

CHAPTER 411

MAINE MEDICAL LABORATORY ACT

ARTICLE 1

TITLE, INTENT AND APPLICATION

§2011. Short title

This Act may be cited as the "Maine Medical Laboratory Act." [PL 1975, c. 218 (RPR).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR).

§2012. Purpose

The proper operation of medical laboratories within the State is a matter of vital concern, since they provide essential health services by aiding 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. [PL 1981, c. 66, §1 (AMD).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1981, c. 66, §1 (AMD).

§2013. Exemptions

(REPEALED)

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1981, c. 470, §A79 (AMD). PL 1987, c. 211, §§1,2 (AMD). PL 1989, c. 72, §1 (RP).

§2013-A. Applicability

In general, this Act applies to all medical laboratories and directors of medical laboratories operating in the State. [PL 1989, c. 72, §2 (NEW).]

1. Exemptions. Subject to the limitations set forth in subsections 2 and 3, the following entities are exempted from the provisions of this Act under the following circumstances:

A. Medical laboratories operated by the United States Government, the State or municipalities of the State; [PL 1989, c. 72, §2 (NEW).]

B. Laboratory facilities and laboratory services operated in a hospital licensed by the State; [PL 1989, c. 72, §2 (NEW).]

C. Physicians and medical staff pursuant to this paragraph:

(1) Physicians, physician assistants, family nurse practitioners, Medicare-certified rural health clinics, professional associations or group practices performing only tests acceptable to the department, as defined by rule, exclusively for the examination of their own patients; and

(2) Physicians, physician assistants, family nurse practitioners, Medicare-certified rural health clinics, professional associations or group practices performing tests, other than those listed in

subparagraph (1), exclusively for the examination of their own patients are subject only to sections 2024, 2025 and 2039.

Notwithstanding subparagraphs (1) and (2), laboratories incorporated for the mutual use of physician or group practice owners are subject to all provisions of this Act; [PL 2005, c. 383, §21 (AMD).]

D. Medical laboratories in a school, college, university or industrial plant that are under the direct supervision of, and whose services are used exclusively by, a duly licensed physician and that perform only tests acceptable to the department; otherwise, only sections 2024, 2025 and 2039 apply; [PL 2005, c. 383, §21 (AMD).]

E. Laboratories operated and maintained for research and teaching purposes that are recognized by the department or involve no patient or public health service; [PL 2005, c. 383, §21 (AMD).]

F. The practice of radiology by a radiologist; and [PL 1989, c. 72, §2 (NEW); PL 1989, c. 456, §1 (AMD).]

G. Laboratory services performing health screening tests as defined and regulated by rule adopted by the department. Services exempted under this paragraph include, but are not limited to, the performance of screening tests for cholesterol and colon cancer. [PL 1993, c. 600, Pt. B, §4 (AMD).]

[PL 2005, c. 383, §21 (AMD).]

2. Maternal serum alpha-fetoprotein testing. Notwithstanding subsection 1, all medical laboratories and directors of medical laboratories shall be subject to all provisions of this Act, and rules promulgated under it, which govern the performance of maternal serum alpha-fetoprotein testing. [PL 1989, c. 72, §2 (NEW).]

3. Public health reporting requirements. Notwithstanding subsection 1, any facility, regardless of location, that receives, forwards or analyzes specimens of material from the human body or referred cultures of specimens from the human body and reports the results to health care providers who use the data for purposes of patient care must comply with chapter 250. [PL 2005, c. 383, §22 (NEW).]

SECTION HISTORY

PL 1989, c. 72, §2 (NEW). PL 1989, c. 456, §§1,2 (AMD). PL 1989, c. 665, §1 (AMD). PL 1993, c. 600, §§B2-4 (AMD). PL 2005, c. 383, §§21,22 (AMD).

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. [PL 1975, c. 218 (RPR).]

1. Commission.

[PL 1993, c. 600, Pt. B, §5 (RP).]

2. Department. "Department" means the Department of Health and Human Services of the State of Maine.

[PL 1975, c. 218 (RPR); PL 1975, c. 293, §4 (AMD); PL 2003, c. 689, Pt. B, §6 (REV).]

