



**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED
BY THE WEST VIRGINIA LEGISLATURE**

AGENCY: Health TITLE-SERIES: 64-109

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: medical cannabis program-general provisions

CITE STATUTORY AUTHORITY: 16A-3-1(b)

The above rule has been authorized by the West Virginia Legislature.

Authorization is cited in (house or senate bill number) SB 339

Section 64-5-1(g) Passed On 3/5/2020 12:00:00 AM

This rule is filed with the Secretary of State. This rule becomes effective on the following date:

April 21, 2020

This rule shall terminate and have no further force or effect from the following date:

April 21, 2025

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

April L Robertson -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

**TITLE 64
LEGISLATIVE RULE
BUREAU FOR PUBLIC HEALTH**

**SERIES 109
MEDICAL CANNABIS PROGRAM – GENERAL PROVISIONS**

§64-109-1. General.

1.1. Scope. The provisions of these rules include general provisions related to the permitting of medical cannabis organizations pursuant to the West Virginia Medical Cannabis Act (W. Va. Code §16A-1-1 *et seq.*)

1.2. Authority. W. Va. Code §16A-3-1(b).

1.3. Filing Date. April 21, 2020.

1.4. Effective Date. April 21, 2020.

1.5. Sunset Provision. These rules shall terminate and have no further force or effect on April 21, 2025.

1.6. Applicability. These rules apply to a person or entity that desires to hold a permit as a medical cannabis organization in this state.

§64-109-2. Definitions.

2.1. "Act" means the West Virginia Medical Cannabis Act (W. Va. Code §16A-1-1 *et seq.*)

2.2. "Adverse event" means an injury resulting from the use of medical cannabis dispensed at a dispensary. An injury includes physical harm, mental harm, or loss of function.

2.3. "Adverse loss" means a loss, discrepancy in inventory, diversion or theft of seeds, immature medical cannabis plants, medical cannabis plants, medical cannabis, funds, or other property of a medical cannabis organization.

2.4. "Advertising" means the publication, dissemination, solicitation, or circulation, for a fee, that is visual, oral, written, or electronic to induce directly or indirectly an individual to patronize a particular dispensary or to purchase particular medical cannabis.

2.5. "Applicant" means a person who wishes to submit or submits an application to the bureau for a permit to operate as a grower/processor or dispensary, or both, under the Act and these rules.

2.6. "Bureau" means the West Virginia Bureau for Public Health within the West Virginia Department of Health and Human Resources.

2.7. "Cannabis" means all parts of the plant of the genus cannabis whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or its resin, including cannabis concentrate.

"Cannabis" does not include industrial hemp, nor does it include fiber produced from the stalks, oil, or cake made from the seeds of the plant, sterilized seed of the plant which is incapable of germination, or the weight of any other ingredient combined with cannabis to prepare topical or oral administrations, food, drink, or other product.

2.8. "CBD" means Cannabidiol.

2.9. "Caregiver" means an individual designated by a patient or, if the patient is under 18 years of age, an individual authorized under W. Va. Code §16A-5-1 *et seq.* to deliver medical cannabis.

2.10. "Certified medical use" means the acquisition, possession, use, or transportation of medical cannabis by a patient, or the acquisition, possession, delivery, transportation, or administration of medical cannabis by a caregiver, for use as part of the treatment of the patient's serious medical condition, as authorized in a patient certification issued under the Act, including enabling the patient to tolerate treatment for the serious medical condition.

2.11. "Change in control" means the acquisition by a person or group of persons acting in concert of a controlling interest in an applicant or permittee either all at one time or over the span of a 12-consecutive-month period.

2.12. "Change in ownership" means the addition or removal of a principal, operator, or financial backer, or a change in control of a medical cannabis organization after the bureau approves an initial permit application or a permit renewal application.

2.13. "Clinical Registrant" means an entity that:

2.13.a. Holds a permit as both a grower/processor and a dispensary; and

2.13.b. Has a contractual relationship with an academic clinical research center under which the academic clinical research center or its affiliate provides advice to the entity, regarding, among other areas, patient health and safety, medical applications and dispensing, and management of controlled substances.

2.14. "Controlled substance" means a drug, substance, or immediate precursor included in Schedules I through V of the West Virginia Uniform Controlled Substance Act (W. Va. Code §60A-2-1 *et seq.*).

2.15. "Controlling interest" means:

2.15.a. For a publicly traded company, voting rights that entitle a person to elect or appoint one or more of the members of the board of directors or other governing board, or the ownership or beneficial holding of five percent or more of the securities of the publicly traded company; or

2.15.b. For a privately held entity, the ownership of any security in the entity.

2.16. "Dispensary" means:

2.16.a. A person who holds a permit issued by the bureau to dispense medical cannabis.

2.16.b. The term does not include a health care medical cannabis organization as defined by W. Va. Code §16A-13-1 *et seq.*

2.17. "Electronic tracking system" means an electronic seed-to-sale system prescribed by the bureau that is implemented by:

2.17.a. A grower/processor to log, verify, and monitor the receipt, use and sale of seeds, immature medical cannabis plants, or medical cannabis plants, the funds received by a grower/processor for the sale of medical cannabis to another medical cannabis organization, the disposal of medical cannabis waste, and the recall of defective medical cannabis;

2.17.b. A dispensary to log, verify, and monitor the receipt of medical cannabis product from a grower/processor, the verification of the validity of an identification card presented by a patient or caregiver, the dispensing of medical cannabis product to a patient or caregiver, the disposal of medical cannabis waste, and the recall of defective medical cannabis; and

2.17.c. An approved laboratory to log, verify, and monitor the receipt of samples and test samples for testing, the results of tests performed by the approved laboratory, and the disposal of tested and untested samples.

2.18. "Employee" means an individual who is hired for a wage, salary, fee, or payment to perform work for an applicant or permittee.

2.19. "Excipients" means solvents, chemicals, or materials reported by a medical cannabis organization and approved by the bureau for use in the processing of medical cannabis.

2.20. "Facility" means a structure and other appurtenances or improvements where a medical cannabis organization grows and processes or dispenses medical cannabis.

2.21. "Family or household member" has the same meaning as it does in W. Va. Code §48-27-204.

2.22. "Financial backer" means an investor, mortgagee, bondholder, note holder, or other source of equity, capital, or other assets other than a financial institution.

2.23. "Financial institution" means:

2.23.a. Any bank or savings association;

2.23.b. A person who is an institution-affiliated party, as that term is defined in the Federal Deposit Insurance Act, 12 U.S.C. § 1813(u);

2.23.c. Any federal credit union or state-chartered credit union, including an institution-affiliated party of a credit union; and

2.23.d. Any benefit association, insurance company, safe deposit company, money-market mutual fund, or similar entity authorized to do business in this state.

2.24. "Form of medical cannabis" means the characteristics of the medical cannabis recommended or limited for a particular patient, including the method of consumption and any particular dosage, strain, variety, and quantity or percentage of medical cannabis, or particular active ingredient.

2.25. "Fund" means the Medical Cannabis Program Fund established in W. Va. Code §16A-9-2.

2.26. "Grower/processor" means:

2.26.a. A person who holds a permit from the bureau under the Act to grow or process medical cannabis.

2.26.b. The term does not include a health care medical cannabis organization as defined under W. Va. Code §16A-13-1 *et seq.*

2.27. "Health care medical cannabis organization" means a vertically integrated health system approved by the bureau to dispense medical cannabis or grow and process medical cannabis, or both, in accordance with a research study under W. Va. Code §16A-13-1 *et seq.*

2.28. "Hydroponic nutrient solution" means a mixture of water, minerals, and essential nutrients without soil used to grow medical cannabis plants.

2.29. "Identification card" means a document issued under W. Va. Code §16A-5-1 that authorizes access to medical cannabis under the Act.

2.30. "Immature medical cannabis plant" means a nonflowering part of a medical cannabis plant that is no taller than eight inches and no wider than eight inches produced from a cutting, clipping, or seedling and that is in a growing/cultivating container that is no larger than two inches wide and two inches tall that is sealed on the sides and bottom.

2.31. "Immediate family" has the same meaning as it does in W. Va. Code §6B-1-3(f).

2.32. "Industrial hemp" means the plant *Cannabis, sativa L.*, and any part of the plant, whether growing or not, containing no greater than one percent tetrahydrocannabinol.

2.33. "Initial permit application" means the document submitted to the bureau by an applicant that, if approved, grants a permit to an applicant.

2.34. "Laboratory" means a place, establishment, or institution within the State of West Virginia that has been issued a certificate by the bureau's Office of Laboratory Services.

2.35. "Limited access area" means any area on a site or within a facility where:

2.35.a. Immature medical cannabis plants or medical cannabis plants are growing or being processed into medical cannabis;

2.35.b. Immature medical cannabis plants, medical cannabis plants, medical cannabis, or medical cannabis products are being loaded into or out of transport vehicles;

2.35.c. Medical cannabis is packaged for sale or stored;

2.35.d. Medical cannabis waste is processed, stored, or destroyed; and

2.35.e. Surveillance system devices are stored.

2.36. “Medical cannabis” means cannabis that is grown and sold pursuant to the provisions for certified medical use as set forth in the Act and in a form set forth in the provisions of §64-110-10.

2.37. “Medical cannabis container” means a sealed, traceable, food compliant, tamper resistant, tamper evident container used for the purpose of containment of packaged medical cannabis being transported from a grower/processor to a medical cannabis organization or a laboratory.

2.38. “Medical cannabis organization” means:

2.38.a. A dispensary or a grower/processor.

2.38.b. The term does not include a health care medical cannabis organization under sections W. Va. Code §16A-13-1 *et seq.* or a clinical registrant under W. Va. Code §16A-14-1 *et seq.*

2.39. “Medical cannabis plant” means a plant which is greater than eight vertical inches in height from where the base of the stalk emerges from the growth medium to the tallest point of the plant, or greater than eight horizontal inches in width from the end of one branch to the end of another branch.

2.40. “Medical cannabis program” means the program authorized under the Act and implemented by the bureau.

2.41. “Medical cannabis waste” means:

2.41.a. Solid, liquid, semi-solid, or contained gaseous materials that are generated by a grower/processor or an approved laboratory.

2.41.b. The term includes:

2.41.b.1. Unused, surplus, returned, recalled, contaminated, or expired medical cannabis;

2.41.b.2. Any medical cannabis plant material that is not used in the growing, harvesting, or processing of medical cannabis, including flowers, stems, trim, leaves, seeds, dead medical cannabis plants, dead immature medical cannabis plants, unused medical cannabis plant parts, and unused immature medical cannabis plant parts or roots;

2.41.b.3. Spent hydroponic nutrient solution;

2.41.b.4. Unused containers for growing immature medical cannabis plants or medical cannabis plants or for use in the growing and processing of medical cannabis;

2.41.b.5. Unused fertilizers and pesticides;

2.41.b.6. Unused excipients; and

2.41.b.7. Wastewater.

2.42. "Municipality" means an incorporated city or town in this state.

2.43. "Nutrient" means the essential elements and compounds necessary for the growth, metabolism, and development of medical cannabis plants.

2.44. "Nutrient practice" means the use by a grower/processor of essential elements and compounds necessary for the growth, metabolism, and development of seeds, immature medical cannabis plants, or medical cannabis plants.

2.45. "Operations" means the time at which the bureau determines that a medical cannabis organization is ready, willing and able to properly carry on the activity for which a permit has been issued under these rules, including the implementation of an electronic tracking system.

2.46. "Operator" means an individual who directly oversees or manages the day-to-day business functions for an applicant or permittee and has the ability to direct employee activities onsite and offsite or within a facility for which a permit is sought or has been issued under these rules.

2.47. "Patient" means an individual who:

2.47.a. Has a serious medical condition;

2.47.b. Has met the requirements for certification under the Act; and

2.47.c. Is a resident of the State of West Virginia.

2.48. "Permit" means an authorization issued by the bureau to an applicant to conduct activities authorized under the Act.

2.49. "Permittee" means a person who has been issued an authorization to operate as a medical cannabis organization under the Act and these rules.

2.50. "Person" means a natural person, corporation, foundation, organization, business trust, estate, limited liability company, licensed corporation, trust, partnership, limited liability partnership, association, or other form of legal business entity.

2.51. "Practitioner" means a physician who is registered with the bureau under W. Va. Code §16A-4-1.

2.52. "Principal" means an officer, director, or person who directly or beneficially owns securities of an applicant or permittee, or a person who has a controlling interest in an applicant or permittee, or who has the ability to elect the majority of the board of directors of an applicant or permittee, or otherwise control an applicant or permittee, other than a financial institution.

2.53. "Publicly traded company" means a person other than an individual who:

2.53.a. Has a class or series of securities registered under the Securities Exchange Act of 1934 (15 U.S.C.A. §§ 78a—78pp) or on a foreign stock exchange determined by the bureau to have similar listing and reporting requirements to exchanges that are regulated under the Securities Exchange Act of 1934;

2.53.b. Is a registered management company under the Investment Company Act of 1940 (15 U.S.C.A. §§ 80a-1—80a-64); or

2.53.c. Is subject to the reporting obligations imposed by section 15(d) of the Securities Exchange Act of 1934 (15 U.S.C.A. § 78o(d)), by reason of having filed a registration statement which has become effective under the Securities Act of 1933 (15 U.S.C.A. §§ 77a—77aa).

2.54. “Security” means the term as defined in W. Va. Code §32-4-401(n) of the Uniform Securities Act.

2.55. “Serious medical condition” means any of the following conditions:

2.55.a. Cancer;

2.55.b. Positive status for Human Immunodeficiency Virus or Acquired Immune Deficiency Syndrome;

2.55.c. Amyotrophic lateral sclerosis;

2.55.d. Parkinson's disease;

2.55.e. Multiple sclerosis;

2.55.f. Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity;

2.55.g. Epilepsy;

2.55.h. Neuropathies;

2.55.i. Huntington's disease;

2.55.j. Crohn's disease;

2.55.k. Post-traumatic stress disorder;

2.55.l. Intractable seizures;

2.55.m. Sickle cell anemia;

2.55.n. Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain; or

2.55.o. Terminally ill.

2.56. "Site" means the total area contained within the property line boundaries in which a facility is operated by a medical cannabis organization.

2.57. "Solid waste" means the term as defined in W. Va. Code §22-15-2(31) of the Solid Waste Management Act.

2.58. "Spent hydroponic nutrient solution" means hydroponic nutrient solution that has been used and can no longer serve the purpose for which it was produced.

2.59. "Terminally ill" means a medical prognosis of life expectancy of approximately one year or less if the illness runs its normal course.

2.60. "THC" means Tetrahydrocannabinol.

2.61. "Transport vehicle" means a vehicle that meets the requirements of the Act and is used to transport medical cannabis between medical cannabis organizations or between medical cannabis organizations and a laboratory.

2.62. "Unit" means the weight or volume of total usable medical cannabis in the finished product, calculated in metric units.

2.63. "Vaporization or nebulization" means the generation of medical cannabis in the form of vapor or fine spray for medicinal inhalation.

§64-109-3. Records subject to disclosure; confidentiality.

3.1. The following records are public records and are subject to disclosure under the West Virginia Freedom of Information Act (W. Va. Code §29A-1-1 *et seq.*):

3.1.a. An application submitted under the Act, except to the extent that the application contains any of the information listed in subsection 3.2.;

3.1.b. The name, business address, and medical credentials of a practitioner; and

3.1.c. Information regarding penalties or other disciplinary actions taken against a permittee by the bureau for a violation of the Act.

3.2. The following information is considered confidential, is not subject to the West Virginia Freedom of Information Act, and shall not otherwise be released to a person unless pursuant to court order:

3.2.a. Information in the possession of the bureau or any of its contractors regarding a practitioner's registration information that is not listed as a public record under subsection 3.1;

3.2.b. The name or other personal identifying information of a patient or caregiver who applies for or is issued an identification card;

3.2.c. A patient certification issued by a practitioner;

3.2.d. Any information on an identification card;

3.2.e. Information provided by the West Virginia State Police regarding a caregiver, including criminal history record information, as set forth in section 7 (Background checks);

3.2.f. Information regarding a patient's serious medical condition.

3.2.g. Other information regarding a patient, caregiver, practitioner, or medical cannabis organization not included in subsection 3.1. that falls within an exception to the West Virginia Freedom of Information Act or is otherwise considered to be confidential proprietary information by other law.

3.2.h. Information regarding the physical features of, and security measures installed in, a facility; and

3.2.i. Information maintained in the electronic tracking system of a grower/processor and a dispensary.

3.3. An applicant must identify and mark confidential proprietary information as confidential proprietary information prior to submission to the bureau.

§64-109-4. General requirements for application.

4.1. The types of applications to be submitted to the bureau under these rules include:

4.1.a. An initial permit application;

4.1.b. A permit renewal application;

4.1.c. An application for approval of a change in ownership of a medical cannabis organization authorized by a permit;

4.1.d. An application for approval of a change of location of a facility authorized by a permit;

4.1.e. An application for approval of alteration of a facility authorized by a permit; and

4.1.f. An application for an additional grower location.

4.2. By submitting an application to the bureau, an applicant consents to any investigation of the applicant's ability to meet the requirements under the Act applicable to the application.

4.3. An application is not complete and shall be rejected by the bureau unless:

4.3.a. The payment of the applicable application and permit fees in section 5 (Fees) are submitted with the application;

4.3.b. The applicant and its principals, and other persons affiliated with the applicant, are current in all tax obligations due and owing to the state. An applicant, as part of the application, must provide tax clearance certificates issued by the W. Va. State Tax Department and WorkForce West Virginia for the applicant and its principals and other affiliated persons verifying that the applicant does not have outstanding tax obligations to the state. The bureau may consider the application to be complete if the

applicant states on a form prescribed by the W. Va. State Tax Department and the WorkForce West Virginia that tax clearance certificates have been requested at the time the application was submitted to the bureau; and

4.3.c. All required information for each section of the application, including attachments and any supplemental information required by the bureau, is submitted to the bureau.

4.4. An application that is rejected by the bureau shall be returned to the applicant without further consideration by the bureau along with the refund of the initial permit fee.

4.5. An application submitted under these rules must contain the following statement signed by the applicant: "A false statement made in this application is punishable under the applicable provisions of W. Va. Code §61-3-37."

§64-109-5. Fees.

5.1. An applicant for an initial grower/processor permit or renewal permit must pay the following fees by certified check or money order to the bureau:

5.1.a. Initial permit application fee. The initial permit application fee of \$5,000 must be submitted with the initial permit application and is nonrefundable, except as provided in sections 4.4 and 6.1.c (initial permit application);

5.1.b. Initial permit fee. The initial permit fee of \$50,000 must be submitted with the initial permit application and shall be refunded if the initial permit is not granted; and

5.1.c. Permit renewal fee. The permit renewal fee of \$5,000 must be submitted with a renewal application and shall be refunded if the renewal permit is not granted.

5.2. An applicant for an initial dispensary permit or renewal permit must pay the following fees by certified check or money order to the bureau:

5.2.a. Initial permit application fee. The initial permit application fee of \$2,500 must be submitted with the initial permit application and is nonrefundable, except as otherwise provided in these rules;

5.2.b. Initial permit fee. The initial permit fee of \$10,000 for each dispensary location must be submitted with the initial permit application and shall be refunded if the initial permit is not granted; and

5.2.c. Permit renewal fee. The permit renewal fee of \$2,500 must be submitted with a renewal application and shall be refunded if the renewal permit is not granted.

5.3. A medical cannabis organization must pay a fee of \$250 by certified check or money order to the bureau with the submission of the following:

5.3.a. An application for approval of a change in ownership of a medical cannabis organization;

5.3.b. An application for approval of a change of location of a facility authorized by a permit; or

5.3.c. An application for approval of alteration of a facility authorized by a permit.

§64-109-6. Initial permit application.

6.1. The bureau shall publish in the State Register and on the bureau's website notice of initial permit application availability and the time frame during which initial permit applications will be accepted.

6.1.a. An applicant may only use the initial permit application form prescribed by the bureau made available on its web site.

6.1.b. An applicant must submit an initial permit application to the bureau in a manner prescribed by the initial permit application instructions.

6.1.c. An initial permit application received from an applicant after the time frame during which the bureau is accepting applications shall be rejected by the bureau and returned to the applicant without further consideration along with the return of fees submitted by the applicant with the application.

