct and responsible supervision and direction of the person possessing those qualifications required by Article 6 of this Act.

§ 2038. Penalties

The performance of any of the acts specified in section 2037 shall constitute a misdemeanor punishable, upon conviction, by a fine or not less than \$50 nor more than \$500, or by imprisonment for not more than one year, or by both.

ARTICLE 10. INJUNCTIONS**§ 2039. Injunction**

The operation or maintenance of an unlicensed medical laboratory in violation of this Act, is declared a nuisance inimical to the public health, welfare and

safety. The department, in the name of the people of the State of Maine, through the Attorney General, may, in addition to other remedies provided, bring an action for an injunction to restrain such violation or to enjoin the future operation or maintenance of any such medical laboratory unless compliance with this Act has been obtained.

ARTICLE II. APPEALS

§ 2040. Appeal

Any person aggrieved by a decision of the department or the board may appeal to the Administrative Hearing Commissioner under Title 5, chapter 301 to 307.