

MAINE STATE LEGISLATURE

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114th MAINE LEGISLATURE

FIRST REGULAR SESSION - 1989

Legislative Document

No. 413

H.P. 301

House of Representatives, February 23, 1989

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

Ed Pert

EDWIN H. PERT, Clerk

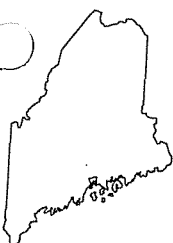
Presented by Representative PENDLETON of Scarborough.

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.**



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

3 Sec. 1. 22 MRSA §2013, as amended by PL 1987, c. 211, §§1 and
5 2, is repealed.

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

9 §2013-A. Applicability

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

13 1. Exemptions. Subject to the limitations set forth in
14 subsection 2, the following entities are exempted from the
15 provisions of this Act under the following circumstances:

17 A. Medical laboratories operated by the United States
18 Government, the State or municipalities of the State;

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

23 C. Physicians and medical staff pursuant to this paragraph:

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

31 (2) Physicians, physician assistants, family nurse
32 practitioners, Medicare-certified rural health clinics,
33 professional associations or group practices performing
34 tests, other than those listed in subparagraph (1),
35 exclusively for the examination of their own patients
36 are subject only to sections 2024, 2025 and 2039.

37 Notwithstanding subparagraphs (1) and (2), laboratories
38 incorporated for the mutual use of physician or group
39 practice owners shall be subject to all provisions of this
40 Act;

41 D. Medical laboratories in a school, college, university or
42 industrial plant which are under the direct supervision of,
43 and which services are used exclusively by, a duly licensed
44 physician and which perform only tests acceptable to the
45 department and the commission; otherwise, only sections
46 2024, 2025 and 2039 apply;

1 E. Laboratories operated and maintained for research and
3 teaching purposes which are recognized by the department
5 after consultation with the commission or involve no patient
7 or public health service; and

9 F. The practice of radiology by a radiologist.

11 2. Maternal serum alpha-fetoprotein testing.
13 Notwithstanding subsection 1, all medical laboratories and
15 directors of medical laboratories shall be subject to all
17 provisions of this Act, and rules promulgated under it, which
19 govern the performance of maternal serum alpha-fetoprotein
21 testing.

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

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

35 4. Equipment. Equipment essential in the opinion of the
37 department and the commission to proper conduct and operation of
39 a medical laboratory; and

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

43 5. Standards of performance. Standards of performance
45 essential to the achievement of accurate, reliable results and
47 the protection of public health, including standards for maternal
49 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

1 testing services to assure that screening results are interpreted
properly.

3

5 Recently, the United States Food and Drug Administration has
licensed test kits for maternal serum alpha-fetoprotein testing,
7 and firms have begun marketing these kits to many laboratories.
In order to assure that all tests results are reliable, that no
9 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
11 serum alpha-fetoprotein, utilizing extensive quality control
measures and affiliated with adequate counseling and follow-up
13 testing services.

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