FIRST REGULAR SESSION

ONE HUNDRED AND THIRTEENTH LEGISLATURE

Legislative Document No. 518

S.P. 191 In Senate, February 24, 1987

Reference to the Committee on Human Resources suggested and ordered printed.

JOY J. O'BRIEN, Secretary of the Senate

Presented by Senator GILL of Cumberland.

Cosponsored by Senator BALDACCI of Penobscot, Representative MANNING of Portland, Representative PINES of Limestone.

STATE OF MAINE

IN THE YEAR OF OUR LORD
NINETEEN HUNDRED AND EIGHTY-SEVEN

AN ACT to Revise the Maine Medical Laboratory Act.

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

Sec. 1. 22 MRSA §2013, sub-§3, as amended by PL 1981, c. 470, Pt. A, §79, is further amended to read:

3. Physicians. Physicians, professional associations or group practices, excluding laboratories incorporated for the mutual use by physician or group practice owners, registered in the State who operate a medical laboratory exclusively for the examination of their own patients and only perform testing using approved procedures for urine specific gravity, semi-quantitative chemical examination of urine by

dipstick, chemical examination of blood for glucose by dipstick, pregnancy testing using commercially available kit methods, hematocrit, sedimentation rate, culture to transport media, qualitative fecal occult blood, microscopic Scotch tape test for pinworms, microscopic wet mount trichomonas and candida albicans, infectious mononucleosis, rheumatoid factor, beta-hemolytic streptococci, nonculture, screening tests using commercially available kit methods, urine microscopic or other tests acceptable to the department and the commission, otherwise only sections 2024, 2025 and 2039 apply, provided if referred work is received in the laboratory all provisions of this Act shall apply;

Sec. 2. 22 MRSA §2013, sub-§4, as repealed and replaced by PL 1975, c. 218, is amended to read:

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 and only perform testing using approved procedures for urine specific gravity, semi-quantitative chemical examination of urine by dipstick, chemical examination of blood for glucose by dipstick, pregnancy testing using commercially available kit methods, hematocrit, sedimentation rate, culture to transport media, qualitative fecal occult blood, microscopic Scotch tape test for pinworms, microscopic wet mount for trichmonoas and candida albicans, infectious mononucleosis, rheumatoid factor, beta-hemolytic streptococci, nonculture, screening tests using commercially available kit methods, urine microscopic or other tests acceptable to the department and the commission, otherwise only sections 2024, 2025 and 2039 apply;

Sec. 3. 22 MRSA §2014, sub-§4, as repealed and replaced by PL 1975, c. 218, is amended to read:

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.

Sec. 4. 22 MRSA §2016, first paragraph, as repealed and replaced by PL 1975, c. 218, is amended to read:

Application shall be made on a form prescribed by the department. Licenses shall be issued to perform testing in one or more of the following categories or specialties: Histocompatability; 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 shall be accompanied by a license application fee of ~~$100~~ $200 for the first category and $60 for each additional category. The fee for adding categories after initial licensure shall be $20 each year or fraction thereof of the unexpired term of the license. The application shall be notarized and shall contain the following information:

Sec. 5. 22 MRSA §2017, first paragraph, as repealed and replaced by PL 1975, c. 218, is amended to read:

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~~ $200 for the first category and $60 for each additional category.

Sec. 6. 22 MRSA §2023, sub-§1, as repealed and replaced by PL 1975, c. 218, is amended to read:

1. Qualifications of directors and technical personnel. The qualifications of directors and technical personnel of medical laboratories;

Sec. 7. 22 MRSA §2024, as repealed and replaced by PL 1975, c. 218, is amended to read:

§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.

Sec. 8. 22 MRSA §2025, as repealed and replaced by PL 1975, c. 218, is repealed and replaced and the following enacted in its place:

§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 and the commission covering all categories or subcategories in which testing is offered. Evaluated copies of results shall be forwarded to the department.

Sec. 9. 22 MRSA §2029, last paragraph, as repealed and replaced by PL 1975, c. 218, is amended to read:

No medical laboratory ~~shall~~ may 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 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.

Sec. 10. 22 MRSA 2039, as repealed and replaced by PL 1975, c. 218, is amended to read:

§2039. Injunction

The operation or maintenance of ~~an unlicensed~~ 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 ~~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.

STATEMENT OF FACT

Over the years, weaknesses have surfaced in the Maine Medical Laboratory Act which allow substandard testing to be performed in currently unregulated laboratories. Not only is substandard testing of little diagnostic value, but also taxpayers are paying for these tests through Medicare and Medicaid reimbursement programs.

By redefining the exemptions allowed by this Act, limiting tests unregulated laboratories can perform to those which are inherently reliable and requiring all other medical laboratories to demonstrate proficiency in the testing they do, this bill will provide for the improved quality of clinical testing in this State.

Further, the licensing fees used to offset the cost of administering this Act are unrealistically low and will be adjusted to more accurately reflect this cost.

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