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Submitted by the Department of Human Services pursuant to Joint Rule 24. Reference to the Committee on Human Resources suggested and ordered printed.

EDWIN H. PERT, Clerk

Presented by Representative PENDLETON of Scarborough.
Cosponsored by Senator GILL of Cumberland, Senator BERUBE of Androscoggin and Representative BURKE of Vassalboro.

STATE OF MAINE

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

An Act to Regulate Maternal Serum Alpha-fetoprotein Screening Programs.

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

Sec. 1. 22 MRSA §2013, as amended by PL 1987, c. 211, §§1 and 2, is repealed.

Sec. 2. 22 MRSA §2013-A is enacted to read:

§2013-A. Applicability

In general, this Act applies to all medical laboratories and directors of medical laboratories operating in the State.

1. **Exemptions.** Subject to the limitations set forth in subsection 2, 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;

B. Laboratory facilities and laboratory services operated in a hospital licensed by the State;

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 and the commission, 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 shall be subject to all provisions of this Act;

D. 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 which perform only tests acceptable to the department and the commission; otherwise, only sections 2024, 2025 and 2039 apply;

E. 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; and

F. The practice of radiology by a radiologist.

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.

Sec. 2. 22 MRSA §2023, sub-§§3 and 4, as repealed and replaced by PL 1975, c. 218, are amended to read:

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~~ ensure 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~~.~~ ; and

Sec. 3. 22 MRSA §2023, sub-§5 is enacted to read:

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.

STATEMENT OF FACT

Maternal serum alpha-fetoprotein testing is a sensitive screening technique capable of detecting most open neural tube defects, such as open spine and anencephaly, and other open fetal defects. Until recently, this test was offered in the research environment and has been utilized by about 2/3 of the mothers of the State's 17,000 annual live births. This test requires exceptional care in its performance and interpretation and the presence of superior and timely counseling and follow-up

testing services to assure that screening results are interpreted properly.

Recently, the United States Food and Drug Administration has licensed test kits for maternal serum alpha-fetoprotein testing, and firms have begun marketing these kits to many laboratories. In order to assure that all tests results are reliable, that no detectable defects are missed and no fetus falsely diagnosed as affected, it is essential that this testing be performed in laboratories handling a large volume of testing for maternal serum alpha-fetoprotein, utilizing extensive quality control measures and affiliated with adequate counseling and follow-up testing services.

This bill establishes that any laboratory or laboratory director involved in maternal serum alpha-fetoprotein testing is subject to all provisions of this Act and clarifies the confusing wording of the subsection concerning physician exemptions. The bill also authorizes the Department of Human Services to promulgate rules relating to the conduct of maternal serum alpha-fetoprotein testing.