WEST VIRGINIA LEGISLATURE
REGULAR SESSION, 1989

ENROLLED
Com. Sub. for
HOUSE BILL No. 2253
(By DeL Petrolo Mezzatesta)

Passed April 8, 1989
In Effect Ninety Days from Passage
ENROLLED
COMMITTEE SUBSTITUTE
FOR
H. B. 2253
(BY DELEGATES PITROLO AND MEZZATESTA)

[Passed April 8, 1989; in effect ninety days from passage.]

AN ACT to amend chapter sixteen of the code of West Virginia, one thousand nine hundred thirty-one, as amended, by adding thereto a new article, designated article five-j, relating to public health: regulation and licensing of clinical laboratories and laboratory technicians and technologists; providing legislative findings; defining phrase "clinical laboratory"; requiring state health director to promulgate rules; providing for certain exemptions; enumerating powers and duties of such director with respect to licensure and inspection; creating an advisory board and providing for appointment, membership and terms of office; providing for hearings and appeals from director's decisions; creating misdemeanor offense relating to certain solicitation, receipt, delivery or transmission of human material for or to unlicensed laboratories; exceptions thereto; providing a severability clause; providing for licensure and certification of laboratory technicians and technologists and rules and regulations pertaining thereto; exempting technicians and technologists so employed on effective date of act from such requirements; and providing that certain technicians and technologists shall be deemed certified.
Be it enacted by the Legislature of West Virginia:

That chapter sixteen of the code of West Virginia, one thousand nine hundred thirty-one, as amended, be amended by adding thereto a new article, designated article five-j, to read as follows:

ARTICLE 5J. CLINICAL LABORATORIES QUALITY ASSURANCE ACT.

§16-5J-1. Legislative findings.

The Legislature finds that the diagnosis and treatment of human affliction is or may be largely determined by the results of laboratory testing and that inaccurate laboratory test results endanger the health and lives of the citizens of West Virginia. A due respect for the citizenry of the state requires that all such testing be done under the supervision of qualified and competent persons having sufficient expertise and experience to assure the quality and accuracy of clinical laboratory testing. Further, it is imperative that laboratories be regulated and licensed to ensure that the intent of this article be met.

§16-5J-2. Definition.

The term “clinical laboratory” means any facility or place, however named, for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, crytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings.

§16-5J-3. Rules; recognized external standards.

The director of the department of health shall promulgate, pursuant to chapter twenty-nine-a of this code, rules required to implement this article, and such rules shall specifically address, among other things, training, education and experience requirements. The standards to be adopted by the department of health shall be equal to or higher than such standards currently applicable and as established by the college of
American pathologists, the center for disease control, American Osteopathic Board of Pathology, American Osteopathic Hospital Association, the medicare program or the joint commission for the accreditation of hospitals: Provided, That any laboratory in this state accredited by or certified by one of these organizations or the medicare program shall be exempt from the requirements of licensure with no further inquiry by the department of health, and any such accredited or certified laboratory shall be exempt from the provisions of this article as long as such laboratories remain so accredited or certified: Provided, however, That all laboratories shall have five years from the effective date of this article to come into compliance.


In addition to promulgating rules specified in section three of this article, the director of the department of health, with the advice of the advisory board created in section five of this article, has the power to:

(a) Adopt rules for clinical laboratory licensure;

(b) Establish rules for continued evaluation of laboratory testing, such rules and evaluations being at least equivalent to the appropriate section of the “Clinical Laboratory Improvement Act of 1967”;

(c) Institute and administer a program of inspection to ensure compliance with standards established in this article and rules established pursuant to this article;

(d) Issue a license to those clinical laboratories which meet requirements for licensure under this article;

(e) Set a reasonable fee for application and licensure;

(f) Withhold, revoke or suspend or restrict the license of any clinical laboratory which fails to meet requirements for licensure or relicensure.

The cost of the initial inspection of any new laboratory constructed after July 1, 1990, shall be the responsibility of the prospective licensee.

Within the limit of available funds, the department of
23 health shall inspect clinical laboratories on a periodic
24 basis to ensure compliance with standards and
regulations.