6.2. In addition to the requirements in section 4 (General requirements for application), the applicant must provide the bureau with the following information in the initial permit application:

6.2.a. The legal name of the applicant;

6.2.b. Certified copies of the applicant's organizational documents, if applicable, and if the applicant was not organized in this state, evidence that it is authorized to conduct business in this state;

6.2.c. The physical address of the applicant's proposed site and facility, including the following, as applicable:

6.2.c.1. Evidence of the applicant's clear legal title to or option to purchase the proposed site and the facility;

6.2.c.2. A fully executed copy of the applicant's unexpired lease for the proposed site and facility that includes the consent by the property owner to the use by the applicant of that site and facility on the proposed site for, at a minimum, the term of the initial permit; or

6.2.c.3. Other evidence satisfactory to the bureau that shows the applicant has the authority to use the proposed site and facility as a site and facility for, at a minimum, the term of the permit.

6.2.d. Evidence that the applicant is or will be in compliance with the zoning requirements of any municipality in which the applicant intends to operate.

6.2.e. The following apply to the proposed facility:

6.2.e.1. If the facility is in existence at the time the initial permit application is submitted to the bureau, the applicant must submit plans and specifications drawn to scale for the interior of the facility.

6.2.e.2. If the facility is in existence at the time the initial permit application is submitted to the bureau, and the applicant intends to make alterations to the facility, the applicant must submit renovation plans and specifications for the interior and exterior of the facility to be altered.

6.2.e.3. If the facility is not in existence at the time the initial permit application is submitted to the bureau, the applicant must submit a plot plan that shows the proposed location of the facility and an architect's drawing of the facility, including a detailed drawing, to scale, of the interior of the facility.

6.2.f. The name, residential address, date of birth, title, and a curriculum vitae of each principal, operator, financial backer, and employee of the applicant, or of any person holding an interest in the applicant's proposed site or facility, including:

6.2.f.1. A verification of identity that is satisfactory to the bureau;

6.2.f.2. Evidence of good moral character and reputation of each principal, operator, financial backer, or employee; and

6.2.f.3. A copy of a criminal history records check for each individual performed in accordance with section 7 (Background checks). This paragraph does not apply to an applicant who is an owner of securities in a publicly traded company if the bureau determines that the owner of the securities is not substantially involved in the activities of the applicant.

6.2.f.4. An affidavit from each principal or operator of the applicant setting forth the following:

6.2.f.4.A. Any position of management or ownership held during the 10 years preceding the filing date of the initial permit application of a controlling interest in any other business in this state or any other jurisdiction involving the manufacturing or distribution of medical cannabis or a controlled substance; and

6.2.f.4.B. Whether the principal, operator, or financial backer has been convicted of a felony criminal offense.

6.2.g. If a principal, operator or financial backer is a corporation or limited liability company:

6.2.g.1. The names, residential addresses, titles, and the curricula vitae of each principal of the corporation or limited liability company;

6.2.g.2. A certified copy of the filed articles of incorporation of the corporation or filed certificate of organization of the limited liability company; and

6.2.g.3. Unless the corporation or limited liability company is a publicly traded company, the names and mailing addresses of all persons owning securities in the corporation or membership interests in the limited liability company.

6.2.h. If a principal, operator, or financial backer is a general partnership, limited partnership, limited liability partnership, or limited liability limited partnership:

6.2.h.1. The names, residential addresses, titles, and the curricula vitae of each partner and general partner of a general partnership, limited partnership, limited liability partnership, or limited liability limited partnership, and if any of the partners is a corporation or a limited liability company, the

names, residential addresses, titles, and short version of the curricula vitae of each principal of that corporation or limited liability company;

6.2.h.2. A certified copy of its filed certificate of limited partnership or other formation document, if applicable;

6.2.h.3. A certified copy of its partnership agreement; and

6.2.h.4. Unless the entity is a publicly traded company, the names, and mailing addresses of each of its partners.

6.2.i. Evidence that the applicant is responsible and capable of successfully establishing and operating a facility, including the following:

6.2.i.1. Demonstrated experience, if any, running a for-profit or nonprofit organization or other business within this state or any other jurisdiction, and the nature of the business conducted by the organization;

6.2.i.2. History relating to a similar license, permit, or other authorization in other jurisdictions, including provisional licenses, suspensions, revocations, or disciplinary actions, including civil monetary penalties or warnings;

6.2.i.3. History of response to sanctions, disciplinary actions, or civil monetary penalties imposed relating to any similar license, permit, or other authorization in another jurisdiction, and the plans of correction or other responses made to those actions;

6.2.i.4. Evidence that the applicant and its principals, and other persons affiliated with the applicant identified by the bureau, is in compliance with all the laws of the state regarding the payment of state taxes as shown on the tax clearance certificates issued by the State Department and Workforce West Virginia under section 4;

6.2.i.5. Evidence of any felony criminal action under the laws of the state or any other state, the United States or a military, territorial, or tribal authority, against a principal, operator, financial backer, or employee, or which involved the possession, transportation, or sale of illegal drugs, or which related to the provision of cannabis for medical purposes, including any action against an organization providing cannabis for medical purposes in which those individuals either owned shares of stock or served as executives, and which resulted in a conviction, guilty plea, or plea of nolo contendere, or an admission of sufficient facts;

6.2.i.6. Evidence of any civil or administrative action under the laws of the state or any other state, the United States or a military, territorial, or tribal authority relating to a principal, operator, financial backer, or employee of the applicant's profession, or occupation or fraudulent practices, including fraudulent billing practices;

6.2.i.7. Evidence of any attempt by the applicant to obtain a registration, license, permit, or other authorization to operate a medical cannabis organization in any jurisdiction by fraud, misrepresentation, or the submission of false information; and

6.2.i.8. A statement that the applicant must provide evidence of workers' compensation insurance if the applicant is issued a permit and the facility is determined to be operational by the bureau.

6.2.j. A description of the duties, responsibilities, and roles of each principal, operator, financial backer, and employee;

6.2.k. A timetable outlining the steps the applicant will take to become operational;

6.2.l. A summary of the intended plan of operation that describes, at a minimum, how the applicant's proposed business operations will comply with the Act and these rules relating to:

6.2.l.1. Security;

6.2.l.2. Employee qualifications and training;

6.2.l.3. Transportation of medical cannabis;

6.2.l.4. Storage of medical cannabis;

6.2.l.5. Labeling of medical cannabis;

6.2.l.6. Inventory management;

6.2.l.7. With respect to a grower/processor's facility, nutrient practice;

6.2.l.8. With respect to a grower/processor's facility, quality control and testing of medical cannabis for potential contamination;

6.2.l.9. Recordkeeping;

6.2.l.10. Preventing unlawful diversion of medical cannabis; and

6.2.l.11. With respect to a grower/processor's facility, growing of medical cannabis, including a detailed summary of policies and procedures for its growth.

6.2.m. The relevant financial information in section 25 (capital requirements);

6.2.n. Statements that:

6.2.n.1. The applicant and each principal, operator, financial backer, and employee are of good moral character;

6.2.n.2. The applicant possesses the ability to obtain in an expeditious manner the right to use the proposed site and facility, including equipment, to properly perform the activity described in the initial permit application;

6.2.n.3. The applicant can continuously maintain effective security, surveillance, and accounting control measures to prevent diversion, abuse, and other illegal conduct regarding medical cannabis plants and medical cannabis; and

6.2.n.4. The applicant can continuously comply with all applicable laws of the state, the Act, these rules, and the terms and conditions of the initial permit;

6.2.o. The applicant must provide the bureau with releases sufficient to obtain information from a governmental agency, financial institutions, an employer, or any other person. Failure to provide these releases will result in the rejection of the initial permit application; and

6.2.p. Other information required by the bureau.

6.3. If the bureau determines that an initial permit application is complete but lacking sufficient information upon which to make a determination, the bureau will notify the applicant in writing of the factors that require additional information and documentation. An applicant has 30 days from the mailing date of the notice to provide the requested information and documentation to the bureau. An applicant's failure to provide the requested information to the bureau by the deadline may be grounds for denial of the issuance of a permit.

6.4. At the discretion of the bureau, the bureau may extend the deadline in subsection 6.3 for up to an additional 15 days.

6.5. The bureau may conduct an inspection to determine the appropriateness of a proposed site and facility, the applicant's operational status, the applicant's compliance with the laws and rules of the state, the municipality's zoning requirements relating to the applicant's proposed site and facility, if applicable, and its use as outlined in the permit application. The bureau may do the following:

6.5.a. Interview principals, operators, financial backers, and employees, including physicians and pharmacists, engaged and to be engaged in the applicant's operations for the purpose of verifying the information contained in the initial permit application.

6.5.b. Inspect transport vehicles that are or will be utilized in the transportation of medical cannabis to a facility or a laboratory.

§64-109-7. Background checks.

7.1. To provide the criminal history record check required under section 6 (Initial permit application), an applicant must submit fingerprints of its principals, financial backers, operators, and employees to the West Virginia State Police. The West Virginia State Police or its authorized agent must submit the fingerprints to the Federal Bureau of Investigation for the purpose of verifying the identity of the individuals whose fingerprints have been submitted and obtaining a current record of criminal arrests and convictions.

7.2. The bureau may only use criminal history background check information obtained under this section to determine the character, fitness, and suitability to serve in the designated capacity of the principal, financial backer, operator, and employee.

7.3. This section does not apply to an owner of securities in a publicly traded company if the bureau determines that the owner is not substantially involved in the activities of the medical cannabis organization.

7.4. A financial backer, principal, or employee may not hold a volunteer position, position for remuneration, or otherwise be affiliated with a medical cannabis organization or a clinical registrant if the individual has been convicted of a criminal offense relating to the sale or possession of illegal drugs, narcotics, or controlled substances.

§64-109-8. Review of initial permit applications.

The bureau will review initial permit applications submitted by applicants according to the criteria in W. Va. Code §16A-6-3(a) and this rule.

§64-109-9. Permit renewal applications.

9.1. A medical cannabis organization wishing to renew its permit must submit to the bureau a permit renewal application not more than six months, nor less than four months, prior to the current permit's expiration.

9.2. A medical cannabis organization must submit the applicable fee in section 5 (Fees) with the permit renewal application.

9.3. A medical cannabis organization must include the following in the permit renewal application:

9.3.a. Information regarding any charge, or any initiated, pending, or concluded investigation, during the period of the initial permit or prior renewal period, by any governmental, or administrative agency with respect to:

9.3.a.1. Any incident involving the theft, loss, or possible diversion of medical cannabis by the medical cannabis organization or from the medical cannabis organization's facility.

9.3.a.2. Compliance by the medical cannabis organization with the laws of the state with respect to any substance in the Uniform Controlled Substance Act (W. Va. Code §60A-4-401 *et seq.*)

9.3.a.3. Information concerning the medical cannabis organization's ability to carry on the activity for which the permit was issued, including medical cannabis product shortages or wait lists occurring during the 12-months prior to the date the renewal permit application was submitted.

9.3.a.4. The medical cannabis organization's history of compliance with the Act and these rules.

9.4. If the bureau determines that a permit renewal application is complete but lacking sufficient information upon which to make a determination, the bureau will notify the medical cannabis organization in writing of the factors that require additional information and documentation. The medical cannabis organization will have 30 days from the mailing date of the notice to provide the requested information and documentation to the bureau. A medical cannabis organization's failure to provide the requested information to the bureau by the deadline may be grounds for denial of the permit renewal application.

9.5. The bureau may conduct an onsite inspection of the medical cannabis organization's site and facility to determine an applicant's continuing compliance with the Act and these rules.

§64-109-10. Denial of renewal of a permit.

10.1. The bureau will deny the renewal of a permit if the bureau determines:

10.1.a. The medical cannabis organization has not or is unlikely to be able to continuously maintain effective control against diversion of medical cannabis at its facility.

10.1.b. The medical cannabis organization falsified any part of the permit renewal application or any other application submitted to the bureau under these rules.

10.1.c. The medical cannabis organization is unlikely to comply with all state and local laws applicable to the activities in which it may engage under the permit, if renewed.

10.2. An existing permit is immediately invalid upon expiration if the medical cannabis organization has not filed a permit renewal application in accordance with section 9 (Permit renewal applications) and remitted the required fees in accordance with section 5 (Fees).

10.3. Except as provided in subsection 10.5, a medical cannabis organization may not operate if its permit is not renewed prior to expiration.

10.4. If the bureau denies renewal of the permit or if the medical cannabis organization fails to submit a permit renewal application and permit renewal fee as required under section 5 (Fees) the medical cannabis organization must do the following upon the expiration of the permit:

10.4.a. Cease all operations authorized by the permit.

10.4.b. In the case of a grower/processor, dispose of any remaining medical cannabis, medical cannabis products, plant matter, seed, or any growing equipment as set forth in 64CSR110.22.

10.4.c. In the case of a dispensary, return the medical cannabis or medical cannabis products to the grower/processor where the medical cannabis and medical cannabis products originated.

10.5. If a medical cannabis organization submits a permit renewal application and permit renewal fee to the bureau as required under section 5 (Fees), the bureau may administratively extend the existing permit from the date the existing permit expires until the bureau can complete its permit renewal application review.

§64-109-11. Duty to report.

11.1. During the application process, or at any time during the permit period if a permit is issued, an applicant or permittee must notify the bureau:

11.1.a. In writing of any change in facts or circumstances reflected in the initial permit application or any permit renewal application submitted to the bureau, or any newly discovered or occurring fact or circumstance which would have been included in the application if known at the time the application was submitted.

11.1.b. In writing of any proposed modification of its plan of operation at least 30 days prior to the proposed modification.

11.1.c. Immediately upon becoming aware, and state and local law enforcement immediately upon becoming aware, of any adverse loss from the permittee's facility or any vehicle transporting medical cannabis to or from the permittee's facility.

11.2. If the change in information involves a change in control of the medical cannabis organization, the medical cannabis organization must surrender its existing permit to the bureau, unless the medical cannabis organization submits an application for approval of a change in ownership of a medical cannabis organization in accordance with section 12 (Application for approval of a change in ownership of a medical cannabis organization).

11.3. If the change in information involves a change in any of the activities on the medical cannabis organization site, including any of the following, the medical cannabis organization must surrender its existing permit to the bureau and take action as required under section 16 (Closure of a facility):

11.3.a. Discontinuance of operations.

11.3.b. Removal of all medical cannabis from the sites and locations by state or federal authority.

§64-109-12. Application for approval of a change in ownership of a medical cannabis organization.

12.1. In the event of an impending change in ownership of a medical cannabis organization from the ownership listed in the initial permit application or a permit renewal application, the medical cannabis organization must submit an application for approval of a change in ownership, on a form prescribed by the bureau, to the bureau together with the fee required under section 5 (Fees).

12.2. The bureau, in its sole discretion, may permit the medical cannabis organization to incorporate by reference all of the information in the medical cannabis organization's initial permit application, and any previously submitted permit renewal application, into the application for approval of a change in ownership.

12.3. A medical cannabis organization's application for approval of a change in ownership will not be considered complete by the bureau until all portions of the application are completed and the appropriate application fee contained in section 6 is submitted. The bureau may reject an incomplete application.

12.4. For each individual that is part of the proposed change in ownership, the medical cannabis organization must include all of the information required under section 6 (Initial permit application) for the individuals listed in those capacities in the medical cannabis organization's initial permit application or any previously submitted permit renewal application.

12.5. If the bureau determines that an application for approval of a change in ownership is lacking sufficient information upon which to make a determination, the bureau will notify the medical cannabis organization in writing of the factors that require additional information and documentation. The medical cannabis organization has 30 days from the mailing date of the notice to provide the requested information and documentation to the bureau. A medical cannabis organization's failure to provide the required information and documentation to the bureau by the deadline may be grounds for the denial of approval for the requested change in ownership.

12.6. A change in ownership of a medical cannabis organization that occurs without the bureau's prior written approval of the change as provided in this section is a violation of the Act and these rules.

§64-109-13. Application for approval of a change in location of a facility.

13.1. A medical cannabis organization desiring to change the location of a site or facility authorized under a permit issued to the medical cannabis organization must submit an application for approval of a change in location to the bureau together with the fee required by section 5 (Fees).

13.2. A change in location of a facility authorized by a permit may not occur until the bureau approves the change, in writing.

13.3. The medical cannabis organization must submit an application for approval of a change in location on a form prescribed by the bureau.

13.4. An application for approval of a change in location must include the reason for requesting the change and other information about the new location as the bureau may require.

13.5. The bureau will issue a new permit to the medical cannabis organization for the new location if the request is approved.

13.6. Within 180 days of the issuance by the bureau of a new permit under subsection 13.5, the medical cannabis organization must change the location of its operation to the new location designated in the new permit. Simultaneously with the completion of the move, the medical cannabis organization must cease to operate at the former location and surrender its existing permit to the bureau. The following conditions apply:

13.6.a. At no time may a medical cannabis organization operate or exercise any of the privileges granted under the permit in both locations;

13.6.b. At the discretion of the bureau, the bureau may extend the 180-day deadline for relocation for up to an additional 90 days; and

13.6.c. Once the new facility is determined to be operational by the bureau, the medical cannabis organization may resume operations under the new permit at the new location.

§64-109-14. Application for approval of alteration of a facility.

14.1. Except as provided in subsection 14.2, after the issuance of a permit, a medical cannabis organization may not make a physical change, alteration, or modification of the facility that materially or substantially alters the facility or its usage as described in the plot plans originally approved by the bureau.

14.2. A medical cannabis organization wishing to make any of the following alterations to the facility for which its permit was issued must submit an application for approval of alteration of a facility, on a form prescribed by the bureau, to the bureau together with the fee required by section 5 (Fees):

14.2.a. An increase or decrease in the total square footage of the facility;

14.2.b. The sealing off, creation of, or relocation of a common entryway, doorway, passage, or other means of public ingress or egress when the common entryway, doorway, or passage alters or changes limited access areas;

14.2.c. Any of the following made to enhance activities authorized under the permit:

14.2.c.1. Additional electric fixtures or lighting equipment;

14.2.c.2. The lowering of a ceiling; and

14.2.c.3. Electrical modifications that require inspection by state or local governmental entity.

§64-109-15. Failure to be operational.

15.1. No more than six months from the date of issuance of a permit, a medical cannabis organization must notify the bureau, on a form prescribed by the bureau, that it is operational.

15.2. After the bureau receives the notification in subsection 15.1, the bureau will inspect the facility to determine if the medical cannabis organization is operational to the satisfaction of the bureau.

15.3. If the medical cannabis organization has not met the operational timetable in the initial permit application to the satisfaction of the bureau at the time of the inspection conducted under subsection 15.2, the bureau will notify the medical cannabis organization of the deficiencies. Within 30 days of receiving the bureau's notice, the medical cannabis organization must submit to the bureau for approval a plan of correction that sets forth the medical cannabis organization's timeline and a date certain for correcting the deficiencies, which may not extend beyond 90 days following the date the bureau approves the plan of correction.

15.4. If the medical cannabis organization does not comply with its plan of correction as approved by the bureau within 90 days following the bureau's approval, the bureau may revoke or suspend the medical cannabis organization's permit under section 20 (General penalties and sanctions).

§64-109-16. Closure of a facility.

16.1. A medical cannabis organization must notify the bureau in writing immediately, but in no event less than 60 days prior to the projected date of closure, upon making a determination that it intends to close its facility.

16.2. A medical cannabis organization may not accept or purchase seeds, immature medical cannabis plants, medical cannabis plants, medical cannabis, other plant matter, medical cannabis products, equipment, or medical devices or instruments as of the date of notice submitted pursuant to subsection 16.1.

16.3. The notice must be accompanied by the medical cannabis organization's written plan for closing the facility which must include the following information:

16.3.a. The projected date of closure.

16.3.b. How it intends to notify in writing, prior to the projected date for closure, any person to which the medical cannabis organization provides medical cannabis or medical cannabis services prior to closure.

16.3.c. How it intends to dispose of seeds, immature medical cannabis plants, medical cannabis plants, medical cannabis, medical cannabis products, or other plant matter projected to still be in the facility at the time of the projected closure in accordance with 64CSR110.22.

16.3.d. How it intends to dispose of equipment or medical devices or instruments used by the medical cannabis organization in its operations at the facility.

16.4. A medical cannabis organization may not remove or destroy any seeds, immature medical cannabis plants, medical cannabis plants, medical cannabis, other plant matter, medical cannabis products, equipment, or medical devices or instruments until the bureau has approved its plan for closure submitted under subsection 16.3 and must comply with all requirements regarding disposal of medical cannabis 64CSR110.22.