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.

[PL 1975, c. 218 (RPR).]

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 blood, 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 detect drugs or toxic substances or which produces information used as a basis for health advice or which purports to offer such examinations unless otherwise provided by law. [PL 1987, c. 211, §3 (AMD).]

5. Person. "Person" means any individual, corporation, partnership or association. [PL 1975, c. 218 (RPR).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1975, c. 293, §4 (AMD). PL 1987, c. 211, §3 (AMD). PL 1993, c. 600, §B5 (AMD). PL 2003, c. 689, §B6 (REV).

ARTICLE 3

APPLICATION FOR AND ISSUANCES OF LICENSES AND RENEWALS

§2015. License

The department 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. [PL 1993, c. 600, Pt. B, §6 (AMD).]

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. [PL 1975, c. 218 (RPR).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1993, c. 600, §B6 (AMD).

§2016. Application

Application must be made on a form prescribed by the department. Licenses must be issued to perform testing in one or more of the following categories or specialties: Histocompatibility; microbiology, including subcategories bacteriology, mycology, parasitology, virology; immunology or serology, including subcategories syphilis and nonsyphilis; chemistry, including subcategories routine, clinical microscopy or urinalysis and other, including toxicology; hematology, including coagulation; immunohematology, including subcategories blood group and Rh typing, Rh titers, cross matching, antibody detection and identification; pathology, including subcategories tissue, oral, diagnostic cytology; and radiobioassay. All applications must be accompanied by a license application fee. The application must contain the following information: [PL 2011, c. 531, §1 (AMD).]

1. Name and location. The name and location of the medical laboratory; [PL 1975, c. 218 (RPR).]

2. Director and owners. The name of the director of the laboratory and the name of the owner or owners, if different;

[PL 1975, c. 218 (RPR).]

3. Services. A description of the services provided by such medical laboratory; and

[PL 1975, c. 218 (RPR).]

4. Other information. Such other information as the department may deem necessary or expedient in carrying out its powers and duties under this Act.

[PL 1975, c. 218 (RPR).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1987, c. 211, §4 (AMD). PL 1991, c. 528, §J1 (AMD). PL 1991, c. 528, §RRR (AFF). PL 1991, c. 591, §J1 (AMD). PL 2011, c. 531, §1 (AMD).

§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 \$200 for the first category and \$60 for each additional category.

[PL 1987, c. 211, §5 (AMD).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1987, c. 211, §5 (AMD).

§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. [PL 1975, c. 218 (RPR).]

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. [PL 1975, c. 218 (RPR).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR).

§2019. Display

A person maintaining, conducting or operating a medical laboratory shall display, in a prominent place in the medical laboratory, the license issued to the person by the department. A medical laboratory may 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. [RR 2021, c. 2, Pt. B, §112 (COR).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). RR 2021, c. 2, Pt. B, §112 (COR).

§2020. Fees

Fees required under this Act may not be returned to the applicant or licensee under any circumstances. [PL 1975, c. 218 (RPR).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR).

§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 money is appropriated to be used by the department in carrying out this Act. The expenditures of the department may be paid from that money. [PL 1993, c. 600, Pt. B, §7 (AMD).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1993, c. 600, §B7 (AMD).

§2022. Duplicate

A licensee may obtain a duplicate copy of the license upon payment of \$2 to the department. [PL 1975, c. 218 (RPR).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR).

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

The department shall prescribe and publish rules and regulations for medical laboratories. These rules and regulations shall relate to: [PL 1993, c. 600, Pt. B, §8 (AMD).]

1. Qualifications of directors and technical personnel. The qualifications of directors and technical personnel of medical laboratories;
[PL 1987, c. 211, §6 (AMD).]

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;
[PL 1975, c. 218 (RPR).]

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 ensure the protection of the public health;
[PL 1989, c. 72, §3 (AMD).]

4. Equipment. Equipment essential in the opinion of the department to proper conduct and operation of a medical laboratory; and
[PL 1993, c. 600, Pt. B, §9 (AMD).]

