
#In the Greater Appalachia Assembly

September, 2021

#Haze Act

This is an act to get rid of the Haze surrounding regulations on Medicinal Marijuana

Whereas, Regulations are needed to ensure the best standards

THEREFORE, BE IT ENACTED by the General Assembly of the Commonwealth of Greater Appalachia that:

****Section 1. Title****

(A) This bill shall be referred to as the "Haze Act"

****Section 2. Provisions****

(a) No person shall operate a pharmaceutical processor or a cannabis dispensing facility without first obtaining a permit from the Board. The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmaceutical processor's dispensing area or cannabis dispensing facility. The Board shall establish an application fee and other general requirements for such application.

(b) Each permit shall expire annually on a date determined by the Board in regulation. The number of permits that the Board may issue or renew in any year is limited to one pharmaceutical processor and up to ten cannabis dispensing facilities for each health service area established by the Board of Health. Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor and cannabis dispensing facility.

(c) The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors and cannabis dispensing facilities. Such regulations shall include requirements for:

- (1) physical standards;
- (2) location restrictions;
- (3) security systems and controls;
- (4) minimum equipment and resources;
- (5) recordkeeping;
- (6) labeling, including the potency of each botanical cannabis product and the amounts recommended by the practitioner or dispensing pharmacist, and packaging;
- (7) routine inspections no more frequently than once annually;
- (8) processes for safely and securely dispensing and delivering in person cannabis products to a registered patient, their registered agent, or, if such patient is a minor or an incapacitated adult, such patient's parent or legal guardian;
- (9) dosage limitations for cannabis that provide that each dispensed dose of cannabis shall not exceed 50 milligrams of delta-9-tetrahydrocannabinol;
- (10) a process for the wholesale distribution of and the transfer of usable cannabis, botanical cannabis, cannabis oil, and cannabis products between pharmaceutical processors, between a pharmaceutical processor and a cannabis dispensing facility, and between cannabis dispensing facilities;
- (11) an allowance for the sale of devices for administration of dispensed cannabis products and hemp-based CBD products that meet the applicable standards set forth in state and federal law, including the laboratory testing standards set forth in subsection m;
- (12) an allowance for the use and distribution of inert product samples containing no cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility, and not for further distribution or sale, without the need for a written certification;
- (13) a process for acquiring extracts from industrial hemp extract and formulating such hemp extract with Cannabis plant extract into allowable doses of cannabis; and

(14) an allowance for the advertising and promotion of the pharmaceutical processor's products and operations, which shall not limit the pharmaceutical processor from the provision of educational material to practitioners who issue written certifications and registered patients.

(c1) The Board shall also adopt regulations for pharmaceutical processors that include requirements for:

(1) processes for safely and securely cultivating Cannabis plants intended for producing cannabis products,

(2) the secure disposal of agricultural waste, and

(3) a process for registering cannabis products.

(d) The Board shall require that, after processing and before dispensing any cannabis products, a pharmaceutical processor shall make a sample available from each batch of cannabis product for testing by an independent laboratory located in Greater Appalachia meeting Board requirements. A valid sample size for testing shall be determined by each laboratory and may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing or distribution from each homogenized batch of cannabis is required to achieve a representative cannabis sample for analysis. A minimum sample size, to be determined by the certified testing laboratory, from each batch of botanical cannabis is required to achieve a representative botanical cannabis sample for analysis. Botanical cannabis products shall only be tested for the following: total cannabidiol (CBD); total tetrahydrocannabinol (THC); terpenes; pesticide chemical residue; heavy metals; mycotoxins; moisture; and microbiological contaminants. Testing thresholds shall be consistent with generally accepted cannabis industry thresholds. The pharmaceutical processor may remediate cannabis that fails any quality testing standard. Following remediation, all remediated cannabis shall be subject to laboratory testing and approved upon satisfaction of testing standards applied to cannabis generally. If the batch fails retesting, it shall be considered usable cannabis and may be processed into cannabis oil, unless the failure is related to pesticide requirements, in which case the batch shall not be considered usable cannabis and shall not be processed into cannabis oil. Stability testing shall not be required for any cannabis oil product with an expiration date assigned by the pharmaceutical processor of six months or less from the date of packaging.

(e) A laboratory testing samples for a pharmaceutical processor shall obtain a controlled substances registration certificate and shall comply with quality standards established by the Board in regulation.