16.5. The bureau may enter the site and facility and inspect the medical cannabis organization's vehicles following receipt of a medical cannabis organization's plan of closure to determine whether to approve the medical cannabis organization's closure plan.

16.6. If the bureau approves the medical cannabis organization's plan to close the facility submitted under this section, the medical cannabis organization must surrender its permit to the bureau on or before the date for closure provided in the plan.

§64-109-17. Insurance requirements.

17.1. A medical cannabis organization must obtain and maintain an appropriate amount of insurance coverage that insures the site, facility, and equipment used in the operation of the facility. An adequate amount of comprehensive liability insurance covering the medical cannabis organization's activities authorized by the permit must begin on the date the initial permit is issued by the bureau and continuing for a long as the medical cannabis organization is operating under the permit.

17.2. A medical cannabis organization must obtain and maintain workers' compensation insurance coverage for employees at the time the medical cannabis organization is determined to be operation by the bureau.

§64-109-18. Inspection and investigation.

18.1. The bureau may conduct announced or unannounced inspections or investigations to determine the medical cannabis organization's compliance with its permit, the Act or these rules.

18.2. An investigation or inspection may include:

18.2.a. Inspection of a medical cannabis organization's site, facility, vehicles, books, records, papers, documents, data, and other physical or electronic information.

18.2.b. Questioning of employees, principals, operators, and financial backers of the medical cannabis organization.

18.2.c. Inspection of a grower/processor facility's equipment, instruments, tools, and machinery that are used to grow, process, and package medical cannabis, including containers and labels.

18.3. The bureau and its authorized agents will have free access to review and, if necessary, make copies of books, records, papers, documents, data, or other physical or electronic information that relates to the business of the medical cannabis organization, including financial data, sales data, shipping data, pricing data, and employee data.

18.4. Failure of a medical cannabis organization to provide the bureau and its authorized agents immediate access to any part of a medical cannabis organization's site or facility, requested material, physical or electronic information, or individual as part of an inspection or investigation may result in the imposition of a civil monetary penalty, suspension, or revocation of its permit, or an immediate cessation of operations pursuant to a cease and desist order issued by the bureau.

18.5. The bureau and its authorized agents will have free access to any area within a site or facility that is being used to store medical cannabis for testing purposes and are permitted to collect test samples for testing at an approved laboratory.

§64-109-19. Reports.

19.1. A medical cannabis organization must submit the following reports to the bureau, on forms prescribed by the bureau, at the end of the first 12-month period following the issuance of a permit, and as of the end of each three-month period thereafter:

19.1.a. In the case of a grower/processor:

19.1.a.1. The amount of medical cannabis sold by the grower/processor during the period for which the report is being submitted.

19.1.a.2. The per-dose price of an amount of medical cannabis sold by the grower/processor to a medical cannabis organization in a unit of measurement as determined by the bureau.

19.1.b. In the case of a dispensary:

19.1.b.1. The amount of medical cannabis purchased by the dispensary during the period for which the report is being submitted.

19.1.b.2. The per-dose price of medical cannabis purchased by a dispensary in a unit of measurement as determined by the bureau.

19.1.b.3. The per-dose price of an amount of medical cannabis dispensed to a patient or caregiver by a dispensary and in a unit of measurement as determined by the bureau.

19.2. The bureau will aggregate the information in the reports submitted by medical cannabis organizations under subsection 19.1 and post the information on the bureau's web site.

19.3. The bureau may require ongoing reporting of operational and financial information in a form and manner prescribed by the bureau.

19.4. The bureau may require any reports necessary to carry out its responsibilities under the Act and these rules.

§64-109-20. General penalties and sanctions.

20.1. In addition to any other penalty imposed by law for violations of the Act or these rules, the bureau may take one or more of the following actions:

20.1.a. Suspend or revoke a permit if any of the following occur:

20.1.a.1. The medical cannabis organization fails to maintain effective control against diversion of medical cannabis from its facility or under its control;

20.1.a.2. The medical cannabis organization violates a provision of the Act or these rules, or an order issued under the Act or these rules;

20.1.a.3. The medical cannabis organization violates a provision of other state or local laws regarding the operation of its facility; or

20.1.a.4. The medical cannabis organization engages in conduct, or an event occurs, that would have disqualified the medical cannabis organization from being issued a permit or having its permit renewed.

20.1.b. Impose a civil penalty of not more than \$10,000 for each violation and an additional penalty of not more than \$1,000 for each day of the continuing violation. In determining the amount of each penalty, the bureau will take the following into consideration:

20.1.b.1. The gravity of the violation.

20.1.b.2. The potential harm resulting from the violation to patients, caregivers, or the general public.

20.1.b.3. The willfulness of the violation.

20.1.b.4. Previous violations, if any, by the medical cannabis organization being assessed.

20.1.b.5. The economic benefit to the person being assessed for failing to comply with the requirements of the Act, these rules, or an order issued under the Act or these rules.

20.1.c. Suspend or revoke a permit pending the outcome of a hearing if the bureau determines that the health, safety, or welfare of the public, a patient, or a caregiver is at risk;

20.1.d. Order the restitution of funds or property unlawfully obtained or retained by a medical cannabis organization;

20.1.e. Issue a cease and desist order to immediately stop or restrict the operations of a medical cannabis organization conducted under a permit to protect the public's health, safety, and welfare. The following apply:

20.1.e.1. An order may include a requirement that a medical cannabis organization cease or restrict some or all of its operations. In addition, the order may prohibit the use of some or all of the medical cannabis grown, processed, or to be sold by the medical cannabis organization;

20.1.e.2. An order may be issued by an authorized agent of the bureau immediately upon the completion of an inspection or investigation if the agent observes or suspects an operational failure or determines that the conditions will likely create a diversion of medical cannabis, contamination of medical cannabis, or a risk to patients or the public; and

20.1.e.3. An order may include:

20.1.e.3.A. An immediate evacuation of the site and facility, and the sealing of the entrances to the facility;

20.1.e.3.B. A quarantine of some or all of the medical cannabis found at the facility; and

20.1.e.3.C. The suspension of the sale or shipment of some or all of the medical cannabis found at the facility.

20.1.f. Issue a written warning if the bureau determines that either:

20.1.f.1. The public interest will be adequately served under the circumstances by the issuance of the warning; or

20.1.f.2. The violation does not threaten the safety or health of a patient, caregiver, or the general public, and the medical cannabis organization took immediate action to remedy the violation.

20.2. A person who aids, abets, counsels, induces, procures, or causes another person to violate the Act or these rules, or an order issued under the Act, or these rules, will also be subject to the civil penalties provided for under this section.

20.3. Before the bureau may act under subsection 20.1 or 20.2, the bureau will provide the medical cannabis organization or other person with written notice specifying the nature of the alleged violation or conduct. The notice will fix a time and place for hearing. The hearing will be scheduled at least 10 days after the date of the notice. Hearings will be held in accordance with the procedures contained in 64CSR1 (Rules of Procedure for Contested Case Hearings and Declaratory Rulings).

20.4. Notwithstanding subsection 20.3, for violations of the Act or these rules, the bureau may require a medical cannabis organization to develop and adhere to a plan of correction approved by the bureau. The bureau will monitor compliance with the plan of correction. Failure to comply with the plan of correction may result in the bureau's taking action under applicable provisions of this section as it deems appropriate.

20.5. The bureau's action under subsections 20.1., 20.2., and 20.3. are subject to 64CSR1 (Rules of Procedure for Contested Case Hearings and Declaratory Rulings).

§64-109-21. Training.

21.1. As required under the Act, the following individuals must complete a two-hour training course developed by the bureau within the times specified:

21.1.a. Each principal of a medical cannabis organization, prior to starting initial operation of a facility.

21.1.b. Each employee of a medical cannabis organization who has direct contact with patients or caregivers or who physically handles medical cannabis, within 90 days after starting work at the facility.

21.2. The training course required under subsection 21.1 must provide the following information:

21.2.a. The provisions of the Act and rules relevant to the responsibilities of principals and employees of grower/processors.

21.2.b. Proper handling of medical cannabis.

21.2.c. Proper recordkeeping.

21.2.d. How to prevent and detect the diversion of medical cannabis.

21.2.e. Best practice security procedures.

21.2.f. Best practice safety procedures, including responding to the following:

21.2.f.1. A medical emergency.

21.2.f.2. A fire.

21.2.f.3. A chemical spill.

21.2.f.4. A threatening event including:

21.2.f.4.A. An armed robbery.

21.2.f.4.B. A burglary.

21.2.f.4.C. A criminal incident.

21.3. A medical cannabis organization must retain the training attendance records of its principals and employees and make them available for inspection by the bureau and its authorized agents upon request.

§64-109-22. Zoning.

22.1. A grower/processor must meet the same municipal zoning and land use requirements as other manufacturing, processing, and production facilities that are located in the same zoning district.

22.2. A dispensary must meet the same municipal zoning and land use requirements as other commercial facilities that are located in the same zoning district.

§64-109-23. Advertising by a medical cannabis organization.

23.1. In the advertising and marketing of medical cannabis, a medical cannabis organization must be consistent with the federal regulations governing prescription drug advertising and marketing in 21 C.F.R. § 202.1 (Prescription-drug advertisements).

23.2. Advertising Restrictions

23.2.a. Medical cannabis advertising may not:

23.2.a.1. Contain statements that are deceptive, false, or misleading;

23.2.a.2. Contain any content that can reasonably be considered to target individuals under the age of 21, including but not limited to images of minors, cartoons, toys, or similar images and items typically marketed towards minors, or references to products that are commonly associated with minors or marketed by minors;

23.2.a.3. Specifically encourages the transportation of medical cannabis items across state lines or otherwise encourages illegal activity;

23.2.a.4. Display consumption of medical cannabis items;

23.2.a.5. A medical cannabis organization may not make any deceptive, false, or misleading assertions or statements on any informational material, any sign, or any document provided to a consumer.

23.2.b. A medical cannabis organization must include the following statements on all print, billboard, television, radio and internet advertising in font size legible to the viewer:

23.2.b.1. "Do not operate a vehicle or machinery under the influence of this drug."; and

23.2.b.2. "Keep out of the reach of children."

23.3. Advertising Media, Coupons, and Promotions.

23.3.a. Advertising through handbills that are passed out in public areas such as parking lots and publicly owned property is prohibited.

23.3.b. A medical cannabis organization may not utilize television, radio, billboards, print media, or internet advertising unless the medical cannabis organization has reliable evidence that no more than 30 percent of the audience for the program, publication, or internet web site in or on which the advertising is to air or appear is reasonably expected to be under the age of 21.

23.3.c. A medical cannabis organization that advertises via web page must utilize appropriate measures to ensure that individuals visiting the web page are over 21 years of age.

23.3.d. A medical cannabis organization may not engage in advertising via marketing directed towards location-based devices, including but not limited to cellular phones, unless the marketing is a

mobile device application installed on the device by the owner of the device who is 21 years of age or older and includes a permanent and easy opt-out feature.

23.4. Removal of Objectionable and Non-Conforming Advertising.

23.4.a. A medical cannabis organization must remove any sign, display, or advertisement if the bureau finds it violates these rules.

23.4.b. The bureau will notify the medical cannabis organization and specify a reasonable time period for the medical cannabis organization to remove any sign, display, or advertisement that the bureau finds objectionable.

23.5. Promotional, advertising, and marketing materials must be approved by the bureau prior to their use.

23.6. This section does not apply to information provided by a grower/processor to a dispensary listing various medical cannabis items that the grower/processor is offering for sale to the dispensary.

§64-109-24. Technical advisories.

The bureau may issue technical advisories to assist permittees in complying with the Act and these rules. Technical advisories do not have the force of law or rule, but will provide guidance on the bureau's interpretation of, and how a permittee may maintain compliance with, the Act and these rules. Notice of the availability of a technical advisory will be published in the State Register.

§64-109-25. Capital requirements.

25.1. An applicant for grower/processor permit must provide an affidavit that the applicant has at least two million dollars in capital, \$500,000 of which must be on deposit with one or more financial institutions.

25.2. An applicant for a dispensary permit must provide an affidavit that the applicant has at least \$150,000 on deposit with one or more financial institutions.

25.3. The affidavit must be in a form as prescribed by the bureau.

25.4. An applicant must submit with the initial permit application a signed release allowing the bureau to contact each financial institution listed in the application to verify the requirements of subsections 25.1 and 25.2.



WEST VIRGINIA SECRETARY OF STATE
MAC WARNER
ADMINISTRATIVE LAW DIVISION

eFILED

3/30/2023 3:15:55 PM

Office of West Virginia
Secretary Of State

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED
BY THE WEST VIRGINIA LEGISLATURE**

AGENCY: Health TITLE-SERIES: 64-110

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: MEDICAL CANNABIS PROGRAM
GROWER/PROCESSORS

CITE STATUTORY AUTHORITY: 16A-3-1

The above rule has been authorized by the West Virginia Legislature.

Authorization is cited in (house or senate bill number) HB2648

Section 64-5-1(e) Passed On 3/6/2023 12:00:00 AM

This rule is filed with the Secretary of State. This rule becomes effective on the following date:

April 1, 2023

This rule shall terminate and have no further force or effect from the following date:

August 01, 2028

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

April L Robertson -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

**TITLE 64
LEGISLATIVE RULE
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH**

**SERIES 110
MEDICAL CANNABIS PROGRAM – GROWER/PROCESSORS**

§64-110-1. General.

- 1.1. Scope. The provisions of this rule include general provisions related to grower/processors pursuant to the West Virginia Medical Cannabis Act (W. Va. Code §16A-1-1 *et seq.*)
- 1.2. Authority. W. Va. Code §16A-3-1(b), §16A-7-3, and §16A-13-7.
- 1.3. Filing Date. March 30, 2023.
- 1.4. Effective Date. April 1, 2023.
- 1.5. Sunset Provision. This rule will terminate and have no further force or effect on August 1, 2028.
- 1.6. Applicability. This rule applies to a person or entity that desires to hold a permit as a medical cannabis organization in the state.

§64-110-2. Definitions.

- 2.1. "Act" means the West Virginia Medical Cannabis Act (W. Va. Code §16A-1-1 *et seq.*)
- 2.2. "Adverse event" means an injury resulting from the use of medical cannabis dispensed at a dispensary. An injury includes physical harm, mental harm, or loss of function.
- 2.3. "Adverse loss" means a loss, discrepancy in inventory, diversion or theft of seeds, immature medical cannabis plants, medical cannabis plants, medical cannabis, funds, or other property of a medical cannabis organization.
- 2.4. "Applicant" means a person who wishes to submit or submits an application to the bureau for a permit to operate as a grower/processor or dispensary, or both, under the Act and this rule.
- 2.5. "Approved laboratory" means a laboratory that has applied for, and received, the approval of the bureau to identify, collect, handle, and conduct tests on samples from a grower/processor and test samples from the bureau used in the growing, processing, or dispensing of medical cannabis as required by the Act and this rule.
- 2.6. "Bureau" means the West Virginia Bureau for Public Health within the West Virginia Department of Health and Human Resources.
- 2.7. "CBD" means Cannabidiol.

2.8. "Cannabis" means all parts of the plant of the genus cannabis whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or its resin, including cannabis concentrate. "Cannabis" does not include industrial hemp, nor does it include fiber produced from the stalks, oil, or cake made from the seeds of the plant, sterilized seed of the plant which is incapable of germination, or the weight of any other ingredient combined with cannabis to prepare topical or oral administrations, food, drink, or other product.

2.9. "Caregiver" means the individual designated by a patient or, if the patient is under 18 years of age, and individual authorized under W. Va. Code §16A-5-1 *et seq.* to deliver medical cannabis.

2.10. "Certified medical use" means the acquisition, possession, use, or transportation of medical cannabis by a patient, or the acquisition, possession, delivery, transportation, or administration of medical cannabis by a caregiver, for use as part of the treatment of the patient's serious medical condition, as authorized in a patient certification issued under the Act, including enabling the patient to tolerate treatment for the serious medical condition.

2.11. "Clinical Registrant" means an entity that:

2.11.a. Holds a permit as both a grower/processor and a dispensary.

2.11.b. Has a contractual relationship with an academic clinical research center under which the academic clinical research center or its affiliate provides advice to the entity, regarding, among other areas, patient health and safety, medical applications and dispensing, and management of controlled substances.

2.12. "Controlled substance" means a drug, substance or immediate precursor included in Schedules I through V as listed in the Uniform Controlled Substance Act (W. Va. Code §60A-2-1 *et seq.*).

2.13. "Dispensary" means:

2.13.a. A person who holds a permit issued by the bureau to dispense medical cannabis.

2.13.b. The term does not include a health care medical cannabis organization as defined under W. Va. Code §16A-13-1 *et seq.*

2.14. "Electronic tracking system" means an electronic seed-to-sale system prescribed by the bureau that is implemented by:

2.14.a. A grower/processor to log, verify and monitor the receipt, use and sale of seeds, immature medical cannabis plants or medical cannabis plants, the funds received by a grower/processor for the sale of medical cannabis to another medical cannabis organization, the disposal of medical cannabis waste, and the recall of defective medical cannabis.

2.14.b. A dispensary to log, verify, and monitor the receipt of medical cannabis product from a grower/processor, the verification of the validity of an identification card presented by a patient or caregiver, the dispensing of medical cannabis product to a patient or caregiver, the disposal of medical cannabis waste, and the recall of defective medical cannabis.

2.14.c. An approved laboratory to log, verify and monitor the receipt of samples and test samples for testing, the results of tests performed by the approved laboratory, and the disposal of tested and untested samples.

2.15. "Employee" means an individual who is hired for a wage, salary, fee, or payment to perform work for an applicant or permittee.

2.16. "Excipients" means solvents, chemicals, or materials reported by a medical cannabis organization and approved by the bureau for use in the processing of medical cannabis.

2.17. "Facility" means a structure and other appurtenances or improvements where a medical cannabis organization grows and processes or dispenses medical cannabis.

2.18. "Financial backer" means an investor, mortgagee, bondholder, note holder, or other source of equity, capital, or other assets other than a financial institution.

2.19. "Form of medical cannabis" means the characteristics of the medical cannabis recommended or limited for a particular patient, including the method of consumption and any particular dosage, strain, variety, and quantity or percentage of medical cannabis, or particular active ingredient.

2.20. "Grower/processor means:

2.20.a. A person who holds a permit from the bureau under the Act to grow or process medical cannabis.

2.20.b. The term does not include a health care medical cannabis organization as defined under W. Va. Code §16A-13-1 *et seq.*

2.21. "Harvest batch" means a specifically identified quantity of medical cannabis plant that is uniform in strain, cultivated utilizing the same growing practices, harvested at the same time and at the same location, and cured under uniform conditions.

2.22. "Harvest lot" means a specifically identified quantity of medical cannabis plant taken from a harvest batch.

2.23. "Health care medical cannabis organization" means a vertically integrated health system approved by the bureau to dispense medical cannabis or grow and process medical cannabis, or both, in accordance with a research study under W. Va. Code §16A-13-1 *et seq.*

2.24. "Hydroponic nutrient solution" means a mixture of water, minerals, and essential nutrients without soil used to grow medical cannabis plants.

2.25. "Identification card" means a document issued under W. Va. Code §16A-5-1 that authorizes access to medical cannabis under the Act.

2.26. "Immature medical cannabis plant" means a nonflowering part of a medical cannabis plant that is no taller than eight inches and no wider than eight inches produced from a cutting, clipping, or seedling and that is in a growing/cultivating container that is no larger than two inches wide and two inches tall that is sealed on the sides and bottom.

2.27. "Laboratory" means a place, establishment, or institution within the State of West Virginia that has been issued a certificate by the bureau's Office of Laboratory Services.

2.28. "Limited access area" means any area on a site or within a facility where:

2.28.a. Immature medical cannabis plants or medical cannabis plants are growing or being processed into medical cannabis.

2.28.b. Immature medical cannabis plants, medical cannabis plants, medical cannabis, or medical cannabis products are being loaded into or out of transport vehicles.

2.28.c. Medical cannabis is packaged for sale or stored.

2.28.d. Medical cannabis waste is processed, stored, or destroyed.

2.28.e. Surveillance system devices are stored.

2.29. "Medical cannabis" means cannabis that is grown and sold pursuant to the provisions for certified medical use as set forth in the Act and in a form set forth in the provisions of §64-110-10.

2.30. "Medical cannabis container" means a sealed, traceable, food compliant, tamper resistant, tamper evident container used for the purpose of containment of packaged medical cannabis being transported from a grower/processor to a medical cannabis organization or a laboratory.

