

MAINE STATE LEGISLATURE

The following document is provided by the
LAW AND LEGISLATIVE DIGITAL LIBRARY
at the Maine State Law and Legislative Reference Library
<http://legislature.maine.gov/lawlib>



Reproduced from scanned originals with text recognition applied
(searchable text may contain some errors and/or omissions)

(EMERGENCY)
(New draft of H. P. 334, L. D. 406)

ONE HUNDRED AND SEVENTH LEGISLATURE

Legislative Document

No. 1835

H. P. 1522

House of Representatives, April 21, 1975

Reported by Mr. Goodwin of South Berwick from Committee on Health and Institutional Services. Printed under Joint Rules No. 18.

EDWIN H. PERT, Clerk

STATE OF MAINE

IN THE YEAR OF OUR LORD NINETEEN HUNDRED
SEVENTY-FIVE

AN ACT to Revise the Maine Medical Laboratory Act.

Emergency preamble. Whereas, Acts of the Legislature do not become effective until 90 days after adjournment unless enacted as emergencies; and

Whereas, medical laboratories provide essential health services to the people of the State; and

Whereas, the licensing and regulation of such laboratories will assure the quality of medical laboratory services produced by this industry; and

Whereas, Public Law 1967, chapter 380, "The Maine Medical Laboratory Act", upon review by the Department of Health and Welfare and the Maine Medical Laboratory Act Advisory Commission, has been found inadequate to safeguard public health and has been determined to be restrictive towards encouraging private enterprise participation in medical laboratory financing; and

Whereas, in the judgment of the Legislature, these facts create an emergency within the meaning of the Constitution of Maine and require the following legislation as immediately necessary for the preservation of the public peace, health and safety; now, therefore,

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

22 MRSA c. 411, as enacted by PL 1967, c. 380, and as amended, is repealed and the following enacted in place thereof:

CHAPTER 411

MAINE MEDICAL LABORATORY ACT

ARTICLE I. TITLE, INTENT AND APPLICATION

§ 2011. Short title

This Act may be cited as the "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. Exemptions

This Act applies to medical laboratories 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 department after consultation with the commission or involve no patient or public health service;

6. Radiology. The practice of radiology by a radiologist.

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. Commission. The "commission" means the Maine Medical Laboratory Commission as organized hereunder.

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 produces information used as a basis for health advice or which purports to offer such examinations.

5. Person. "Person" means any individual, corporation, partnership or association.

ARTICLE 3. APPLICATION FOR AND ISSUANCES OF LICENSES AND RENEWALS

§ 2015. License

The department, with the approval of the 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 when 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, for the unexpired length of time of the original license, may be secured, without the payment of any additional fee, 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.

This section is not to be construed as limiting the ownership of laboratories to persons who qualify under the provisions of this chapter as a director, but rather is intended to stipulate that a director as defined in section 2014, subsection 3, is necessary in order for a laboratory to obtain a license.

§ 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 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 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 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, the 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 department and the 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, except when other qualifications are acceptable to the department and the commission.

ARTICLE 5. MAINE MEDICAL LABORATORY COMMISSION

§ 2026. Membership

There is hereby created the Maine Medical Laboratory Commission which shall consist of 10 members who are residents of the State. The commissioner of the department or a person appointed by him shall be a member and is hereby designated and shall serve as the chairman. The Maine Osteopathic Association and the Maine Medical Association shall each nominate one person, which nominees shall be appointed to the commission by the Governor. The remaining 7 members shall be appointed by the Governor and 3 of these members shall be certified by the American Board of Pathology and one member shall be certified by the American Osteopathic Board

of Pathology. If persons possessing such qualifications are unavailable or unable to serve, the Governor may substitute any allopathic physician licensed in the State in lieu of an individual certified by the American Board of Pathology and any osteopathic physician licensed by the State in lieu of the individual certified by the American Osteopathic Board of Pathology. The remaining 3 members shall be public members who shall not derive any significant part of their income from the medical care industry.

Each member shall hold office for a term of 3 years. However, of those members appointed by the Governor who are certified by the American Board of Pathology or are appointed in lieu of such persons, one shall serve for one year, one for 2 years and one for 3 years and of those public members appointed by the Governor, one shall serve for one year, one for 2 years and one for 3 years.

No member, except the chairman, shall be eligible for more than 3 consecutive terms 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. No vacancy in the membership of the commission shall impair the right of such members to exercise all the rights and perform all the duties of the commission.

§ 2027. Expenses

Members of the 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 commission shall consult with the department on matters of policy affecting the administration of this Act and in the development, revision and enforcement of the rules and regulations promulgated. The 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 commission.

ARTICLE 6. QUALIFICATIONS OF A DIRECTOR OF A MEDICAL LABORATORY

§ 2029. Director

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 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 accept-

able to the department and the commission and equivalent to such certification; or

2. Special qualifications. He is a physician licensed to practice medicine with special qualifications acceptable to the department and the commission.

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 department and the commission, or unless he is a dentist licensed in Maine and is certified by the American Board of Oral Pathology.

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. A copy of the itemized statement shall be sent to the patient.

§ 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; or
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 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.

§ 2038. Penalties

The performance of any of the acts specified in section 2037 shall constitute a misdemeanor punishable, upon conviction, by a fine of 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 11. APPEALS**§ 2040. Appeal**

Any person aggrieved by a decision of the department or the commission may appeal to the Administrative Court Judge under Title 5, chapters 301 to 307.

Emergency clause. In view of the emergency cited in the preamble, this Act shall take effect when approved.