§16-5J-5. Advisory board.
1 There is hereby created an advisory board which shall
2 be composed of the following persons:
3 (a) Two board certified pathologists licensed and
4 currently practicing in this state;
5 (b) A board certified physician or doctor of osteo-
6 pathy, licensed and currently practicing in this state in
7 a specialty other than pathology;
8 (c) Two clinical laboratory practitioners who hold
9 professional certification from an agency acceptable to
10 the department of health. These two must have had a
11 minimum of three years experience in a clinical
12 laboratory setting during the five years preceding
13 appointment. One of the two must hold a minimum of
14 a baccalaureate degree;
15 (d) One lay person to represent the interests of the
16 people of this state.
17 The advisory board shall be appointed by the gover-
18 nor, with the advice and consent of the Senate.
19 Appointments of professional members shall be made
20 from lists of candidates submitted from among their
21 peers. These lists may be solicited from the West
22 Virginia association of pathology, the West Virginia
23 state society for medical technology, the West Virginia
24 state medical association, the West Virginia society of
25 state American medical technologists and other similar
26 professional organizations. The lists submitted shall
27 contain at least one name in excess of the number of
28 appointments to be made. Appointments shall be for a
29 term of three years beginning the first day of July of
30 the year of appointment, except for the first board
31 appointed, whose terms shall be as follows:
32 (a) The pathologists and one baccalaureate clinical
33 practitioner shall serve a one-year term;
34 (b) The nonpathologist physician or doctor of osteo-
pathy, and the other clinical practitioner shall serve for  
a two-year term;  
(c) The lay person shall serve for a three-year term.  
Successors to those first board members will serve
three-year terms. Board members may succeed them-

selves once, but may not serve for a total period in excess
of six years. In the event of a vacancy on the advisory
board the governor shall appoint a successor in the same
manner as the original appointment was made. The
successor will serve for the unexpired term and may be
eligible for reappointment: Provided, That any member
shall serve until such time as his or her successor is
appointed.

§16-5J-6. Hearing and judicial review.

If a license is withheld, suspended or revoked, the
laboratory is entitled to a hearing before representatives
of the department of health within sixty days of the
withholding, suspension or revocation decision. Such
laboratory may be represented at the hearing by counsel
and may present evidence in its defense. The final order
of the director will be based on a record of the hearing
and shall contain findings of fact and conclusions of law.
The laboratory may appeal an adverse order to the
circuit court of Kanawha County or the circuit court of
the county in which the laboratory is located to
determine whether the director abused his discretion or
exceeded his jurisdiction. The department of health has
the power to obtain an injunction during the time
preceding the hearing against any laboratory which
fails to meet licensure requirements and whose con-
tinued operation poses a significant threat to the public
health.


This article does not include or apply to any labora-
tory or laboratories maintained and operated by the
federal government or to any laboratory or laboratories
maintained and operated purely for research or teach-
ing purposes nor to any laboratory operated by a
primary health care center having tax exempt status
and receiving contributions which are deductible to the
contributor under provisions of federal law. All county
health departments shall be exempt from this article.

§16-5J-8. Unlawful conduct; penalties.

It is a misdemeanor for any person to solicit, receive,
accept, deliver or transmit, by mail or otherwise,
material originating from the human body on behalf of
any person operating a laboratory not in possession of
a license under this article regardless of whether such
laboratory is located in this state and, upon conviction
thereof, such person shall be fined not less than five
hundred dollars. The provisions of this section do not
apply to transactions with any person operating a
laboratory located in another state, which laboratory has
been issued a license or permit in conformity with the
"Clinical Laboratories Improvement Act of 1967," and
related statutes. Neither does this section apply to
transactions with laboratories operated in this state
which are exempt from the license requirements of this
article.

§16-5J-9. Interpretation of article; severability.

The provisions of this article are severable and if any
of its provisions shall be held unconstitutional, the
decision of the court shall not affect or impair any of
the remaining provisions of this article. It is hereby
declared to be the legislative intent that this article
would have been adopted had such unconstitutional
provisions not been included herein.

§16-5J-10. Licensure of technicians; fee; rules and
regulations.

(a) The director of the department of health shall
promulgate rules and regulations for the licensure and
certification of lab technicians and lab technologists. All
such persons being so employed on the effective date of
this article shall be automatically certified and exempt
from this requirement: Provided, That any technologist
and technician who is certified by the American medical
technologists or the American society of clinical
pathologists or the national certification agency for
medical laboratory personnel or any federal certification program shall be considered certified.

(b) All laboratory technicians or technologists shall pay an annual license fee of $25.00 to the director of the department of health to cover the costs of licensure.

(c) All rules and regulations required under this section or other provisions of this article may not be filed as emergency rules until after the set of rules is approved by the Legislature.

(d) All fees and interest earned or collected by the department under this article shall be used to pay for the implementation of this article.
The Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

Chairman Senate Committee

Chairman House Committee

Originating in the House.

Takes effect ninety days from passage.

Clerk of the Senate

Clerk of the House of Delegates

President of the Senate

Speaker of the House of Delegates

The within is approved this the 27th day of April, 1989.

Governor