2.31. "Medical cannabis organization" means:

2.31.a. A dispensary or a grower/processor.

2.31.b. The term does not include a health care medical cannabis organization under sections W. Va. Code §16A-13-1 *et seq.* or a clinical registrant under W. Va. Code §16A-14-1 *et seq.*

2.32. "Medical cannabis plant" means a plant which is greater than 8 vertical inches in height from where the base of the stalk emerges from the growth medium to the tallest point of the plant, or greater than 8 horizontal inches in width from the end of one branch to the end of another branch.

2.33. "Medical cannabis program" means the program authorized under the Act and implemented by the bureau.

2.34. "Medical cannabis waste" means:

2.34.a. Solid, liquid, semi-solid, or contained gaseous materials that are generated by a grower/processor or an approved laboratory.

2.34.b. The term includes:

2.34.b.1. Unused, surplus, returned, recalled, contaminated, or expired medical cannabis.

2.34.b.2. Any medical cannabis plant material that is not used in the growing, harvesting, or

processing of medical cannabis, including flowers, stems, trim, leaves, seeds, dead medical cannabis plants, dead immature medical cannabis plants, unused medical cannabis plant parts, and unused immature medical cannabis plant parts or roots.

2.34.b.3. Spent hydroponic nutrient solution.

2.34.b.4. Unused containers for growing immature medical cannabis plants or medical cannabis plants or for use in the growing and processing of medical cannabis.

2.34.b.5. Unused fertilizers and pesticides.

2.34.b.6. Unused excipients.

2.34.b.7. Wastewater.

2.35. "Municipality" incorporated city or town in this state.

2.36. "Nutrient" means the essential elements and compounds necessary for the growth, metabolism, and development of medical cannabis plants.

2.37. "Nutrient practice" means the use by a grower/processor of essential elements and compounds necessary for the growth, metabolism, and development of seeds, immature medical cannabis plants, or medical cannabis plants.

2.38. "Operations" means the time at which the bureau determines that a medical cannabis organization is ready, willing, and able to properly carry on the activity for which a permit has been issued under this rule, including the implementation of an electronic tracking system.

2.39. "Operator" means an individual who directly oversees or manages the day-to-day business functions for an applicant or permittee and has the ability to direct employee activities onsite and offsite or within a facility for which a permit is sought or has been issued under this rule.

2.40. "Patient" means an individual who:

2.40.a. Has a serious medical condition.

2.40.b. Has met the requirements for certification under the Act.

2.40.c. Is a resident of the State of West Virginia.

2.41. "Permit" means an authorization issued by the bureau to an applicant to conduct activities authorized under the Act.

2.42. "Permittee" means a person who has been issued an authorization to operate as a medical cannabis organization under the Act and this rule.

2.43. "Person" means a natural person, corporation, foundation, organization, business trust, estate, limited liability company, licensed corporation, trust, partnership, limited liability partnership, association, or other form of legal business entity.

2.44. "Practitioner" means a physician who is registered with the bureau under W. Va. Code §16A-4-1.

2.45. "Principal" means an officer, director, or person who directly or beneficially owns securities of an applicant or permittee, or a person who has a controlling interest in an applicant or permittee, or who has the ability to elect the majority of the board of directors of an applicant or permittee, or otherwise control an applicant or permittee, other than a financial institution.

2.46. "Processing" means the compounding or conversion of medical cannabis extract by a grower/processor into a medical cannabis product.

2.47. "Serious medical condition" means any of the following conditions:

2.47.a. Cancer;

2.47.b. Positive status for Human Immunodeficiency Virus or Acquired Immune Deficiency Syndrome;

2.47.c. Amyotrophic lateral sclerosis;

2.47.d. Parkinson's disease;

2.47.e. Multiple sclerosis;

2.47.f. Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity;

2.47.g. Epilepsy;

2.47.h. Neuropathies;

2.47.i. Huntington's disease;

2.47.j. Crohn's disease;

2.47.k. Post-traumatic stress disorder;

2.47.l. Intractable seizures;

2.47.m. Sickle cell anemia;

2.47.n. Severe chronic or intractable pain of neuropathic origin, or severe chronic or intractable pain.; or

2.47.o. Terminally ill.

2.48. "Site" means the total area contained within the property line boundaries in which a facility is operated by a medical cannabis organization.

2.49. "Solid waste" means the term as defined in W. Va. Code §22-15-2(31) of the Solid Waste Management Act.

2.50. "Spent hydroponic nutrient solution" means hydroponic nutrient solution that has been used and can no longer serve the purpose for which it was produced.

2.51. "Terminally ill" means a medical prognosis of life expectancy of approximately one year or less if the illness runs its normal course.

2.52. "Sample" means medical cannabis collected by an employee of an approved laboratory from a grower/processor for testing by the laboratory.

2.53. "Test sample" means an amount of medical cannabis or an amount of soil, growing medium, water, or solvents used to grow or process medical cannabis, dust, or other particles obtained from the swab of a counter or equipment used in the growing or processing of medical cannabis, or other item used in the growing or processing of medical cannabis in a facility taken by an employee of an approved laboratory or an agent of the bureau at the request of the bureau from a grower/processor and provided to an approved laboratory for testing.

2.54. "THC" means Tetrahydrocannabinol.

2.55. "Transport vehicle" means a vehicle that meets the requirements of the Act and is used to transport medical cannabis between medical cannabis organizations or between medical cannabis organizations and a laboratory.

2.56. "Unit" means the weight or volume of total usable medical cannabis in the finished product, calculated in metric units.

§64-110-3. Growers/processors generally.

3.1. The qualifications that a grower/processor must meet to receive a permit are continuing qualifications to maintain the permit.

3.2. In addition to any other requirements in the Act or this rule, a grower/processor must comply with the following:

3.2.a. A grower/processor may not engage in the business of growing, processing, possessing, selling, or offering to sell medical cannabis to another medical cannabis organization or to a clinical registrant within this state without first being issued a permit by the bureau and without first being determined operational by the bureau as required under 64CSR109.15 (Failure to be operational).

3.2.b. A grower/processor may not employ an individual at its facility who is under 18 years of age.

§64-110-4. Plans of operation.

4.1. At the time the bureau determines a grower/processor to be operational, the grower/processor must provide the bureau with a full and complete plan of operation for review that includes the following:

4.1.a. Employment policies and procedures;

4.1.b. Security policies and protocols including:

 4.1.b.1. Staff identification measures;

 4.1.b.2. Monitoring of attendance of staff and visitors;

 4.1.b.3. Alarm systems;

 4.1.b.4. Video surveillance;

 4.1.b.5. Monitoring and tracking inventory; and

 4.1.b.6. Personal security.

4.1.c. A process for growing, receiving, processing, packaging, labeling, handling, tracking, transporting, storing, disposing, and recalling of medical cannabis and a process for handling, tracking, transporting, storing, and disposing of medical cannabis waste in accordance with applicable laws, rules and regulations.

4.1.d. Workplace safety, including conducting necessary safety checks prior to starting the growing and processing of medical cannabis.

4.1.e. Contamination protocols.

4.1.f. Maintenance, cleaning, and sanitation of equipment in the facility or on the site, or both.

4.1.g. Maintenance and sanitation of the site or the facility, or both.

4.1.h. Proper handling and storage of any solvent, gas, or other chemical used in growing or processing medical cannabis in accordance with this rule and other applicable laws, rules and regulations.

4.1.i. Quality control, including regulation of the amount of THC in each process lot, proper labeling, and minimization of medical cannabis contamination.

4.1.j. Inventory maintenance and reporting procedures.

4.1.k. The investigation of complaints and potential adverse events from other medical cannabis organizations, patients, caregivers or practitioners regarding the operation of the grower/processor.

4.1.l. A recall plan meeting the requirements of section 23 (Complaints about or recall of medical cannabis).

4.2. A grower/processor must make the full and complete plan of operation available to the bureau upon request and during any inspection of the site and facility.

§64-110-5. Grower/processor facilities.

5.1. A grower/processor may only grow, store, harvest, or process medical cannabis in an indoor, enclosed, secure facility as approved by the bureau.

5.2. The following areas of a facility must be clearly marked with proper signage:

5.2.a. Medical cannabis growing and processing areas. These areas must be easily observed by the bureau and its authorized agents and by law enforcement.

5.2.b. Nongrowing and non-processing areas.

5.2.c. Limited access areas. All areas of ingress and egress to a limited access area must be clearly identified by the posting of a sign which must be not less than 12 inches wide and 12 inches long, composed of letters not less than one-half inch in height, which must state: "Do Not Enter—Limited Access Area—Access Limited to Authorized Personnel and Escorted Visitors."

5.2.d. Areas that include business offices and reception rooms.

5.3. A facility must have an enclosed secure area out of public sight for the loading and unloading of medical cannabis into and from a transport vehicle.

§64-110-6. Start-up inventory.

6.1. A grower/processor may obtain seeds or immature medical cannabis plants from outside of this state for the purpose of securing its start-up inventory. Seeds or immature medical cannabis plants obtained from outside of this state must be obtained within 30 days from the date that the bureau determines that the grower/processor is operational.

6.2. Except for as provided by subsection 6.1, a grower/processor may not obtain medical cannabis plants from outside of this state at any time.

6.3. A grower/processor must, within 24 hours of receipt, record in the electronic tracking system each seed and immature medical cannabis plant that enters the site during the 30-day period under subsection 6.1.

6.4. After the 30-day period in subsection 6.1, a grower/processor must only grow medical cannabis plants from seeds or immature medical cannabis plants located physically in its facility, or purchase seeds, immature medical cannabis plants, or medical cannabis plants from another grower/processor.

§64-110-7. Visitor access to grower/processor facilities.

7.1. A grower/processor facility may not be open to the general public. A grower/processor must require visitors, including vendors, contractors, and other individuals requiring access to the facility for purposes regarding the growing, processing, or testing of medical cannabis, to sign a visitor log and wear a visitor identification badge that is visible to others at all times while on the site and in the facility.

7.2. A grower/processor must require visitors to present government-issued identification that contains a photo to gain access to the site and facility.

7.3. No one under 18 years of age is permitted to enter a grower/processor site and facility.

7.4. A grower/processor must post a sign in a conspicuous location at each entrance of the site and facility that states: THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE. NO ONE UNDER THE AGE OF 18 IS PERMITTED TO ENTER.

7.5. A grower/processor must do all of the following when admitting a visitor to its site and facility:

7.5.a. Require the visitor to sign a visitor log upon entering and leaving the facility.

7.5.b. Check the visitor's government-issued identification to verify that the name on the identification provided matches the name in the visitor log. A photocopy of the identification must be retained with the log.

7.5.c. Issue a visitor identification badge with the visitor's name and company, if applicable, and a badge number.

7.5.d. Escort the visitor while the visitor remains in the facility or on the site.

7.5.e. Ensure that the visitor does not touch any medical cannabis plant or medical cannabis located in a limited access area.

7.6. The following apply to the visitor log required under subsections 7.1 and 7.5:

7.6.a. The grower/processor must maintain the log for four years and make the log available to the bureau, law enforcement, and other federal or state government officials upon request if necessary, to perform the government officials' functions and duties.

7.6.b. The log must include the full name of each visitor, the visitor identification badge number, the time of arrival, the time of departure and the purpose of the visit, including the areas of the site and the facility visited and the name of each employee visited.

7.7. This section does not limit the right of the bureau or its authorized agents, or other federal, state government officials, from entering any area of a grower/processor site and facility if necessary, to perform the governmental officials' functions and duties.

7.8. A principal, financial backer, operator or an employee of a grower/processor may not receive any type of consideration or compensation for allowing a visitor to enter a limited access area.

§64-110-8. Security and surveillance.

8.1. A grower/processor must have security and surveillance systems, utilizing commercial-grade equipment, to prevent unauthorized entry and to prevent and detect an adverse loss. The security and surveillance systems must include the following:

8.1.a. A professionally monitored security alarm system that includes the following:

8.1.a.1. Coverage of all facility entrances and exits; rooms with exterior windows, exterior walls, roof hatches or skylights; storage rooms, including those that contain medical cannabis and safes;

and the perimeter of the facility;

8.1.a.2. A silent security alarm system signal, known as a duress alarm, generated by the entry of a designated code into an arming station to signal that the alarm user is being forced to turn off the system;

8.1.a.3. An audible security alarm system signal, known as a panic alarm, generated by the manual activation of a device intended to signal a life-threatening or emergency situation requiring law enforcement response;

8.1.a.4. A silent alarm signal, known as a holdup alarm, generated by the manual activation of a device intended to signal a robbery in progress;

8.1.a.5. An electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message requesting dispatch, when activated, over a telephone line, radio or other communication system to a law enforcement, public safety, or emergency services agency;

8.1.a.6. A failure notification system that provides an audible, text, or visual notification of any failure in the systems. The failure notification system must provide by telephone, e-mail, or text message an alert to a designated security person within the facility within five minutes after the failure;

8.1.a.7. Smoke and fire alarms

8.1.a.8. Auxiliary power sufficient to maintain operation of specified growing and processing areas identified in the grower/processor's plan of operation for at least 48 hours following a power outage;

8.1.a.9. The ability to ensure all access doors are not solely controlled by an electronic access panel to prevent locks from becoming released during a power outage; and

8.1.a.10. Motion detectors; and

8.1.b. A professionally monitored security and surveillance system that is operational 24 hours a day, seven days a week, and records all activity in images capable of clearly revealing facial detail. The security and surveillance system must include the following:

8.1.b.1. Fixed camera placement that allows for a clear image of all individuals and activities in and around the following:

8.1.b.1.A. All limited access areas;

8.1.b.1.B. A room or area containing a security and surveillance system storage device or equipment;

8.1.b.1.C. Entrances to and exits from the facility. Entrances and exits must be recorded from both indoor and outdoor vantage points;

8.1.b.1.D. Rooms with exterior windows, exterior walls, roof hatches, or skylights and storage rooms, including those that may contain medical cannabis and safes; and

- 8.1.b.1.E. Twenty feet from the exterior of the perimeter of the facility;
 - 8.1.b.2. Auxiliary power sufficient to maintain operation for at least 48 hours following a power outage;
 - 8.1.b.3. Ability to operate under the normal lighting conditions of each area under surveillance;
 - 8.1.b.4. Ability to immediately produce a clear, color, still photograph in a digital format that meets the requirements of this subsection;
- 8.1.c. Ability to clearly and accurately display the date and time. The date and time must be synchronized and set correctly and may not significantly obscure the picture;
- 8.1.d. Ability to record all images captured by each surveillance camera in a format that may be easily accessed for a period not less than 180 days, unless otherwise required for investigative or litigation purposes as described in paragraph 8.2.f.2. The recordings must be kept:
- 8.1.d.1. At the facility:
 - 8.1.d.1.A. In a locked cabinet, closet or other secure place to protect it from tampering or theft; and
 - 8.1.d.1.B. In a limited access area or other room to which access is limited to authorized individuals; or
 - 8.1.d.2. At a secure location other than the location of the facility if approved by the bureau; and
- 8.1.e. A security alarm system separate from the facility's primary security system covering the limited access area or other room where the recordings under subdivision 8.1.d. are stored. The separate security alarm system must meet the same requirements as the facility's primary security alarm system.
- 8.2. The following apply regarding the inspection, servicing or alteration of, and the upgrade to, the site's and facility's security and surveillance systems:
- 8.2.a. The systems must be inspected, and all devices tested once every year by a qualified alarm system vendor and a qualified surveillance system vendor, as approved by the bureau;
 - 8.2.b. The grower/processor must conduct maintenance inspections once every month to ensure that any repairs, alterations, or upgrades to the security and surveillance systems are made for the proper operation of the systems;
 - 8.2.c. The grower/processor must retain at the facility, for at least four years, records of all inspections, servicing, alterations, and upgrades performed on the systems and must make the records available to the bureau and its authorized agents within two business days following a request;

8.2.d. In the event of a mechanical malfunction of the security or surveillance system that a grower/processor anticipates will exceed an eight-hour period, the grower/processor must notify the bureau immediately and, with bureau approval, provide alternative security measures that may include closure of the facility;

8.2.e. The grower/processor must designate an employee to continuously monitor the security and surveillance systems at the facility; and

8.2.f. The following apply regarding records retention:

8.2.f.1. Within two business days following a request, a grower/processor must provide up to four screen captures of an unaltered copy of a video surveillance recording to the bureau or its authorized agents, law enforcement, or other federal or state government officials if necessary to perform the governmental officials' functions and duties; and

8.2.f.2. If a grower/processor has been notified in writing by the bureau or its authorized agents, law enforcement, or other federal or state government officials of a pending criminal or administrative investigation for which a recording may contain relevant information, the grower/processor must retain an unaltered copy of the recording for two years or until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the grower/processor that it is not necessary to retain the recording, whichever is longer.

8.3. The grower/processor must install commercial-grade, nonresidential doors and door locks on each external door of the facility. Keys or key codes for all doors must remain in the possession of designated authorized individuals.

8.4. During all nonworking hours, all entrances to and exits from the site and facility must be securely locked.

8.5. The grower/processor must have an electronic back-up system for all electronic records.

8.6. The grower/processor must install lighting to ensure proper surveillance inside and outside of the facility.

8.7. A grower/processor must limit access to a room containing security and surveillance monitoring equipment to persons who are essential to maintaining security and surveillance operations; federal, state and local law enforcement; security and surveillance system service employees; the bureau or its authorized agents; and other persons with the prior written approval of the bureau. The following apply:

8.7.a. A grower/processor must make available to the bureau or the bureau's authorized agents, upon request, a current list of authorized employees and service employees or contractors who have access to any security and surveillance areas; and

8.7.b. A grower/processor must keep security and surveillance rooms locked at all times and may not use these rooms for any other purpose or function.

§64-110-9. Requirements for growing and processing medical cannabis.

9.1. A grower/processor must use only pesticides, fungicides or herbicides that are approved by the

United States Department of Agriculture for use on medical cannabis plants and listed in Appendix A (Acceptable pesticide active ingredients for use). The bureau will periodically publish a notice in the State Register updating the list of pesticides, fungicides or herbicides.

9.2. A grower/processor must use the pesticides, fungicides or herbicides listed in Appendix A in a manner that is approved by the United States Department of Agriculture on the basis of federal law and regulations.

9.3. A grower/processor must maintain a log of all actions taken to detect pests or pathogens, and the measures taken for control.

9.4. A grower/processor must:

9.4.a. Use appropriate nutrient practices;

9.4.b. Use a fertilizer or hydroponic solution of a type, formulation and at a rate to support healthy growth of plants; and

9.4.c. Maintain records of the type and amounts of fertilizer and any growth additives used.

9.5. A grower/processor must perform visual inspections of growing plants and harvested plant material to ensure there is no visible mold, mildew, pests, rot, or grey or black plant material that is greater than an acceptable level as determined by the bureau.

9.6. A grower/processor may not add any additional active ingredients or materials to medical cannabis that alters the color, appearance, smell, taste, effect, or weight of the medical cannabis unless the grower/processor has first obtained the prior written approval of the bureau. Excipients must be pharmaceutical grade, unless otherwise approved by the bureau.

9.7. A grower/processor must have a separate and secure area for temporary storage of medical cannabis that is awaiting disposal by the grower/processor.

9.8. A grower/processor must only process the parts of the medical cannabis plant that:

9.8.a. Are free of seeds and stems;

9.8.b. Are free of dirt, sand, debris, or other foreign matter; and

9.8.c. Contain a level of mold, rot, or other fungus or bacterial diseases acceptable to the bureau.

9.9. A grower/processor must process the medical cannabis plants in a safe and sanitary manner. The following apply:

9.9.a. Medical cannabis, raw material and other product used in the processing of medical cannabis must be handled on food-grade stainless steel benches or tables;

9.9.b. Proper sanitation must be maintained; and

9.9.c. Proper rodent, bird and pest exclusion practices must be employed.

9.10. A grower/processor must install a system to monitor, record and regulate:

9.10.a. Temperature;

9.10.b. Humidity;

9.10.c. Ventilation;

9.10.d. Lighting; and

9.10.e. Water supply.

§64-110-10. Forms of medical cannabis.

10.1. A grower/processor may only process medical cannabis for dispensing to a patient or caregiver in the following forms:

10.1.a. Pill;

10.1.b. Oil;

10.1.c. Topical forms, including gel, creams, and ointments;

10.1.d. A form medically appropriate for administration by vaporization or nebulization;

10.1.e. Liquid;

10.1.f. Dermal patch; or

10.1.g. Dry leaf or plant form.