5. Standards of performance. Standards of performance essential to the achievement of accurate, reliable results and the protection of public health, including standards for maternal serum alpha-fetoprotein testing, covering, at a minimum, volume of testing, population-based reference data, adjustment for variables affecting interpretation of results, confirmatory analyses, reports, review and

follow-up and procedures to ensure that patients and physicians are provided adequate and reliable follow-up testing and counseling services and that the department is provided with data on test results and pregnancy outcomes.

[PL 1989, c. 72, §4 (NEW).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1987, c. 211, §6 (AMD). PL 1989, c. 72, §§3,4 (AMD). PL 1993, c. 600, §§B8,9 (AMD).

§2023-A. Fees

The department shall adopt a schedule of fees by rulemaking to implement provisions of this chapter. [PL 1991, c. 528, Pt. J, §2 (NEW); PL 1991, c. 528, Pt. RRR (AFF); PL 1991, c. 591, Pt. J, §2 (NEW).]

SECTION HISTORY

PL 1991, c. 528, §J2 (NEW). PL 1991, c. 528, §RRR (AFF). PL 1991, c. 591, §J2 (NEW).

§2024. Inspection

The department is authorized to inspect the premises and operations of all medical laboratories, subject to licensure or any provisions under this Act. [PL 1987, c. 211, §7 (AMD).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1987, c. 211, §7 (AMD).

§2025. Performance evaluation

The department shall require the demonstration of proficiency in the performance of the tests offered by laboratories subject to licensure or the provisions of this paragraph through successful participation in a proficiency testing program acceptable to the department covering all categories or subcategories in which testing is offered. Evaluated copies of results shall be forwarded to the department. [PL 1993, c. 600, Pt. B, §10 (AMD).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1987, c. 211, §8 (RPR). PL 1993, c. 600, §B10 (AMD).

ARTICLE 5

MAINE MEDICAL LABORATORY COMMISSION

§2026. Membership

(REPEALED)

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1983, c. 812, §122 (AMD). PL 1987, c. 211, §9 (AMD). PL 1989, c. 503, §B88 (AMD). PL 1993, c. 600, §B11 (RP).

§2027. Expenses

(REPEALED)

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1983, c. 812, §123 (AMD). PL 1993, c. 600, §B12 (RP).

§2028. Consultation and meetings

(REPEALED)

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1993, c. 600, §B13 (RP).

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 department. The director shall also possess one of the following qualifications: [PL 1993, c. 600, Pt. B, §14 (AMD).]

1. Certification. 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 department and equivalent to such certification; [PL 1993, c. 600, Pt. B, §14 (AMD).]

2. Special qualifications. Is a physician licensed to practice medicine with special qualifications acceptable to the department; or [PL 1993, c. 600, Pt. B, §14 (AMD).]

3. Qualified persons other than physicians. Has an earned doctorate degree in a chemical, physical or biological science from an accredited institution and either is certified in at least one laboratory specialty by the American Board of Clinical Chemistry, American Board of Medical Microbiology or other national accrediting board acceptable to the department. Medical laboratories directed by persons qualified under this subsection shall only perform those examinations within the scientific area in which members of the staff are trained and certified. [PL 1993, c. 600, Pt. B, §14 (AMD).]

A medical laboratory may not perform examinations in the field of pathologic anatomy, including exfoliative cytology, unless the director or an employee of the laboratory 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 the director is a physician licensed to practice medicine in the State who possesses special qualifications acceptable to the department, or unless the director is a dentist licensed in Maine and is certified by the American Board of Oral Pathology. [PL 1993, c. 600, Pt. B, §14 (AMD).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1973, c. 625, §116 (AMD). PL 1975, c. 218 (RPR). PL 1981, c. 66, §§2-4 (AMD). PL 1987, c. 211, §10 (AMD). PL 1993, c. 600, §B14 (AMD).

