WEST VIRGINIA CODE CHAPTER 16 ARTICLE 5J

WV Legislature

§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.

WV Legislature

§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.

WV Legislature

§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.

WV Legislature

§16-5J-4. Powers and duties.

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 health shall inspect clinical laboratories on a periodic basis to ensure compliance with standards and regulations.

WV Legislature

§16-5J-5.

Repealed.

Acts, 2015 Reg. Sess., Ch. 53.

WV Legislature

§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 continued operation poses a significant threat to the public health.

WV Legislature

§16-5J-7. Exemptions.

This article does not include or apply to any laboratory or laboratories maintained and operated by the federal government or to any laboratory or laboratories maintained and operated purely for research or teaching 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.

WV Legislature

§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 $500. 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.

WV Legislature

§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.

WV Legislature

§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 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.

WV Legislature