10.2. A grower/processor may not manufacture, produce, or assemble any medical cannabis product, instrument, or device without prior written approval of the bureau.

§64-110-11. Limit on medical cannabis processing.

11.1. In the form intended to be sold to another medical cannabis organization, medical cannabis must have a specific concentration of total THC and total CBD and must have a consistent cannabinoid profile. The concentration of the following cannabinoids, at a minimum, must be reported to the bureau by an approved laboratory and include the following on the label:

11.1.a. Tetrahydrocannabinol (THC);

11.1.b. Tetrahydrocannabinol acid (THCA);

11.1.c. Tetrahydrocannabivarin (THCV);

11.1.d. Cannabidiol (CBD);

- 11.1.e. Cannabinadiolic acid (CBDA);
- 11.1.f. Cannabidivarine (CBDV);
- 11.1.g. Cannabinol (CBN);
- 11.1.h. Cannabigerol (CBG);
- 11.1.i. Cannabichromene (CBC); and
- 11.1.j. Any other cannabinoid component at > 0.1percent.

11.2. Within the first six months after the bureau determines the grower/processor to be operational, the grower/processor must provide the bureau with a forecast of the amount of medical cannabis it projects it will produce and in what form. The grower/processor must notify the bureau in writing immediately upon becoming aware of a potential increase or decrease in the forecasted amount occurring within any subsequent six-month period.

§64-110-12. Inventory data.

12.1. A grower/processor must maintain the following inventory data in its electronic tracking system which must include an accounting of and an identifying tracking number for:

- 12.1.a. The number, weight, and type of seeds;
- 12.1.b. The number of immature medical cannabis plants;
- 12.1.c. The number of medical cannabis plants;
- 12.1.d. The number of medical cannabis products ready for sale; and
- 12.1.e. The number of damaged, defective, expired, or contaminated seeds, immature medical cannabis plants, medical cannabis plants, and medical cannabis products awaiting disposal.

12.2. A grower/processor must establish inventory controls and procedures to conduct inventory reviews and comprehensive inventories at its facility. The following apply:

12.2.a. Inventory reviews of medical cannabis plants in the process of growing and medical cannabis and medical cannabis products that are being stored for future sale must be conducted monthly;

12.2.b. Comprehensive inventories of seeds, immature medical cannabis plants, medical cannabis plants, medical cannabis, and medical cannabis products must be conducted at least annually; and

12.3. A written or electronic record must be created and maintained of each inventory conducted under subsection 12.2. that includes the date of the inventory, a summary of the inventory findings, and the employee identification numbers and titles or positions of the individuals who conducted the inventory.

§64-110-13. Equipment, operation and maintenance.

13.1. A grower/processor facility must have a written process in place to maintain the sanitation and operation of equipment that comes into contact with medical cannabis to prevent contamination. The

grower/processor must provide a copy of the written process to the bureau upon request.

13.2. As part of the written process required under subsection 13.1., a grower/processor must:

13.2.a. Routinely calibrate, check and inspect the following to ensure accuracy:

13.2.a.1. Automatic, mechanical, or electronic equipment;

13.2.a.2. Scales, balances, or other measurement devices used in the grower/processor's operations; and

13.2.b. Maintain an accurate log recording the following:

13.2.b.1. Maintenance of equipment;

13.2.b.2. Cleaning of equipment; and

13.2.b.3. Calibration of equipment.

§64-110-14. Storage requirements.

14.1. A grower/processor must have separate locked limited access areas for storage of seeds, immature medical cannabis plants, medical cannabis plants, and medical cannabis that are expired, damaged, deteriorated, mislabeled, contaminated, recalled, or whose containers or packaging have been opened or breached until the seeds, immature medical cannabis plants, medical cannabis plants, and medical cannabis are destroyed or otherwise disposed of as required under section 22 (Management and disposal of medical cannabis waste).

14.2. A grower/processor must maintain all storage areas in a clean and orderly condition and free from infestation by insects, rodents, birds and pests.

§64-110-15. Sanitation and safety in a facility.

15.1. A grower/processor must maintain its facility in a sanitary condition to limit the potential for contamination or adulteration of the medical cannabis grown and processed in the facility. The following apply:

15.1.a. Equipment and surfaces, including floors, counters, walls, and ceilings, must be cleaned and sanitized as frequently as necessary to protect against contamination, using a sanitizing agent registered by the United States Environmental Protection Agency, in accordance with the instructions printed on the label. Equipment and utensils must be so designed and of such material and workmanship as to be capable of being adequately cleaned.

15.1.b. Trash must be properly removed.

15.1.c. Floors, walls and ceilings must be kept in good repair.

15.1.d. Equipment, counters and surfaces for processing must be food grade quality and may not react adversely with any solvent being used.

15.1.e. Adequate protection against pests must be provided through the use of integrated pest management practices and techniques that identify and manage plant pathogens and pest problems, and

the regular disposal of trash to prevent infestation.

15.1.f. Toxic cleaning compounds, sanitizing agents, solvents used in the growing and processing of medical cannabis, and pesticide chemicals must be labeled and stored in a manner that prevents contamination of seeds, immature medical cannabis plants, medical cannabis plants, and medical cannabis, and in a manner that otherwise complies with other applicable laws, rules, and regulations.

15.2. An employee must conform to sanitary practices while on duty, including the following:

15.2.a. Maintaining adequate personal hygiene;

15.2.b. Wearing proper clothing, including gloves; and

15.2.c. Washing hands thoroughly in an adequate hand-washing area before starting work and at any other time when hands may have become soiled or contaminated.

15.3. A grower/processor must provide its employees and visitors with adequate and convenient hand-washing facilities furnished with running water at a temperature suitable for sanitizing hands. The following apply:

15.3.a. Hand-washing facilities must be located in processing areas and where good sanitary practices require employees to wash and sanitize their hands; and

15.3.b. Effective nontoxic sanitizing cleansers and sanitary towel service or suitable drying devices must be provided.

15.4. A grower/processor must provide its employees and visitors with adequate, readily accessible lavatories that are maintained in a sanitary condition and in good repair.

15.5. A grower/processor must ensure that its facility is provided with a water supply sufficient for its operations, which must be derived from a source that is a public water system, or a nonpublic system that is capable of providing a safe, potable and adequate supply of water to meet the operational needs of the facility.

15.6. A grower/processor must comply with all other applicable state and local building code requirements.

§64-110-16. Packaging and labeling of medical cannabis.

16.1. A grower/processor must package and label at its facility each form of medical cannabis prepared for sale. The original seal of a package may not be broken, except for quality control testing at an approved laboratory, for adverse loss investigations conducted by the bureau or by a dispensary that purchased the medical cannabis.

16.2. A grower/processor must package the medical cannabis in a package that minimizes exposure to oxygen and that is:

16.2.a. Child-resistant;

16.2.b. Tamper-proof or tamper-evident;

16.2.c. Light-resistant and opaque; and

16.2.d. Resealable.

16.3. A grower/processor must identify each process lot of medical cannabis with a unique identifier.

16.4. A grower/processor must obtain the prior written approval of the bureau of the content of any label to be affixed to a medical cannabis package. Each label must:

16.4.a. Be easily readable;

16.4.b. Made of weather-resistant and tamper-resistant materials;

16.4.c. Be conspicuously placed on the package;

16.4.d. Include the name, address, and permit number of the grower/processor;

16.4.e. List the form, quantity, and weight of medical cannabis included in the package;

16.4.f. List the number of individual doses contained within the package, and the species and percentage of THC and CBD;

16.4.g. Contain an identifier that is unique to a particular harvest batch of medical cannabis, including the number assigned to each harvest lot or process lot in the harvest batch;

16.4.h. Include the date the medical cannabis was packaged;

16.4.i. State the employee identification number of the employee preparing the package and packaging the medical cannabis;

16.4.j. State the employee identification number of the employee shipping the package, if different than the employee described in subdivision 16.4.i.;

16.4.k. Contain the name and address of the dispensary to which the package is to be sold;

16.4.l. List the date of expiration of the medical cannabis;

16.4.m. Include instructions for proper storage of the medical cannabis in the package;

16.4.n. Contain the following warning stating: "This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the practitioner who issued the certification and, in the case of breastfeeding, the infant's pediatrician. This product might impair the ability to drive or operate heavy machinery. Keep out of reach of children.";

16.4.o. Contain a warning that the medical cannabis must be kept in the original container in which it was dispensed; and

16.4.p. Contain a warning that unauthorized use is unlawful and will subject the purchaser to criminal penalties.

16.5. Labeling by a grower/processor of any medical cannabis may not bear:

16.5.a. Any resemblance to the trademarked, characteristic, or product-specialized packaging of any commercially available food or beverage product;

16.5.b. Any statement, artwork, or design that could reasonably lead an individual to believe that the package contains anything other than medical cannabis;

16.5.c. Any seal, flag, crest, coat of arms, or other insignia that could reasonably mislead an individual to believe that the product has been endorsed, manufactured, or approved for use by any state, county, or municipality or any agency thereof; or

16.5.d. Any cartoon, color scheme, image, graphic, or feature that might make the package attractive to children.

§64-110-17. Transportation of medical cannabis.

17.1. A grower/processor may transport and deliver medical cannabis to a medical cannabis organization or an approved laboratory in this state in accordance with this section. The following apply:

17.1.a. A grower/processor may deliver medical cannabis to a medical cannabis organization or an approved laboratory only between 7:00 a.m. and 9:00 p.m.;

17.1.b. A grower/processor may contract with a third-party contractor for delivery so long as the contractor complies with this section;

17.1.c. A grower/processor may not transport medical cannabis to any location outside of this state; and

17.1.d. A grower/processor must use a global positioning system to ensure safe, efficient delivery of the medical cannabis to a medical cannabis organization or an approved laboratory.

17.2. Vehicles permitted to transport medical cannabis must:

17.2.a. Be equipped with a secure lockbox or locking cargo area;

17.2.b. Have no markings that would either identify or indicate that the vehicle is being used to transport medical cannabis;

17.2.c. Be capable of being temperature-controlled for perishable medical cannabis, as appropriate;

17.2.d. Display current state inspection stickers and maintain a current state vehicle registration; and

17.2.e. Be insured in an amount that is commercially reasonable and appropriate.

17.3. A transport vehicle must be staffed with a delivery team consisting of at least two individuals and comply with the following:

17.3.a. At least one delivery team member must remain with the vehicle at all times that the vehicle contains medical cannabis;

17.3.b. Each delivery team member must have access to a secure form of communication with the grower/processor, such as a cellular telephone, at all times that the vehicle contains medical cannabis;

17.3.c. Each delivery team member must carry an identification badge or card at all times and

must, upon demand, produce it to the bureau or its authorized agents, law enforcement, or other federal or state government officials if necessary, to perform the government officials' functions and duties;

17.3.d. Each delivery team member must have a valid driver's license; and

17.3.e. While on duty, a delivery team member may not wear any clothing or symbols that may indicate ownership or possession of medical cannabis.

17.4. Medical cannabis stored inside the transport vehicle may not be visible from the outside of the transport vehicle.

17.5. Except as provided in subsection 17.8., a delivery team shall proceed in a transport vehicle from the facility, where the medical cannabis is loaded, directly to the medical cannabis organization or approved laboratory, where the medical cannabis is unloaded, without unnecessary delays. Notwithstanding the foregoing, a transport vehicle may make stops at multiple facilities or approved laboratories, as appropriate, to deliver medical cannabis.

17.6. A grower/processor must immediately report to the bureau, either through a designated phone line established by the bureau or by electronic communication with the bureau in a manner prescribed by the bureau, vehicle accidents, diversions, losses, or other reportable events that occur during transport of medical cannabis.

17.7. A grower/processor must notify the bureau daily of its delivery schedule, including routes and delivery times, either through a designated phone line established by the bureau or by electronic communication with the bureau in a manner prescribed by the bureau.

17.8. A transport vehicle is subject to inspection by the bureau or its authorized agents, law enforcement, or other federal or state government officials if necessary, to perform the government officials' functions and duties. A transport vehicle may be stopped and inspected along its delivery route or at any medical cannabis organization or approved laboratory.

§64-110-18. Transport manifest.

18.1. A grower/processor must generate a printed or electronic transport manifest that accompanies every transport vehicle and contains the following information:

18.1.a. The name, address, and permit number of the grower/processor and the name of and contact information for a representative of the grower/processor who has direct knowledge of the transport;

18.1.b. The name, address, and permit number of the medical cannabis organization or approved laboratory receiving the delivery and the name of and contact information for a representative of the medical cannabis organization or approved laboratory;

18.1.c. The quantity, by weight or unit, of each medical cannabis harvest batch, harvest lot, or process lot contained in the transport, along with the identification number for each batch or lot;

18.1.d. The date and approximate time of departure;

18.1.e. The date and approximate time of arrival;

18.1.f. The transport vehicle's make and model and license plate number; and

18.1.g. The identification number of each member of the delivery team accompanying the transport.

18.2. When a delivery team delivers medical cannabis to multiple medical cannabis organizations or approved laboratories, the transport manifest must correctly reflect the specific medical cannabis in transit. Each recipient must provide the grower/processor with a printed receipt for the medical cannabis received.

18.3. All medical cannabis being transported must be packaged in shipping containers and labeled in accordance with section 16 (Packaging and labeling of medical cannabis).

18.4. A grower/processor must provide a copy of the transport manifest to the recipient receiving the medical cannabis described in the transport manifest. To maintain confidentiality, a grower/processor may prepare separate manifests for each recipient.

18.5. A grower/processor must, if requested, provide a copy of the printed transport manifest, and any printed receipts for medical cannabis being transported, to the bureau or its authorized agents, law enforcement, or other federal or state government officials if necessary to perform the government officials' functions and duties.

§64-110-19. Transportation of seeds, immature medical cannabis plants and medical cannabis plants.

19.1. A grower/processor may transport seeds, immature medical cannabis plants, and medical cannabis plants within this state for the growing and processing of medical cannabis.

19.2. A grower/processor may not transport seeds, immature medical cannabis plants, or medical cannabis plants to a location outside of this state.

19.3. A grower/processor's authorization to transport seeds, immature medical cannabis plants, or medical cannabis plants are subject to the requirements of sections 17, 18 and 20 (Transportation of medical cannabis; transport manifest; and evidence of adverse loss during transport).

§64-110-20. Evidence of adverse loss during transport.

20.1. If a grower/processor receiving a delivery of medical cannabis or medical cannabis products from a medical cannabis organization discovers a discrepancy in the transport manifest upon delivery, the grower/processor must refuse acceptance of the delivery and immediately report the discrepancy to the bureau either through a designated phone line established by the bureau or by electronic communication with the bureau in a manner prescribed by the bureau, and to the appropriate law enforcement authorities.

20.2. If a grower/processor discovers evidence of, or reasonably suspects, a theft, or diversion of medical cannabis or medical cannabis products during transport, the grower/processor must immediately report its findings or suspicions to the bureau either through a designated phone line established by the bureau or by electronic communication with the bureau in a manner prescribed by the bureau and to law enforcement.

20.3. If a grower/processor discovers a discrepancy in the transport manifest, the grower/processor must:

20.3.a. Conduct an investigation;

20.3.b. Amend the grower/processor's standard plan of operation, if necessary, to prevent future discrepancies between the quantity or description of inventory listed in the transport manifest and the quantity or description of inventory delivered; and

20.3.c. Submit a report of the investigation to the bureau. The following apply:

20.3.c.1. A written preliminary report of the investigation must be submitted to the bureau within seven days of discovering the discrepancy; and

20.3.c.2. A final written report of the investigation must be submitted to the bureau within 30 days of discovering the discrepancy.

§64-110-21. Electronic tracking system.

A grower/processor must use the electronic tracking system prescribed by the bureau containing the requirements in W. Va. Code §16A-7-1. The bureau will publish notice of the electronic tracking system to be utilized by a grower/processor in the State Register 60 days prior to the implementation date of the system.

§64-110-22. Management and disposal of medical cannabis waste.

22.1. Medical cannabis waste generated by a grower/processor or an approved laboratory must be stored, collected and transported in accordance with W. Va. Code §22-15-1 *et seq.* (Solid Waste Management Act), provided the medical cannabis waste is not hazardous.

22.2. The following types of medical cannabis waste must be rendered unusable and unrecognizable prior to being transported from a grower/processor or an approved laboratory:

22.2.a. Unused, surplus, returned, recalled, contaminated, or expired medical cannabis; and

22.2.b. Any medical cannabis plant material that is not used in the growing, harvesting, or processing of medical cannabis, including flowers, stems, trim, leaves, seeds, dead medical cannabis plants, dead immature medical cannabis plants, unused medical cannabis plant parts, and unused immature medical cannabis plant parts or roots.

22.3. Medical cannabis waste is unusable and unrecognizable if all components of the waste are indistinguishable and incapable of being ingested, inhaled, injected, swallowed, or otherwise used for certified medical use. Acceptable methods of rendering the waste unusable and unrecognizable include thermal treatment or melting; shredding, grinding or tearing; and incorporating the medical cannabis waste with other municipal waste.

22.4. Unusable and unrecognizable medical cannabis waste identified in subsection 22.2. and other solid or semi-solid medical cannabis waste that is not hazardous must be disposed of at a permitted municipal waste landfill or processed at a permitted resource recovery facility or incinerator.

22.5. Wastewater or spent hydroponic nutrient solution generated or produced from the growing, harvesting, or processing of immature medical cannabis plants or medical cannabis plants must be managed in accordance with one of the following:

22.5.a. Discharged into a permitted sewage treatment system in accordance with local, federal and state requirements, including the Water Pollution Control Act (W. Va. Code §22-11-1 *et seq.*);

22.5.b. Treated and discharged into waters of the state under a National Pollutant Discharge Elimination System permit or water quality management permit in accordance with the requirements of including the Water Pollution Control Act (W. Va. Code §22-11-1 *et seq.*); and

22.5.c. Disposed in a solid waste landfill if placed in a container that is less than 1 gallon in size.

22.6. Hazardous waste must be managed in accordance with federal and state law, rules and regulations related to hazardous waste, including sections 3001—3024 of the Resource Conservation and Recovery Act of 1976 (42 U.S.C.A. §§ 6921—6939g), the Hazardous Waste Management Act (W. Va. Code §22-18-1 *et seq.*) and rules promulgated thereunder.

22.7. The type of medical cannabis waste identified in subdivision 22.2.b. may be composted and beneficially used at the grower/processor facility through a permit provided the requirements of 33CSR3 (Yard Waste Composting Rule) are satisfied, and the compost is beneficially used at the grower/processor facility as a soil substitute, soil conditioner, soil amendment, fertilizer, or mulch.

§64-110-23. Complaints about or recall of medical cannabis.

23.1. A dispensary shall notify the bureau and the grower/processor immediately upon becoming aware of any complaint made to the dispensary by a patient, caregiver, or practitioner who reports an adverse event from using medical cannabis purchased by the dispensary from the grower/processor. A grower/processor must investigate the report. The following apply:

23.1.a. A grower/processor must investigate a complaint to determine if a voluntary or mandatory recall of medical cannabis is necessary or if any further action is required; and

23.1.b. If a grower/processor determines that further action is not required, the grower/processor must notify the bureau of its decision and, within 24 hours, submit a written report to the bureau stating its rationale for not taking further action.

23.2. The following apply to voluntary recalls:

23.2.a. A grower/processor may voluntarily recall medical cannabis from the market at its discretion for reasons that do not pose a risk to public health and safety; and

23.2.b. If a grower/processor initiates a recall for a reason that does not pose a risk to public health and safety, the grower/processor must notify the bureau at the time the grower/processor begins the recall.

23.3. The following apply to mandatory recalls:

23.3.a. If a grower/processor discovers that a condition relating to the medical cannabis grown or processed at its facility poses a risk to public health and safety, the grower/processor must:

23.3.a.1. Immediately notify the bureau by phone; and

23.3.a.2. Secure, isolate and prevent the distribution of the medical cannabis that may have been affected by the condition and remains in its possession. The grower/processor may not dispose of affected medical cannabis prior to notifying the bureau and coordinating the disposal with the bureau.

23.3.b. If a grower/processor fails to cooperate with the bureau in a recall, or fails to immediately notify the bureau of a need for a recall under subdivision 23.1, the bureau may seek a cease and desist order under 64CSR109.20 (General penalties and sanctions) and the grower/processor may be subject to any other penalties or sanctions provided for in the Act or this rule.

