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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

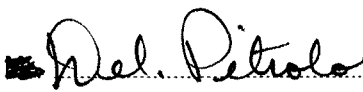
WEST VIRGINIA LEGISLATURE

REGULAR SESSION, 1989

— ● —

ENROLLED

Com. Sub. for
HOUSE BILL No. 2253

(By  Del. Petrola + 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.

1 The Legislature finds that the diagnosis and treat-
2 ment of human affliction is or may be largely deter-
3 mined by the results of laboratory testing and that
4 inaccurate laboratory test results endanger the health
5 and lives of the citizens of West Virginia. A due respect
6 for the citizenry of the state requires that all such
7 testing be done under the supervision of qualified and
8 competent persons having sufficient expertise and
9 experience to assure the quality and accuracy of clinical
10 laboratory testing. Further, it is imperative that
11 laboratories be regulated and licensed to ensure that the
12 intent of this article be met.

§16-5J-2. Definition.

1 The term "clinical laboratory" means any facility or
2 place, however named, for the biological, microbiolog-
3 ical, serological, chemical, immuno-hematological,
4 hematological, biophysical, cytological, pathological, or
5 other examination of materials derived from the human
6 body for the purpose of providing information for the
7 diagnosis, prevention or treatment of any disease or
8 impairment of, or the assessment of the health of human
9 beings.

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

1 The director of the department of health shall
2 promulgate, pursuant to chapter twenty-nine-a of this
3 code, rules required to implement this article, and such
4 rules shall specifically address, among other things,
5 training, education and experience requirements. The
6 standards to be adopted by the department of health
7 shall be equal to or higher than such standards
8 currently applicable and as established by the college of

9 American pathologists, the center for disease control,
 10 American Osteopathic Board of Pathology, American
 11 Osteopathic Hospital Association, the medicare program
 12 or the joint commission for the accreditation of hospitals:
 13 *Provided*, That any laboratory in this state accredited
 14 by or certified by one of these organizations or the
 15 medicare program shall be exempt from the require-
 16 ments of licensure with no further inquiry by the
 17 department of health, and any such accredited or
 18 certified laboratory shall be exempt from the provisions
 19 of this article as long as such laboratories remain so
 20 accredited or certified: *Provided, however*, That all
 21 laboratories shall have five years from the effective date
 22 of this article to come into compliance.

§16-5J-4. Powers and duties.

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

5 (a) Adopt rules for clinical laboratory licensure;

6 (b) Establish rules for continued evaluation of labor-
 7 atory testing, such rules and evaluations being at least
 8 equivalent to the appropriate section of the "Clinical
 9 Laboratory Improvement Act of 1967";

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

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

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

16 (f) Withhold, revoke or suspend or restrict the license
 17 of any clinical laboratory which fails to meet require-
 18 ments for licensure or relicensure.

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

22 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-

35 pathy, and the other clinical practitioner shall serve for
36 a two-year term;

37 (c) The lay person shall serve for a three-year term.

38 Successors to those first board members will serve
39 three-year terms. Board members may succeed them-
40 selves once, but may not serve for a total period in excess
41 of six years. In the event of a vacancy on the advisory
42 board the governor shall appoint a successor in the same
43 manner as the original appointment was made. The
44 successor will serve for the unexpired term and may be
45 eligible for reappointment: *Provided*, That any member
46 shall serve until such time as his or her successor is
appointed.

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

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

§16-5J-7. Exemptions.

1 This article does not include or apply to any labora-
2 tory or laboratories maintained and operated by the
3 federal government or to any laboratory or laboratories
4 maintained and operated purely for research or teach-
5 ing purposes nor to any laboratory operated by a
6 primary health care center having tax exempt status

7 and receiving contributions which are deductible to the
8 contributor under provisions of federal law. All county
9 health departments shall be exempt from this article.

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

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

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

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

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

1 (a) The director of the department of health shall
2 promulgate rules and regulations for the licensure and
3 certification of lab technicians and lab technologists. All
4 such persons being so employed on the effective date of
5 this article shall be automatically certified and exempt
6 from this requirement: *Provided*, That any technologist
7 and technician who is certified by the American medical
8 technologists or the American society of clinical
9 pathologists or the national certification agency for

10 medical laboratory personnel or any federal certification
11 program shall be considered certified.

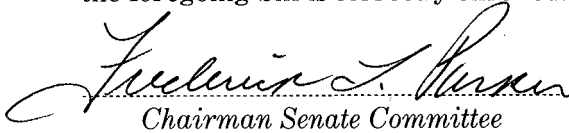
12 (b) All laboratory technicians or technologists shall
13 pay an annual license fee of \$25.00 to the director of the
14 department of health to cover the costs of licensure.

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

19 (d) All fees and interest earned or collected by the
20 department under this article shall be used to pay for
21 the implementation of this article.

Enr. Com. Sub. for H. B. 2253] 8

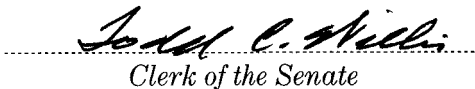
The Joint Committee on Enrolled Bills hereby certifies that
the foregoing bill is correctly enrolled.

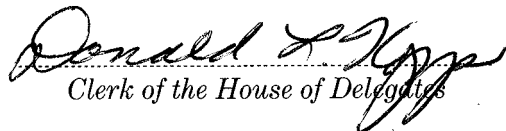

Chairman Senate Committee

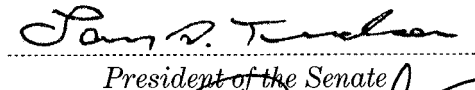

Chairman House Committee

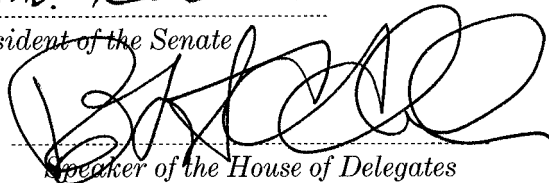
Originating in the House.

Takes effect ninety days from passage.

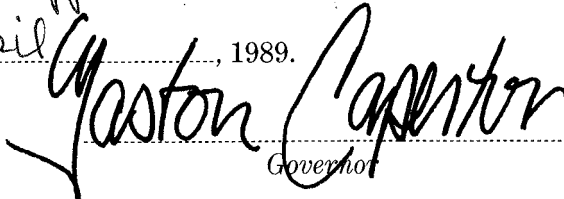

Clerk of the Senate


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

PRESENTED TO THE

GOVERNOR

Date 4/21/89

Time 2:35 *HC*