ARTICLE 7

ACCEPTANCE, COLLECTION, IDENTIFICATION AND EXAMINATION OF SPECIMENS AND REPORTS OF FINDINGS

§2030. Requested

1. Request from authorized person. 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.
[PL 1989, c. 665, §2 (NEW).]

2. Exceptions. Notwithstanding this section, a medical laboratory may examine specimens without a physician referral for a limited number of laboratory services to be determined by rules adopted by the department. Those services include testing for:

A. Glucose for patients who have been previously diagnosed as having diabetes; [PL 1989, c. 665, §2 (NEW).]

B. Pregnancy; [PL 1989, c. 665, §2 (NEW).]

C. Colon cancer; and [PL 1989, c. 665, §2 (NEW).]

D. Cholesterol. [PL 1989, c. 665, §2 (NEW).]
[PL 1993, c. 600, Pt. B, §15 (AMD).]

3. Testing without referral. This section does not require any medical laboratory to perform laboratory services without a physician referral.
[PL 1989, c. 665, §2 (NEW).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1989, c. 665, §2 (RPR). PL 1993, c. 600, §B15 (AMD).

§2031. Tests reported

The result of a test must 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 must clearly identify that medical laboratory and the director. [RR 2009, c. 2, §50 (COR).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). RR 2009, c. 2, §50 (COR).

§2031-A. Itemized billing statements

A medical laboratory that performs services under this Act shall send an itemized billing statement to the patient. [PL 2011, c. 531, §2 (NEW).]

SECTION HISTORY

PL 2011, c. 531, §2 (NEW).

§2032. Specimens

The following persons may collect or process specimens: licensed health care professionals; designees of licensed health care professionals acting within their scope of practice; and qualified medical laboratory personnel who are authorized by the director of the medical laboratory. [PL 2011, c. 531, §3 (RPR).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 2011, c. 531, §3 (RPR).

§2033. Rebates or fee splitting prohibited

The owner or director of a laboratory licensed under this Act, either personally or through an agent, may not practice in any manner that 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. [PL 2011, c. 531, §4 (AMD).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1973, c. 179 (AMD). PL 1975, c. 218 (RPR). PL 2011, c. 531, §4 (AMD).

§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. [PL 1975, c. 218 (RPR).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR).

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: [PL 1975, c. 218 (RPR).]

1. Violation of Act. Violation of any of the provisions of this Act or the rules and regulations promulgated by the department hereunder; [PL 1975, c. 218 (RPR).]

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; [PL 1975, c. 218 (RPR).]

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 [PL 1975, c. 218 (RPR).]

4. Lending name. Knowingly lending the use of the name of a licensed medical laboratory or its director to an unlicensed medical laboratory. [PL 1975, c. 218 (RPR).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR).

§2036. Hearing

Before suspension or revocation of its license, if requested, a hearing must be held to show cause why a license should not be suspended or revoked. [PL 1993, c. 600, Pt. B, §16 (AMD).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1993, c. 600, §B16 (AMD).

ARTICLE 9

OFFENSES AND PENALTIES

§2037. Offenses

It is unlawful for any person to: [PL 1975, c. 218 (RPR).]

1. Unlicensed. Operate, maintain, direct or engage in the business of operating a medical laboratory, as defined, unless the person has obtained a medical laboratory license from the department; or
[RR 2021, c. 2, Pt. B, §113 (COR).]

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.
[PL 1975, c. 218 (RPR).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1981, c. 470, §A80 (AMD). RR 2021, c. 2, Pt. B, §113 (COR).

§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. [PL 1975, c. 218 (RPR).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR).

ARTICLE 10

INJUNCTIONS

§2039. Injunction

The operation or maintenance of a medical laboratory subject to licensure or any provisions of this Act, 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, 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. [PL 1987, c. 211, §11 (AMD).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1975, c. 218 (RPR). PL 1987, c. 211, §11 (AMD).

ARTICLE 11

APPEALS

§2040. Appeal

Any person aggrieved by a decision of the department may appeal to the District Court Judge under Title 5, chapter 375. [PL 1993, c. 600, Pt. B, §17 (AMD); PL 1999, c. 547, Pt. B, §78 (AMD); PL 1999, c. 547, Pt. B, §80 (AFF).]

SECTION HISTORY

PL 1967, c. 380 (NEW). PL 1973, c. 303, §3 (AMD). PL 1975, c. 218 (RPR). PL 1981, c. 470, §A81 (AMD). PL 1993, c. 600, §B17 (AMD). PL 1999, c. 547, §B78 (AMD). PL 1999, c. 547, §B80 (AFF).

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