23.4. A grower/processor's recall plan must include the following:

23.4.a. Designation of one or more employees to serve as the recall coordinators. A recall coordinator must be responsible for, among other duties, accepting the recalled medical cannabis;

23.4.b. Procedures for identifying and isolating the affected medical cannabis to prevent or minimize its distribution to patients, caregivers, and other medical cannabis organizations and approved laboratories;

23.4.c. Procedures to retrieve and dispose of the affected medical cannabis; and

23.4.d. A communications plan to notify those affected by the recall, including:

23.4.d.1. The manner in which the grower/processor will notify other medical cannabis organizations or approved laboratories in possession of medical cannabis subject to the recall;

23.4.d.2. The use of press releases and other appropriate notifications to ensure that patients and caregivers are notified of the recall if the affected medical cannabis was dispensed to patients and caregivers;

23.4.e. Procedures for notifying the bureau; and

23.4.f. Procedures for entering information relating to the recall into the grower/processor's electronic tracking system.

23.5. A grower/processor must follow the procedures outlined in its recall plan, unless the grower/processor obtains the prior written approval of the bureau. The grower/processor must conduct recall procedures in a manner that maximizes the recall of affected medical cannabis and minimizes risks to public health and safety.

23.6. A grower/processor must coordinate the disposal of recalled medical cannabis with the bureau. The bureau or its authorized agents may oversee the disposal to ensure that the recalled medical cannabis is disposed of in a manner that will not pose a risk to public health and safety.

23.7. The grower/processor must enter information relevant to the recall into the electronic tracking system as part of the daily inventory, including:

23.7.a. The total amount of recalled medical cannabis, including types, forms, harvest batches, harvest lots, and process lots, if applicable;

23.7.b. The amount of recalled medical cannabis received by the grower/processor, including types, forms, harvest batches, harvest lots, and process lots, if applicable, by date and time;

23.7.c. The total amount of recalled medical cannabis returned to the grower/processor, including types, forms, harvest batches, harvest lots, and process lots, if applicable;

23.7.d. The names of the recall coordinators;

23.7.e. From whom the recalled medical cannabis was received;

23.7.f. The means of transport of the recalled medical cannabis;

23.7.g. The reason for the recall;

23.7.h. The number of recalled samples or test samples, types, forms, harvest batches, harvest lots, and process lots, if applicable, sent to approved laboratories, the names and addresses of the approved laboratories, the dates of testing, and the results by sample or test sample;

23.7.i. The manner of disposal of the recalled medical cannabis, including:

23.7.i.1. The name of the individual overseeing the disposal of the recalled medical cannabis;

23.7.i.2. The name of the disposal company, if applicable;

23.7.i.3. The method of disposal;

23.7.i.4. The date of disposal;

23.7.i.5. The amount disposed of by types, forms, harvest batches, harvest lots, and process lots, if applicable; and

23.7.j. Any other information required by the bureau.

§64-110-24. Pesticides.

24.1. The use of a pesticide by a grower/processor in the growing or processing of medical cannabis must be in accordance with the West Virginia Pesticide Control Act (W. Va. Code §19-16A-1 *et seq.*) and this rule.

24.2. The bureau and the West Virginia Department of Agriculture will cooperate to inspect for and enforce the requirements of this section.

24.3. The following apply regarding recordkeeping requirements for pesticide applications:

24.3.a. The grower/processor shall maintain a record of each application of a pesticide. The record must include the following information:

24.3.a.1. The date of application. For a pesticide requiring a re-entry time, the date of application must include the hour completed;

24.3.a.2. The place of application, including the specific block, section, or immature medical cannabis plants or medical cannabis plants treated;

24.3.a.3. The size of the area treated;

24.3.a.4. The product name of every pesticide used;

24.3.a.5. The United States Environmental Protection Agency product registration number. This requirement is unnecessary for products exempted under section 25 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C.A. § 136w);

24.3.a.6. The total amount of every pesticide used in pounds, ounces, gallons, or liters applied to a treated area;

24.3.a.7. The dosage or rate of application of every pesticide used;

24.3.a.8. If applicable, the employee identification numbers of the individuals involved in making the pesticide and the permit or certification numbers of the individuals making or supervising the application; and

24.3.a.9. Copies of pesticide labels and Safety Data Sheets for the pesticides used at the facility.

24.3.b. A record required to be kept under this section must be completed within 24 hours of the completion of the application and maintained for at least four years. A record must be made immediately available to the bureau or its authorized agents and medical personnel or first responders in an emergency. A record must be made available to the bureau upon request.

24.4. For purposes of enforcement, the West Virginia Pesticide Control Act and 61CSR12A, 61CSR12G, and 61CSR12H are incorporated by reference and adopted as standards for use by the bureau in enforcing this section.

24.5. A grower/processor must only use the pesticide active ingredients in *Appendix A* in the growing and processing of medical cannabis.

24.6. The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise:

24.6.a. "Defoliant" means a substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

24.6.b. "Desiccant" means a substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

24.6.c. "Pesticide" means a substance or mixture of substances intended for preventing, destroying, repelling or mitigating a pest, and a substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant.

24.6.d. "Plant regulator" means:

24.6.d.1. A substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but may not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments.

24.6.d.2. The term does not include any of the nutrient mixtures or soil amendments commonly known as vitamin-hormone horticultural products, which are intended for improvement, maintenance, survival, health and propagation of plants, and are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

§64-110-25. Treatment and quarantine orders.

25.1. If a grower/processor fails or refuses to eradicate a plant pest that is found at its facility, the

bureau, in cooperation with the West Virginia Department of Agriculture, may issue and enforce a treatment order against the grower/processor, including an order to eradicate, for any immature medical cannabis plants or medical cannabis plants that may carry or harbor the plant pest. The order will be issued in writing and set forth the necessary treatment, control or eradication measures required. If the grower/processor fails or refuses to comply with the order, the bureau, acting in cooperation with the West Virginia Department of Agriculture, may carry out the control measures established in the treatment order with all expenses associated with the measures accruing to the grower/processor.

25.2. The West Virginia Department of Agriculture, acting with the cooperation of the bureau, may establish a quarantine to prevent the dissemination of plant pests within this state or to prevent or delay the introduction of a plant pest into this state from any country, state, or territory. The following apply:

25.2.a. Upon finding a plant pest in a facility that has the potential to cause serious damage to other grower/processors or to agriculture in general, the geographic area in which the plant pest was found and any adjacent areas as the West Virginia Department of Agriculture deems necessary may be quarantined.

25.2.b. The quarantine order will establish conditions and restrictions determined by the West Virginia Department of Agriculture to be necessary to prevent or reduce the movement of the plant pest from the quarantined area. Vehicles or any means of conveyance suspected of carrying the plant pest may also be subject to quarantine and a treatment order under subsection 25.1. may be issued as necessary to eradicate the plant pest.

25.2.c. The quarantine order may regulate the planting, growing, or harvesting of any immature medical cannabis plants, or medical cannabis plants that serve as a host or reservoir for the plant pest within the quarantined area and may include prohibiting the processing of a specific harvest batch or harvest lot of medical cannabis within a specific geographic area or during a specified time period. An immature medical cannabis plant or medical cannabis plant suspected of harboring the plant pest may be ordered to be treated or destroyed.

Appendix A. Acceptable Pesticide Active Ingredients for Use

The following pesticides can be used legally in the growing and processing of medical cannabis and in accordance with the West Virginia Pesticide Control Act (W. Va. Code §19-16A-1 *et seq.*). Products containing the following active ingredients must also be labeled for use in greenhouses on food crops to qualify.

EPA Status	Pesticide Type	Comments	Active Ingredient
25(b)	Insecticide		Castor Oil
25(b)	Insecticide		Castor Oil
25(b)	Insecticide		Cinnamon
25(b)	Fungicide, Insecticide		Cinnamon Oil
25(b)	Fungicide, Insecticide		Citric Acid
25(b)	Bactericide, Fungicide		Clove
25(b)	Insecticide		Clove Oil
25(b)	Fungicide		Corn Oil
25(b)	Insecticide		Cottonseed Oil
25(b)	Insecticide		Garlic
25(b)	Insect Repellant		Garlic Oil
25(b)	Fungicide		Geranoil
25(b)	Insecticide		Geranium Oil
25(b)	Fungicide, Insecticide		Lemon Grass Oil
25(b)	Insecticide		Peppermint Oil
25(b)	Insecticide		Peroxyacetic Acid
25(b)	Fungicide		Potassium Sorbate
25(b)	Insecticide		Rosemary
25(b)	Insecticide		Rosemary Oil
25(b)	Fungicide, Insecticide, Miticide		Sesame Oil
25(b)	Fungicide, Insecticide		Sodium Lauryl Sulfate
25(b)	Insecticide		Soybean Oil
25(b)	Fungicide		Thyme

EPA Status	Pesticide Type	Comments	Active Ingredients
25(b)	Fungicide, Insecticide, Miticide		Thyme Oil
25(b)	Insecticide		White Pepper
Sec 3 Products	Insecticide		Azadirachtin
Sec 3 Products	Fungicide		Bacillus Amyloliquefaciens Strain D747
Sec 3 Products	Fungicide	For use in protected growing environments only (for example, greenhouses)	Bacillus Pumilus Strain GHA 180
Sec 3 Products	Fungicide		Bacillus Subtilis QST713 Strain
Sec 3 Products	Insecticide		Bacillus Thuringiensis SSP. Aizawai
Sec 3 Products	Insecticide		Canola Oil
Sec 3 Products	Insect Repellent		Capsicum Oleoresin Extract
Sec 3 Products	Insecticide	Ground application only to nonblooming plants.	Chromobacterium Sub Strain PRAA4-1 Cells
Sec 3 Products	Fungicide, Insecticide		Clarified Hydrophobic Extract of Neem Oil
Sec 3 Products	Fungicide		Copper Octanoate
Sec 3 Products	PGR		Cytokinin (Kinetin)
Sec 3 Products	Insecticide		Diatomaceous Earth
Sec 3 Products	PGR		Gibberellins (Gibberellic Acid)
Sec 3 Products	PGR		Harpin Alpha Beta
Sec 3 Products	Antimicrobial, Fungicide	No foliar applications allowed.	Hydrogen Peroxide
Sec 3 Products	PGR	Applications allowed in furrow at planting or in hydroponics only.	IBA (Indole-3Butyric Acid)

EPA Status	Pesticide Type	Comments	Active Ingredient
Sec 3 Products	Insecticide, PGR		Kaolin
Sec 3 Products	Insecticide		Mineral Oil
Sec 3 Products	Fungicide	Use only allowed prior to final transplant, unless grown in recirculating hydroponics systems.	Mono-Potassium and Di-Potassium Salts of Phosphorous Acid
Sec 3 Products	Insecticide		Monopotassium Phosphate
Sec 3 Products	Nematicide		Myrothecium Verrucaria
Sec 3 Products	Fungicide, Insecticide		Neem Oil, Cold Pressed
Sec 3 Products	Insecticide	Use allowed prior to final transplant	Potassium Laurate
Sec 3 Products	Fungicide, Insecticide		Potassium Salts of Fatty Acids
Sec 3 Products	Insecticide		Pyrethrins
Sec 3 Products	Molluscicide		Sodium Ferric EDTA
Sec 3 Products	Fungicide		Trichoderma Asperellum Strain



WEST VIRGINIA SECRETARY OF STATE
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4/21/2020 9:40:02 AM

Office of West Virginia
Secretary Of State

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED
BY THE WEST VIRGINIA LEGISLATURE**

AGENCY: Health TITLE-SERIES: 64-111

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: medical cannabis program--laboratories

CITE STATUTORY AUTHORITY: 16A-3-1(b)

The above rule has been authorized by the West Virginia Legislature.

Authorization is cited in (house or senate bill number) SB 339

Section 64-5-1(j) Passed On 3/5/2020 12:00:00 AM

This rule is filed with the Secretary of State. This rule becomes effective on the following date:

April 21, 2020

This rule shall terminate and have no further force or effect from the following date:

April 21, 2025

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

April L Robertson -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

**TITLE 64
LEGISLATIVE RULE
BUREAU FOR PUBLIC HEALTH**

**SERIES 111
MEDICAL CANNABIS PROGRAM – LABORATORIES**

§64-111-1. General.

- 1.1. Scope. The provisions of this rule regulate the certification and operation of laboratories that provide testing services to medical cannabis organizations authorized by the West Virginia Medical Cannabis Act (W. Va. Code §16A-1-1 *et seq.*)
 - 1.2. Authority. W. Va. Code §16A-3-1(b) and §16A-7-3.
 - 1.3. Filing Date. April 21, 2020.
 - 1.4. Effective Date. April 21, 2020.
 - 1.5. Sunset Provision. This rule will terminate and have no further force or effect on April 21, 2025.
- 1.6. Applicability. This rule applies to a person or entity that desires to hold a permit as a medical cannabis organization in the state.

§64-111-2. Definitions.

- 2.1. "Act" means the West Virginia Medical Cannabis Act (W. Va. Code §16A-1-1 *et seq.*).
- 2.2. "Accreditation body" means an organization which:
 - 2.2.a. Certifies the competency, expertise and integrity of a laboratory and operates in conformance with the current version of International Organization Standard ISO/IEC 17011;
 - 2.2.b. Determines a laboratory's compliance with and conformance to the relevant standards established by the International Organization for Standardization, including ISO/IEC 17025;
 - 2.2.c. Is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement for Testing; and
 - 2.2.d. Is not affiliated with a laboratory applicant for which it has or will issue a certificate of accreditation.
- 2.3. "Approved laboratory" means a laboratory that has applied for, and received, the approval of the bureau to identify, collect, handle, and conduct tests on samples from a grower/processor and test samples from the bureau used in the growing, processing, or dispensing of medical cannabis as required by the Act and this rule.
- 2.4. "Bureau" means the West Virginia Bureau for Public Health within the West Virginia Department of Health and Human Resources.
- 2.5. "Certificate of accreditation" means a document issued by an accreditation body evidencing that a laboratory is in compliance with International Organization for Standardization Standard ISO/IEC 17025

and other requirements relevant to the operation of laboratories conducting tests on medical cannabis and other items used in the growing, processing, or dispensing of medical cannabis.

2.6. "Certificate of analysis" means a document that confirms that the test performed by an approved laboratory on a harvest batch, harvest lot, or process lot meets the testing requirements set forth by the bureau.

2.7. "Chain of custody" means the written procedures used by employees of an approved laboratory to record the possession and transfer of samples and test samples from the time the samples and test samples are collected until the test of the sample or test sample is completed.

2.8. "Dispensary" means:

2.8.a. A person who holds a permit issued by the bureau to dispense medical cannabis.

2.8.b. The term does not include a health care medical cannabis organization as defined under W. Va. Code §16A-13-1 *et seq.*

2.9. "Electronic tracking system" means an electronic seed-to-sale system prescribed by the bureau that is implemented by:

2.9.a. A grower/processor to log, verify, and monitor the receipt, use and sale of seeds, immature medical cannabis plants, or medical cannabis plants, the funds received by a grower/processor for the sale of medical cannabis to another medical cannabis organization, the disposal of medical cannabis waste, and the recall of defective medical cannabis.

2.9.b. A dispensary to log, verify, and monitor the receipt of medical cannabis product from a grower/processor, the verification of the validity of an identification card presented by a patient or caregiver, the dispensing of medical cannabis product to a patient or caregiver, the disposal of medical cannabis waste, and the recall of defective medical cannabis.

2.9.c. An approved laboratory to log, verify, and monitor the receipt of samples and test samples for testing, the results of tests performed by the approved laboratory, and the disposal of tested and untested samples.

2.10. "Grower/processor" means:

2.10.a. A person who holds a permit from the bureau under the act to grow or process medical cannabis.

2.10.b. The term does not include a health care medical cannabis organization as defined under W. Va. Code §16A-13-1 *et seq.*

2.11. "Harvest batch" means a specifically identified quantity of medical cannabis plant that is uniform in strain, cultivated utilizing the same growing practices, harvested at the same time and at the same location, and cured under uniform conditions.

2.12. "Harvest lot" means a specifically identified quantity of medical cannabis plant taken from a harvest batch.

2.13. "Health care medical cannabis organization" means a vertically integrated health system approved by the bureau to dispense medical cannabis or grow and process medical cannabis, or both, in

accordance with a research study under W. Va. Code §16A-13-1 *et seq.*

2.14. “Laboratory applicant” means a laboratory that submits an application to the bureau for approval to identify, collect, handle, and test medical cannabis and other items used by a medical cannabis organization in the growing, processing, or dispensing of medical cannabis as required under the Act and this rule for the bureau or a grower/processor.

2.15. “Medical cannabis” means cannabis that is grown and sold pursuant to the provisions for certified medical use as set forth in the Act and in a form set forth in the provisions of §64-110-10.

2.16. “Medical cannabis extract” means a substance obtained by separating cannabinoids from medical cannabis plants by a mechanical, chemical, or other process.

2.17. “Medical cannabis organization” means:

2.17.a. A dispensary or a grower/processor.

2.17.b. The term does not include a health care medical cannabis organization under W. Va. Code §16A-13-1 *et seq.* or a clinical registrant under W. Va. Code §16A-14-1 *et seq.*

2.18. “Medical cannabis product” means the final form and dosage of medical cannabis that is grown, processed, produced, sealed, labeled, and tested by a grower/processor and sold to a dispensary.

2.19. “Pharmacist” has the same meaning as the term does in W. Va. Code §30-5-1 *et seq.* (The Larry W. Border Pharmacy Practice Act).

2.20. “Physician” has the same meaning as the term does in W. Va. Code §30-3-1 *et seq.* (The West Virginia Medical Practice Act) and W. Va. Code §30-14-1 *et seq.* (Osteopathic Physicians and Surgeons).

2.21. “Process lot” means any amount of a medical cannabis product of the same type and processed using the same medical cannabis extract, standard operating procedures, and the same or combination of different harvest lots.

2.22. “Processing” means the compounding or conversion of medical cannabis extract by a grower/processor into a medical cannabis product.

2.23. “Sample” means medical cannabis collected by an employee of an approved laboratory from a grower/processor for testing by the laboratory.

2.24. “Test sample” means an amount of medical cannabis or an amount of soil, growing medium, water, or solvents used to grow or process medical cannabis, dust, or other particles obtained from the swab of a counter or equipment used in the growing or processing of medical cannabis, or other item used in the growing or processing of medical cannabis in a facility taken by an employee of an approved laboratory or an agent of the bureau at the request of the bureau from a grower/processor and provided to an approved laboratory for testing.

§64-111-3. Laboratories generally.

3.1. A laboratory may not identify, collect, handle, or conduct tests on samples from a grower/processor or conduct tests on test samples for the bureau unless the laboratory has been approved by the bureau under section 4 of this rule and has entered into a written contract with the grower/processor under section 10 of this rule.

3.2. The bureau will post on its web site a current list of approved laboratories.

3.3. An approved laboratory must employ at least one director to oversee and be responsible for the identification, collection, handling, and testing operations of the approved laboratory. A director must have earned, from a college or university accredited by a national or regional accrediting authority, at least one of the following:

3.3.a. A doctorate of science or an equivalent degree in chemistry, biology, or a subdiscipline of chemistry or biology;

3.3.b. A master's level degree in a chemical or biological science and a minimum of two years post graduate degree laboratory experience related to testing of medicinal or pharmaceutical products or other experience as approved by the bureau; or

3.3.c. A bachelor's degree in a biological science and a minimum of four years post graduate degree laboratory experience related to testing of medicinal or pharmaceutical products or other experience as approved by the bureau.

3.4. A principal or employee of a medical cannabis organization may not also own, be employed by or affiliated with an approved laboratory that has a contract with that medical cannabis organization.

3.5. An approval issued by the bureau to a laboratory under this rule is valid for two years from the date of issuance and is valid only for the laboratory named and the location specified in the approval.

3.6. An approval issued by the bureau to a laboratory under this rule is not transferable to any other person or any other location unless the laboratory obtains the prior written consent of the bureau.

§64-111-4. Approval of laboratories.

4.1. A laboratory intending to identify, collect, handle and conduct tests on samples and test samples and other items used by a grower/processor in the growing and processing of medical cannabis as required under the Act and this rule must submit an application for approval to the bureau on a form and in a manner prescribed by the bureau, in addition to the prescribed fee. The application is available on the bureau's website.

4.2. An application submitted under this section must include the following information:

4.2.a. The name and address of the laboratory applicant or its authorized agent.