(f) Every pharmaceutical processor's dispensing area or cannabis dispensing facility shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor or cannabis dispensing facility. The pharmaceutical processor shall ensure that security measures are adequate to protect the cannabis from diversion at all times, and the pharmacist-in-charge shall have concurrent responsibility for preventing diversion from the dispensing area.

(1) Every pharmaceutical processor shall designate a person who shall have oversight of the cultivation and production areas of the pharmaceutical processor and shall provide such information to the Board. The Board shall direct all communications related to enforcement of requirements related to cultivation and production of cannabis products by the pharmaceutical processor to such designated person.

(g) The Board shall require the material owners of an applicant for a pharmaceutical processor or cannabis dispensing facility permit to submit to fingerprinting and provide personal descriptive information to be forwarded along with their fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information regarding the applicant's material owners. The cost of fingerprinting and the criminal history record search shall be paid by the applicant. The Central Criminal Records Exchange shall forward the results of the criminal history background check to the Board or its designee, which shall be a governmental entity. A pharmaceutical processor shall maintain evidence of criminal background checks for all employees and delivery agents of the pharmaceutical processor. Criminal background checks of employees and delivery agents may be conducted by any service sufficient to disclose any federal and state criminal convictions.

(h) In addition to other employees authorized by the Board, a pharmaceutical processor may employ individuals who may have less than two years of experience:

(1) to perform cultivation-related duties under the supervision of an individual who has received a degree in a field related to the cultivation of plants or a certification recognized by the Board or who has at least two years of experience cultivating plants,

(2) to perform extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants, and

(3) to perform duties at the pharmaceutical processor and cannabis dispensing facility upon certification as a pharmacy technician.

(i) A pharmaceutical processor to whom a permit has been issued by the Board may establish up to ten cannabis dispensing facilities for the dispensing of cannabis products that have been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board. Each cannabis dispensing facility shall be located within the same health service area as the pharmaceutical processor.

(j) No person who has been convicted of a felony under the laws of Greater Appalachia or another jurisdiction within the last five years shall be employed by or act as an agent of a pharmaceutical processor or cannabis dispensing facility.

(k) Every pharmaceutical processor or cannabis dispensing facility shall adopt policies for pre-employment drug screening and regular, ongoing, random drug screening of employees.

(l) A pharmacist at the pharmaceutical processor's dispensing area and the cannabis dispensing facility shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees who can be safely and competently supervised at one time; however, no pharmacist shall supervise more than six persons performing the duties of a pharmacy technician at one time in the pharmaceutical processor's dispensing area or cannabis dispensing facility.

(m) A pharmaceutical processor may acquire industrial hemp extract processed in Greater Appalachia, and in compliance with state or federal law, from a registered industrial hemp dealer or processor. A pharmaceutical processor may process and formulate such extract with cannabis plant extract into an allowable dosage of cannabis oil. Industrial hemp extract acquired by a pharmaceutical processor is subject to the same third-party testing requirements that may apply to cannabis plant extract. Testing shall be performed by a laboratory located in Greater Appalachia and in compliance with state law. The industrial hemp dealer or processor shall provide such third-party testing results to the pharmaceutical processor before industrial hemp extract may be acquired.

(n) The provisions of the public participation guidelines adopted pursuant thereto shall apply to the adoption of any regulation pursuant to this section. Prior to adopting any regulation pursuant to this section, the Board of Pharmacy shall publish a notice of opportunity to comment in the Greater Appalachia Register of Regulations and post the action on the Greater Appalachia Regulatory Town Hall. Such notice of opportunity to comment shall contain:

(1) a summary of the proposed regulation;

(2) the text of the proposed regulation; and

(3) the name, address, and telephone number of the agency contact person responsible for receiving public comments. Such notice shall be made at least 60 days in advance of the last date prescribed in such notice for submittals of public comment. The Board of Pharmacy shall consider and keep on file all public comments received for any regulation adopted pursuant to this section.

(o) The Board shall register all cannabis products that meet testing, labeling, and packaging standards.

****Section 3. Enactment****

(A) This act shall go into effect immediately after it is signed into law.

(B) If any portion of this act is struck down, the rest of the act shall still be in effect.

This piece of legislation was authored by /u/KushGator (D)