4.2.b. The name and address of the owner of the laboratory applicant, and, if applicable, the medical or pharmacy licensure information regarding the owner.

4.2.c. The name of the laboratory applicant's proposed director and technical personnel who are or will be employed by the laboratory at the location to be approved.

4.2.d. A copy of the laboratory applicant's most recent valid certificate of accreditation granted from an ILAC MRA recognized accreditation body.

4.2.e. Copies of the standard operating procedures and sampling procedures adopted by the laboratory applicant and approved by the accreditation body that issued the certificate of accreditation to the laboratory applicant.

4.2.f. A list of the specialized laboratory equipment utilized or to be utilized by the laboratory applicant in its testing operations, including the manufacturer's name and the serial and model number of the equipment, and other specifications as may be required by the bureau.

4.2.g. A description of the accredited tests which are capable of being conducted by the laboratory applicant at the location to be approved.

4.2.h. A description of the laboratory applicant's quality assurance program, which must be in compliance with section 13 of this rule.

4.2.i. The procedures to be followed to establish chain of custody when collecting samples or test samples.

4.2.j. A copy of the evaluation process that the laboratory applicant uses or will use to monitor, evaluate and document the competency of employees when testing samples and test samples and overseeing quality assurance controls.

4.2.k. Other information required by the bureau.

4.3. By submitting an application for approval to the bureau, a laboratory applicant consents to an investigation, to the extent deemed appropriate by the bureau, of the laboratory applicant's ability to meet the requirements under the Act and this rule.

4.4. An application for approval submitted under this rule must include a statement that a false statement made in the application is punishable under the applicable provisions of W. Va. Code §61-3-37.

4.5. The bureau may issue an approval under this rule if the bureau determines that the laboratory applicant is financially and professionally suitable to conduct the testing required under the Act and this rule.

§64-111-5. Suspension or revocation of an approval issued to a laboratory.

5.1. An approval issued by the bureau under this rule may be suspended or revoked if the bureau determines that the approved laboratory has engaged in unethical practices or has failed to do any of the following:

5.1.a. Maintain proper standards of accuracy.

5.1.b. Comply with the requirements of the Act or this rule applicable to the approved laboratory.

5.2. An approval issued by the bureau under this rule may be revoked if the bureau determines that the approved laboratory has engaged in any of the following conduct:

5.2.a. Dishonest reporting.

5.2.b. Repeated errors in conducting the required testing.

5.2.c. Allowing unauthorized individuals to perform testing or to sign reports.

5.2.d. Including false statements in the application for approval or renewal.

5.2.e. Advertising medical cannabis testing services to the general public.

5.2.f. Knowingly accepting a sample from an individual other than a grower/processor or a test sample from an individual other than the bureau or an authorized agent of the bureau.

5.2.g. Failing to maintain standard operating procedures approved by the accrediting body that issued the certificate of accreditation to the approved laboratory.

5.2.h. Failing to properly enter test results into the electronic tracking system.

5.2.i. Loss by the approved laboratory of its certificate of accreditation.

5.3. A laboratory applicant may appeal a determination made by the bureau under this section in accordance with 64CSR1 (Rules of Procedure for Contested Case Hearings and Declaratory Rulings).

§64-111-6. Renewal of an approval issued to a laboratory.

An approved laboratory intending to renew the approval issued to the laboratory under this rule must, not more than six months nor less than four months prior to the expiration of the approval, submit an application under section 4 of this rule and update all of the information required to be submitted with the application.

§64-111-7. Stability testing and retention of samples.

7.1. A grower/processor must request that a sample be identified and collected by an approved laboratory from each harvest batch sufficient to perform stability testing at six-month intervals for a one-year period.

7.2. The stability test must be performed to ensure product potency and purity and provide support for expiration dating.

7.3. An approved laboratory must retain a sample from each harvest batch sufficient to provide for stability testing and properly store the sample for one year.

§64-111-8. Sampling procedures for testing.

8.1. An approved laboratory must ensure that its employees prepare all samples in accordance with policies and procedures that include appropriate information necessary for identifying, collecting and transporting samples in a manner that does not endanger the integrity of the samples for any testing required by this rule.

8.2. The sampling policies must at a minimum be:

8.2.a. Appropriate to the matrix being sampled.

8.2.b. In accordance with guidance provided by the bureau.

8.3. The sampling procedures must include the following:

8.3.a. Surveying the conditions in which the sample is being stored.

8.3.b. Using appropriate sampling equipment and consistent procedures.

8.3.c. Selecting and removing equal portions for each sample.

8.3.d. Random or systematic taking of samples throughout the harvest batch or harvest lot.

8.3.e. Obtaining a minimum number of samples based on harvest batch or harvest lot size.

8.3.f. Checking all parts of the harvest batch when harvest lots are created from that harvest batch.

8.3.g. Recording on a form prescribed by the bureau all observations and procedures used when collecting the sample.

8.3.h. Creating a unique sample identification number that will be linked to the harvest batch or harvest lot number assigned by the grower/processor in the electronic tracking system.

8.3.i. Entering all required information into the electronic tracking system.

§64-111-9. Selection protocols for samples.

9.1. An employee of an approved laboratory may only enter a facility operated by a grower/processor for the purpose of identifying and collecting samples and must have access to limited access areas in the facility for these purposes.

9.2. An employee identifying and collecting samples under subsection 9.1. of this rule must follow the chain of custody procedures included in the approved laboratory's application and approved by the bureau.

9.3. While at a facility operated by a grower/processor, an employee of an approved laboratory must identify and collect the following for testing:

9.3.a. Samples at the time of harvest.

9.3.b. Samples of medical cannabis product before being sold or provided to a dispensary.

9.3.c. Test samples at other times when requested by the bureau.

§64-111-10. Testing requirements.

10.1. Prior to conducting any testing of a sample at the request of a grower/processor, an approved laboratory must enter into a written contract with the grower/processor for testing services. The approved laboratory must provide a copy of the contract to the bureau within two days following the bureau's request.

10.2. A grower/processor must submit through the electronic tracking system a request to the approved laboratory with which it has a written contract under subsection 10.1. of this rule for each test to be conducted.

10.3. At a minimum, an approved laboratory must perform tests as prescribed by the bureau on the following:

10.3.a. Samples from a harvest batch or harvest lot prior to being used to produce a medical cannabis product.

10.3.b. Samples from each process lot before the medical cannabis is sold or offered for sale to

another medical cannabis organization.

10.4. The samples identified in subsection 10.3. of this rule must be tested, at a minimum, for the following:

- 10.4.a. Pesticides;
- 10.4.b. Solvents;
- 10.4.c. Water activity and moisture content;
- 10.4.d. THC and CBD concentration; and
- 10.4.e. Microbiological contaminants.

10.5. Sampling and testing under this rule must be conducted with a statistically significant number and size of samples and with methodologies acceptable to the bureau to ensure that all harvest batches, harvest lots and medical cannabis products are adequately tested for contaminants and that the cannabinoid profile is consistent throughout.

10.6. An approved laboratory may not test any samples when there is evidence of improper collection, improper preservation, apparent spoilage, excessive time lapse between collection of the sample and testing, or any other factor sufficient to render the findings of questionable validity.

10.7. An approved laboratory must enter into the electronic tracking system and, under 64CSR110 (Management and disposal of medical cannabis waste) properly dispose of all tested and untested samples and test samples.

§64-111-11. Standards for testing.

An approved laboratory must follow the methodologies and parameters acceptable to the bureau which are contained in the scope of the certificate of accreditation issued to the laboratory.

§64-111-12. Test results and reporting.

12.1. Only the results of the following tests are in compliance with the testing requirements of this rule:

12.1.a. Tests conducted on harvest batch samples or harvest lot samples requested by a grower/processor under section 10 of this rule and identified and collected by an employee of an approved laboratory.

12.1.b. Tests conducted on process lot samples requested by a grower/processor under section 10 of this rule and identified and collected by either an employee of a grower/processor or an employee of an approved laboratory.

12.2. The test results for each sample must be entered into the electronic tracking system and must only be accessible to the grower/processor submitting the sample and to the bureau.

12.3. If a sample fails any test required under section 10 of this rule, the following apply to the sample:

- 12.3.a. The approved laboratory that performed the initial test may re-test the sample upon a

request from the grower/processor in accordance with subsection 12.4. of this rule.

12.3.b. If the sample passes the re-test, another approved laboratory must sample the same harvest batch, harvest lot or process lot to confirm the passing test result.

12.3.c. If the bureau does not agree to accept the results from the approved laboratory, the sample must be disposed of by the approved laboratory under 64CSR110.22 (Management and disposal of medical cannabis waste).

12.4. A grower/processor must notify the bureau and the approved laboratory through the electronic tracking system of its intent to re-test the sample or test another sample from the same harvest batch, harvest lot, or process lot that failed a test.

12.5. An approved laboratory must issue to a grower/processor a certificate of analysis, including the supporting data, for each harvest batch, harvest lot, or process lot sample that was tested at the request of the grower/processor. The certificate of analysis must include:

12.5.a. Whether the chemical profile of the harvest batch, harvest lot, or process lot conforms to the chemical profile of the strain as determined by the bureau for the following compounds:

12.5.a.1. Tetrahydrocannabinol (THC).

12.5.a.2. Tetrahydrocannabinol acid (THCA).

12.5.a.3. Tetrahydronnabivarain (THCV).

12.5.a.4. Cannabidiol (CBD).

12.5.a.5. Cannabinadiolic acid (CBDA).

12.5.a.6. Cannabidivarine (CBDV).

12.5.a.7. Cannabinol (CBN).

12.5.a.8. Cannabigerol (CBG).

12.5.a.9. Cannabichromene (CBC).

12.5.a.10. Any other cannabinoid component at > 0.1percent.

12.5.b. That the presence of the following contaminants within the harvest batch, harvest lot, or process lot does not exceed the levels as determined by the bureau for the following:

12.5.b.1. Heavy metals, mercury, lead, cadmium or arsenic.

12.5.b.2. Foreign material such as hair, insects, or any similar or related adulterant.

12.5.b.3. Any microbiological impurity, including:

12.5.b.3.A. Total aerobic microbial count.

12.5.b.3.B. Total yeast mold count.

- 12.5.b.3.C. *P. aeruginosa*.
- 12.5.b.3.D. *Aspergillus* spp.
- 12.5.b.3.E. *S. aureus*.
- 12.5.b.3.F. Aflatoxin B1, B2, G1 and G2.
- 12.5.b.3.G. Ochratoxin A.
- 12.5.b.3.H. Pesticide residue.

12.5.b.4. Whether the harvest batch, harvest lot or process lot is within the specification for the strain for the characteristics of:

- 12.5.b.4.A. Odor.
- 12.5.b.4.B. Appearance.
- 12.5.b.4.C. Fineness.
- 12.5.b.4.D. Moisture content.

§64-111-13. Quality assurance program.

13.1. An approved laboratory must establish and implement a quality assurance program to ensure that measurements are accurate, errors are controlled, and devices used for testing are routinely and properly calibrated.

13.2. The quality assurance program required under subsection 13.1. of this rule must include the following components:

- 13.2.a. An organizational chart that includes the testing responsibilities of each employee of the approved laboratory named in the chart.
- 13.2.b. A description of sampling procedures to be utilized.
- 13.2.c. Appropriate chain of custody protocols.
- 13.2.d. Analytical procedures.
- 13.2.e. Data reduction and validation procedures.
- 13.2.f. A plan for implementing corrective action, when necessary.
- 13.2.g. A requirement for the provision of quality assurance reports to management.
- 13.2.h. A description of the internal and external quality control systems.

§64-111-14. Transporting samples.

14.1. An employee of an approved laboratory, grower/processor, or third-party contractor must follow the transportation requirements under 64CSR110.17 and 64CSR110.18 (Transportation of medical

cannabis; and Transport manifest) when transporting a sample or test sample under this rule.

14.2. An employee of an approved laboratory, grower/processor, or third-party contractor who transports process lot samples from a grower/processor to an approved laboratory must:

14.2.a. Protect the physical integrity of the sample.

14.2.b. Keep the composition of the sample intact.

14.2.c. Protect the sample against factors that will interfere with the validity of testing results, including the factors of time, temperature and other environmental factors that may work to jeopardize the integrity of the sample.

§64-111-15. Bureau request for testing.

15.1. The bureau may identify and collect a test sample from a grower/processor at any time and request an approved laboratory to conduct tests.

15.2. The approved laboratory must provide the bureau with a written report of the test results from a test sample tested under subsection 15.1. of this rule within seven days of the collection of the test sample, or sooner if requested by the bureau.

§64-111-16. Laboratory reporting.

16.1. An approved laboratory must enter into the electronic tracking system the following information for each sample collected and each test conducted:

16.1.a. The unique sample identification number the approved laboratory assigns to the sample.

16.1.b. The name of the grower/processor that supplied the sample.

16.1.c. The employee identification number of the employee of the approved laboratory who identified and collected the sample at the request of the grower/processor.

16.1.d. The date and time the sample was collected from the grower/processor.

16.1.e. The date and time the sample was received by the approved laboratory.

16.1.f. The date the test was completed.

16.1.g. The condition of the sample when it was received by the approved laboratory.

16.1.h. A description of each test performed.

16.1.i. The results from the certificate of analysis issued under section 12 of this rule.

16.1.j. The date the testing results were provided to the grower/processor under section 12 of this rule or the bureau under section 15 of this rule.

16.2. An approved laboratory must keep for four years a paper or electronic copy of the certificate of analysis performed on samples submitted by a grower/processor or test samples submitted by the bureau. The laboratory must provide a copy of a certificate of analysis within two days of a request made

by the bureau.

§64-111-17. Advertising.

17.1. An approved laboratory may not advertise, market, or otherwise promote its medical cannabis testing services to the general public. An approved laboratory may advertise, market, or otherwise promote its medical cannabis testing services to a grower/processor as provided in this section.

17.2. Advertising, marketing, and promotional materials proposed to be used by an approved laboratory under this section must be reviewed and approved by the bureau prior to circulation or other use.

17.3. Personal solicitation by an employee, representative or agent of an approved laboratory to a grower/processor is considered advertising, marketing, or otherwise promoting its medical cannabis testing services for the purposes of this section.

17.4. An approved laboratory may only advertise, market or otherwise promote its medical cannabis testing services that are performed onsite at the location designated in the laboratory's application.

17.5. A sign installed at the location of an approved laboratory that is designed to identify the laboratory or access to the laboratory is permissible as long as the sign meets local zoning requirements and does not violate the provisions of this section.

§64-111-18. Ownership prohibition.

18.1. The following individuals may not have a management or a direct or indirect financial or other ownership interest in an approved laboratory:

18.1.a. A principal, owner, financial backer or employee of a medical cannabis organization.

18.1.b. A practitioner.

18.1.c. A physician or pharmacist who is currently employed by a medical cannabis organization.

18.1.d. Any other person, other than a patient, who may receive a direct or indirect financial benefit from the growing, processing, transporting, dispensing or selling of medical cannabis.



WEST VIRGINIA SECRETARY OF STATE
MAC WARNER
ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED
BY THE WEST VIRGINIA LEGISLATURE**

AGENCY: Health TITLE-SERIES: 64-112

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: MEDICAL CANNABIS PROGRAM
DISPENSARIES

CITE STATUTORY AUTHORITY: 16A-3-1

The above rule has been authorized by the West Virginia Legislature.

Authorization is cited in (house or senate bill number) HB2648

Section 64-5-1(f) Passed On 3/6/2023 12:00:00 AM

This rule is filed with the Secretary of State. This rule becomes effective on the following date:

April 1, 2023

This rule shall terminate and have no further force or effect from the following date:

August 01, 2028

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

April L Robertson -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

**TITLE 64
LEGISLATIVE RULE
BUREAU FOR PUBLIC HEALTH**

**SERIES 112
MEDICAL CANNABIS PROGRAM – DISPENSARIES**

§64-112-1. General.

- 1.1. Scope. The provisions of this rule include general provisions related to dispensaries pursuant to the West Virginia Medical Cannabis Act (W. Va. Code §16A-1-1 *et seq.*)
- 1.2. Authority. W. Va. Code §16A-3-1(b) and §16A-7-3.
- 1.3. Filing Date. March 30, 2023.
- 1.4. Effective Date. April 1, 2023.
- 1.5. Sunset Provision. This rule will terminate and have no further force or effect on August 1, 2028.
- 1.6. Applicability. This rule applies to a person or entity that desires to hold a permit as a medical cannabis organization in the state.

§64-112-2. Definitions.

- 2.1. "Act" means the West Virginia Medical Cannabis Act (W. Va. Code §16A-1-1 *et seq.*).
- 2.2. "Advertise" means the publication, dissemination, solicitation, or circulation, for a fee, that is visual, oral, written, or electronic to induce directly or indirectly an individual to patronize a particular dispensary or to purchase particular medical cannabis.
- 2.3. "Bureau" means the West Virginia Bureau for Public Health within the West Virginia Department of Health and Human Resources.
- 2.4. "Cannabis" means all parts of the plant of the genus cannabis whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or its resin, including cannabis concentrate. "Cannabis" does not include industrial hemp, nor does it include fiber produced from the stalks, oil, or cake made from the seeds of the plant, sterilized seed of the plant which is incapable of germination, or the weight of any other ingredient combined with cannabis to prepare topical or oral administrations, food, drink, or other product.
- 2.5. "CBD" means Cannabidiol.
- 2.6. "Caregiver" means the individual designated by a patient or, if the patient is under 18 years of age, an individual authorized under W. Va. Code §16A-5-1 *et seq.* to deliver medical cannabis.
- 2.7. "Device" means an object used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing medical cannabis into the human body.
- 2.8. "Dispense" means the activity of lawfully providing to a patient or caregiver medical cannabis in

a suitable container that is appropriately labeled for subsequent administration or use pursuant to a patient certification issued by a practitioner.

2.9. "Dispensary" means:

2.9.a. A person who holds a permit issued by the bureau to dispense medical cannabis.

2.9.b. The term does not include a health care medical cannabis organization as defined by W. Va. Code §16A-13-1 *et seq.*

2.10. "Employee" means an individual who is hired for a wage, salary, fee, or payment to perform work for an applicant or permittee.

2.11. "Electronic tracking system" means an electronic seed-to-sale system prescribed by the bureau that is implemented by a dispensary to log, verify, and monitor the receipt of medical cannabis product from a grower/processor, the verification of the validity of an identification card presented by a patient or caregiver, the dispensing of medical cannabis product to a patient or caregiver, the disposal of medical cannabis waste, and the recall of defective medical cannabis.

2.12. "Facility" means a structure and other appurtenances or improvements where a dispensary dispenses medical cannabis.

2.13. "Form of medical cannabis" means the characteristics of the medical cannabis recommended or limited for a particular patient, including the method of consumption and any particular dosage, strain, variety, and quantity or percentage of medical cannabis or particular active ingredient.

2.14. "Grower/processor" means:

2.14.a. A person who holds a permit from the bureau under the Act to grow or process medical cannabis.

2.14.b. The term does not include a health care medical cannabis organization as defined under W. Va. Code §16A-13-1 *et seq.*

2.15. "Health care medical cannabis organization" means a vertically integrated health system approved by the bureau to dispense medical cannabis or grow and process medical cannabis, or both, in accordance with a research study under W. Va. Code §16A-13-1 *et seq.*

2.16. "Identification card" means a document issued under W. Va. Code §16A-5-1 that authorizes access to medical cannabis under the Act.

2.17. "Laboratory" means a place, establishment, or institution within the State of West Virginia that has been issued a certificate by the bureau's Office of Laboratory Services.

2.18. "Limited access area" means any area on a site or within a facility where:

2.18.a. Medical cannabis products are being loaded into or out of transport vehicles.

2.18.b. Medical cannabis is packaged for sale or stored.

2.18.c. Medical cannabis waste is processed, stored, or destroyed.

2.18.d. Surveillance system devices are stored.

2.19. "Medical cannabis" means cannabis that is grown and sold pursuant to the provisions for certified medical use as set forth in the Act and in a form set forth in the provisions of §64-110-10.

2.20. "Medical cannabis product" means the final form and dosage of medical cannabis that is grown, processed, produced, sealed, labeled, and tested by a grower/processor and sold to a dispensary.

2.21. "Medical cannabis organization" means:

2.21.a. A dispensary or a grower/processor.

2.21.b. The term does not include a health care medical cannabis organization under W. Va. Code §16A-13-1 *et seq.* or a clinical registrant under W. Va. Code §16A-14-1 *et seq.*

2.22. "Municipality" incorporated city or town in this state.

2.23. "Operations" means the time at which the bureau determines that a dispensary is ready, willing and able to properly carry on the activity for which a permit has been issued under this rule, including the implementation of an electronic tracking system.

2.24. "Operator" means an individual who directly oversees or manages the day-to-day business functions for an applicant or permittee and has the ability to direct employee activities onsite and offsite or within a facility for which a permit is issued.

2.25. "Patient" means an individual who:

2.25.a. Has a serious medical condition;

2.25.b. Has met the requirements for certification under the Act; and

2.25.c. Is a resident of the State of West Virginia.

2.26. "Permit" means an authorization issued by the bureau to an applicant to conduct activities authorized under the Act.

2.27. "Person" means a natural person, corporation, foundation, organization, business trust, estate, limited liability company, licensed corporation, trust, partnership, limited liability partnership, association, or other form of legal business entity.

2.28. "Physician" means an individual currently licensed by this state to engage in the practice of medicine pursuant to the West Virginia Medical Practice Act (W. Va. Code §30-3-1 *et seq.*) and the Osteopathic Medical Practice Act (W. Va. Code §30-14-1 *et seq.*).

2.29. "Photocopy" means to copy printed material by a process in which an image is formed by the action of light usually on an electrically charged surface, or the use any other electronic method to scan, create, and store records or documents.

2.30. "Practitioner" means a physician who is registered with the bureau under W. Va. Code §16A-4-1.

2.31. "Serious medical condition" means any of the following conditions:

2.31. a. Cancer.

2.31.b. Positive status for Human Immunodeficiency Virus or Acquired Immune Deficiency Syndrome.

2.31.c. Amyotrophic lateral sclerosis.

2.31.d. Parkinson's disease.

2.31.e. Multiple sclerosis.

2.31.f. Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity.

2.31.g. Epilepsy.

2.31.h. Neuropathies.

2.31.i. Huntington's disease.

2.32.j. Crohn's disease.

2.31.k. Post-traumatic stress disorder.

2.31.l. Intractable seizures.

2.31.m. Sickle cell anemia.

2.31.n. Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain.

2.31.o. Terminally ill.

2.32. "Site" means the total area contained within the property line boundaries in which a facility is operated by a dispensary.

2.33. "Terminally ill" means a medical prognosis of life expectancy of approximately one year or less if the illness runs its normal course.

2.34. "THC" means Tetrahydrocannabinol.

2.35. "Transport vehicle" means a vehicle that meets the requirements of the Act and is used to transport medical cannabis between medical cannabis organizations or between medical cannabis organizations and a laboratory.

2.36. "Unit" means the weight or volume of total usable medical cannabis in the finished product, calculated in metric units.

§64-112-3. Dispensaries generally.

3.1. The qualifications that a dispensary must meet to receive a permit are continuing qualifications to maintain the permit.

3.2. In addition to any other requirements in the Act or this rule, a dispensary must comply with the following:

3.2.a. A dispensary may not engage in the business of possessing, dispensing, selling, or offering to dispense or sell medical cannabis to a patient or caregiver in this state without first being issued a permit by the bureau and without first being determined operational by the bureau as required under 64CSR109.15.

3.2.b. A dispensary may not employ an individual at its facility who is under 18 years of age.

3.2.c. A dispensary may not permit a patient to self-administer medical cannabis at the facility unless the patient is also an employee of the dispensary, and the dispensary permits self-administration of medical cannabis at the facility by the employees.

§64-112-4. Dispensing medical cannabis.

4.1. A dispensary may only dispense medical cannabis to a patient or caregiver who presents a valid identification card to an employee at the facility who is authorized to dispense medical cannabis at the facility.

4.2. Prior to dispensing medical cannabis to a patient or caregiver, the dispensary must:

4.2.a. Verify the validity of the patient or caregiver identification card using the electronic tracking system.

4.2.b. Review the information on the patient's most recent certification by using the electronic tracking system to access the bureau's database. The following apply:

4.2.b.1. If a practitioner sets forth recommendations, requirements, or limitations as to the form or dosage of medical cannabis on the patient certification, the medical cannabis dispensed to a patient or a caregiver by a dispensary must conform to those recommendations, requirements, or limitations.

4.2.b.2. The dispensary must update the patient certification in the electronic tracking system by entering any recommendation as to the form or dosage of medical cannabis that is provided to the patient.

4.3. Prior to the completion of the transaction, the employee conducting the transaction at the dispensary must prepare a receipt of the transaction and file the receipt information with the bureau utilizing the electronic tracking system. A dispensary must provide a copy of the receipt to the patient or the caregiver, unless the patient or the caregiver declines the receipt. The receipt must include the following information:

4.3.a. The name, address and any permit number assigned to the dispensary by the bureau.

4.3.b. The name and address of the patient and, if applicable, the patient's caregiver.

4.3.c. The date the medical cannabis was dispensed.

4.3.d. Any requirement or limitation noted by the practitioner on the patient's certification as to the form of medical cannabis that the patient should use.

4.3.e. The form and the quantity of medical cannabis dispensed.

4.4. Except as provided in W. Va. Code §16A-14-1 *et seq.*, a dispensary must destroy any paper copy of the patient certification or delete any electronically recorded patient certification stored on the dispensary's network, server, or computer system as the result of a transaction after the receipt relating to that transaction has been filed under subsection 4.3.

§64-112-5. Limitations on dispensing.

5.1. A dispensary may not dispense to a patient or caregiver:

5.1.a. A quantity of medical cannabis that is greater than the amount indicated on the patient's certification, if any.

5.1.b. A form or dosage of medical cannabis that is listed as a restriction or limitation on the patient certification.

5.1.c. A form of medical cannabis not permitted by the Act or this rule, unless otherwise provided in rules adopted by the bureau under W. Va. Code §16A-11-2.

5.2. A dispensary may not dispense an amount of medical cannabis greater than a 30-day supply to a patient or caregiver until the patient has exhausted all but a seven-day supply provided pursuant to the certification currently on file with the bureau.

§64-112-6. Dispensary facilities.

6.1. A dispensary may only dispense medical cannabis to a patient or caregiver in an indoor, enclosed, secure facility as approved by the bureau.

6.2. A dispensary may not be located:

6.2.a. Within 1,000 feet of the property line of a public, private or parochial school, or a day-care center;

6.2.b. At the same site used for growing and processing medical cannabis; or

6.2.c. In the same office space as a practitioner or other physician.

6.3. The bureau may waive or amend the prohibition under subdivision 6.2.a., if it is shown by clear and convincing evidence that the waiver or amendment is necessary to provide patients with adequate access to medical cannabis. A waiver or amendment by the bureau under this subsection may require additional security measures, changes to the physical plant of a facility or other conditions necessary to protect individuals under 18 years of age and to prevent unauthorized access to medical cannabis.

6.4. No one under 18 years of age is permitted to enter a dispensary unless the individual is a patient or accompanied by a parent, guardian or caregiver. If a dispensary facility is located adjacent to a commercial operation, the facility must provide additional means of security satisfactory to the bureau to prevent individuals under 18 years of age from entering the facility from the commercial operation unless the individual is accompanied by an adult.

6.5. The following areas of a dispensary must be clearly marked with proper signage:

6.5.a. Limited access areas. All areas of ingress and egress to a limited access area must be clearly identified by the posting of a sign which must be not less than 12 inches wide and 12 inches long, composed of letters not less than one-half inch in height, which must state: Do Not Enter—Limited Access Area. Access Limited to Authorized Personnel and Escorted Visitors.

6.5.b. Areas that are open to patients and caregivers.

6.6. A dispensary must have an enclosed, secure area out of public sight for the loading and unloading of medical cannabis into and from a transport vehicle.

§64-112-7. Items and services provided at a dispensary.

7.1. A dispensary must dispense the form of medical cannabis in accordance with section 4 of this rule.

7.2. A dispensary must purchase medical cannabis products only from a grower/processor.

7.3. A dispensary may sell, offer for sale, or provide at its facility, with the prior written approval of the bureau, instruments, devices, and services related to the use of medical cannabis.

7.4. A dispensary may dispense a medical cannabis product so long as the dispensary purchases it from a grower/processor and the grower/processor obtained bureau approval under 64CSR110.10 (Forms of medical cannabis).

7.5. A dispensary may not:

7.5.a. Advertise medical cannabis:

7.5.a.1. As a promotional item.

7.5.a.2. As part of a giveaway.

7.5.a.3. As part of a coupon program.

7.5.b. Provide medical cannabis at no cost or free.

7.5.c. Make the dispensing of medical cannabis to a patient or caregiver conditional upon:

7.5.c.1. The purchase of a medical device, instrument, or service provided at a dispensary facility.

7.5.c.2. The purchase of a medical device, instrument, or service provided at a location other than a dispensary facility.

7.5.d. Offer the delivery of or deliver medical cannabis to a patient or caregiver at the patient's or caregiver's home or any other location.

§64-112-8. Labels and safety inserts.

8.1. Medical cannabis products dispensed by a dispensary must only be identified by the name of the grower/processor, the name of the dispensary, the form and species of medical cannabis, the percentage of THC and CBD contained in the medical cannabis product, and any other labeling required by the bureau.

8.2. A dispensary must dispense medical cannabis to a patient or caregiver in a sealed and properly labeled package.

8.3. The dispensary must inspect the label to ensure that the label contains the following:

8.3.a. The information required to be included in the receipt in section 4 of this rule.

8.3.b. The packaging date.

8.3.c. A use by or expiration date.

8.3.d. The following warning stating: "This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the practitioner who issued the certification and, in the case of breastfeeding, the infant's pediatrician. This product might impair the ability to drive or operate heavy machinery. Keep out of reach of children."

8.3.e. The number of individual doses contained within the package and the species and percentage of THC and CBD.

8.3.f. A warning that the medical cannabis must be kept in the original container in which it was dispensed.

8.3.g. A warning that unauthorized use is unlawful and will subject the purchaser or user to criminal penalties.

8.3.h. Any other information required by the bureau.

8.4. The dispensary must inspect the label to ensure that the label does not bear:

8.4.a. Any resemblance to the trademarked, characteristic, or product-specialized packaging of any commercially available food or beverage product.

8.4.b. Any statement, artwork, or design that could reasonably lead an individual to believe that the package contains anything other than medical cannabis.

8.4.c. Any seal, flag, crest, coat of arms, or other insignia that could reasonably mislead an individual to believe that the product has been endorsed, manufactured, or approved for use by any state, county, or municipality or any agency thereof.

8.4.d. Any cartoon, color scheme, image, graphic, or feature that might make the package attractive to children.

8.5. When a dispensary dispenses medical cannabis to a patient or caregiver, the dispensary must also provide the patient or caregiver with a safety insert developed and approved by the bureau that includes the following information:

8.5.a. The method or methods for administering individual doses of medical cannabis.

8.5.b. Any potential dangers stemming from the use of medical cannabis.

8.5.c. How to recognize what may be problematic usage of medical cannabis and how to obtain appropriate services or treatment for problematic usage.

8.5.d. The side effects and contraindications associated with medical cannabis, if any, which may cause harm to the patient.

8.5.e. How to prevent or deter the misuse of medical cannabis by an individual under 18 years of age or others.

8.5.f. Any other information determined by the bureau to be relevant to enhance patient safety.

§64-112-9. Plans of operation.

9.1. At the time the bureau determines a dispensary to be operational, the dispensary must provide the bureau with a full and complete plan of operation for review that includes the following:

9.1.a. Employment policies and procedures.

9.1.b. Security policies and protocols, including:

9.1.b.1. Staff identification measures.

9.1.b.2. Monitoring of attendance of staff and visitors.

9.1.b.3. Alarm systems.

9.1.b.4. Video surveillance.

9.1.b.5. Monitoring and tracking inventory.

9.1.b.6. Personnel security.

9.1.c. A process for receiving, packaging, labeling, handling, tracking, transporting, storing, disposing, returning, and recalling products containing medical cannabis in accordance with all applicable laws, rules and regulations.

9.1.d. Workplace safety.

9.1.e. Maintenance, cleaning and sanitation of the site or facility, or both.

9.1.f. Inventory maintenance and reporting procedures.

9.1.g. The investigation of complaints and potential adverse events from other medical cannabis organizations, patients, caregivers, or practitioners.

9.1.h. The use of the electronic tracking system prescribed by the bureau.

9.2. A dispensary must make the full and complete plan of operation available to the bureau upon request and during any inspection of the site and facility.

§64-112-10. Visitor access to dispensary facilities.

10.1. A dispensary must post a sign in a conspicuous location at each entrance of the facility that reads: THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE. NO ONE UNDER THE AGE OF 18 IS PERMITTED TO ENTER UNLESS THE INDIVIDUAL IS A PATIENT OR ACCOMPANIED BY A PARENT,

GUARDIAN OR CAREGIVER.

10.2. Except as provided in subsection 10.3., only authorized employees of a dispensary may enter a limited access area.

10.3. A dispensary must require visitors, including vendors and contractors requiring access to a limited access area in the dispensary's facility, to present government-issued identification, sign a visitor log and wear a visitor identification badge that is visible to others at all times while in a limited access area.

10.4. When admitting a visitor under subsection 10.3. to a limited access area, a dispensary must:

10.4.a. Require the visitor to sign a visitor log upon entering and leaving the limited access area;

10.4.b. Check the visitor's government-issued identification to verify that the name on the identification provided matches the name in the visitor log. A photocopy of the identification must be retained with the log;

10.4.c. Issue a visitor identification badge with the visitor's name and company, if applicable, and a badge number;

10.4.d. Escort the visitor while the visitor remains in a limited access area; and

10.4.e. Ensure that the visitor does not touch any medical cannabis located in a limited access area.

10.5. The following apply regarding the visitor log required under subsections 10.3. and 10.4.:

10.5.a. The dispensary must maintain the log for two years and make the log available to the bureau, state, or local law enforcement and other state government officials upon request if necessary, to perform the government officials' functions and duties.

10.5.b. The log must include the full name of each visitor, the visitor identification badge number, the time of arrival, the time of departure, and the purpose of the visit, including the areas visited and the name of each employee visited.

10.6. This section does not limit the right of the bureau or its authorized agents, or other federal, state, or local government officials, from entering any area of a dispensary if necessary, to perform the government officials' functions and duties.

10.7. A principal, financial backer, operator, or an employee of a dispensary may not receive any type of consideration or compensation for allowing a visitor to enter a limited access area.

§64-112-11. Security and surveillance.

11.1. A dispensary must have security and surveillance systems, utilizing commercial-grade equipment, to prevent unauthorized entry, and to prevent and detect an adverse loss. The security and surveillance systems must include the following:

11.1.a. A professionally monitored security alarm system that includes the following:

11.1.a.1. Coverage of all facility entrances and exits; rooms with exterior windows, exterior

walls, roof hatches or skylights; storage rooms, including those that contain medical cannabis, and safes; and the perimeter of the facility.

11.1.a.2. A silent security alarm system signal, known as a duress alarm, generated by the entry of a designated code into an arming station in order to signal that the alarm user is being forced to turn off the system.

11.1.a.3. An audible security alarm system signal, known as a panic alarm, generated by the manual activation of a device intended to signal a life-threatening or emergency situation requiring law enforcement response.

11.1.a.4. A silent alarm signal, known as a holdup alarm, generated by the manual activation of a device intended to signal a robbery in progress.

11.1.a.5. An electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message requesting dispatch, when activated, over a telephone line, radio, or other communication system to a law enforcement, public safety or emergency services agency.

11.1.a.6. A failure notification system that provides an audible, text, or visual notification of any failure in the systems. The failure notification system must provide by telephone, e-mail, or text message an alert to a designated security person within the facility within five minutes after the failure.

11.1.a.7. Smoke and fire alarms.

11.1.a.8. Auxiliary power sufficient to maintain security and surveillance systems for at least 48 hours following a power outage.

11.1.a.9. The ability to ensure all access doors are not solely controlled by an electronic access panel to prevent locks from becoming released during a power outage.

11.1.a.10. Motion detectors.

11.1.b. A professionally monitored security and surveillance system that is operational 24 hours a day, seven days a week and records all activity in images capable of clearly revealing facial detail. The security and surveillance system must include the following:

11.1.b.1. Fixed camera placement that allows for a clear image of all individuals and activities in and around the following:

11.1.b.1.A. Any area of the facility where medical cannabis is loaded or unloaded into or from transport vehicles.

11.1.b.1.B. Entrances to and exits from the facility. Entrances and exits must be recorded from both indoor and outdoor vantage points.

11.1.b.1.C. Rooms with exterior windows, exterior walls, roof hatches, or skylights and storage rooms, including those that may contain medical cannabis and safes.

11.1.b.1.D. Five feet from the exterior of the perimeter of the facility.

11.1.b.1.E. All limited access areas.

11.1.b.2. Auxiliary power sufficient to maintain security and surveillance systems for at least 48 hours following a power outage.

11.1.b.3. Ability to operate under the normal lighting conditions of each area under surveillance.

11.1.b.4. Ability to immediately produce a clear, color, still photograph in a digital format that meets the requirements of this subsection.

11.1.c. Ability to clearly and accurately display the date and time. The date and time must be synchronized and set correctly and may not significantly obscure the picture.

11.1.d. Ability to record all images captured by each surveillance camera in a format that may be easily accessed for a period not less than 180 days, unless otherwise required for investigative or litigation purposes as described in paragraph 11.2.f.2. The recordings must be kept:

11.1.d.1. At the facility:

11.1.d.1.A. In a locked cabinet, closet or other secure place to protect it from tampering or theft; and

11.1.d.1.B. In a limited access area or other room to which access is limited to authorized individuals; or

11.1.d.2. At a secure location other than the location of the facility if approved by the bureau.

11.1.e. A security alarm system separate from the facility's primary security system covering the limited access area or other room where the recordings under subdivision 12.1.d. are stored. The separate security alarm system must meet the same requirements as the facility's primary security alarm system.

11.2. The following apply regarding the inspection, servicing or alteration of, and the upgrade to, the dispensary facility's security and surveillance systems:

11.2.a. The systems must be inspected, and all devices tested once every year by a qualified alarm system vendor and a qualified surveillance system vendor, as approved by the bureau.

11.2.b. The dispensary must conduct maintenance inspections once every month to ensure that any repairs, alterations, or upgrades to the security and surveillance systems are made for the proper operation of the systems.

11.2.c. The dispensary must retain at the facility, for at least four years, records of all inspections, servicing, alterations, and upgrades performed on the systems and must make the records available to the bureau and its authorized agents within two business days following a request.

11.2.d. In the event of a mechanical malfunction of the security or surveillance system that the dispensary anticipates will exceed a four-hour period, the dispensary must notify the bureau immediately and, with bureau approval, provide alternative security measures that may include closure of the facility.

11.2.e. The dispensary must designate an employee to continuously monitor the security and surveillance systems at the facility.

11.2.f. The following apply regarding records retention:

11.2.f.1. Within two business days following a request, a dispensary must provide up to four screen captures of an unaltered copy of a video surveillance recording to the bureau or its authorized agents, law enforcement, or other federal, state, or local government officials if necessary to perform the government officials' functions and duties.

11.2.f.2. If a dispensary has been notified in writing by the bureau or its authorized agents, law enforcement, or other federal, state, or local government officials of a pending criminal or administrative investigation for which a recording may contain relevant information, the dispensary must retain an unaltered copy of the recording for two years or until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the dispensary that it is not necessary to retain the recording, whichever is longer.

11.3. A dispensary must install commercial-grade, nonresidential doors and door locks on each external door of the facility. Keys or key codes for all doors must remain in the possession of designated authorized individuals.

11.4. During all nonworking hours, all entrances to and exits from the facility must be securely locked.

11.5. A dispensary must have an electronic back-up system for all electronic records.

11.6. A dispensary must install lighting to ensure proper surveillance inside and outside of the facility.

11.7. A dispensary must limit access to a room containing security and surveillance monitoring equipment to persons who are essential to maintaining security and surveillance operations; federal, state, and local law enforcement; security and surveillance system service employees; the bureau or its authorized agents; and other persons with the prior written approval of the bureau. The following apply:

11.7.a. A dispensary must make available to the bureau or the bureau's authorized agents, upon request, a current list of authorized employees and service employees, or contractors who have access to any security and surveillance areas.

11.7.b. A dispensary must keep security and surveillance rooms locked at all times and may not use these rooms for any other purpose or function.

§64-112-12. Inventory data.

12.1. A dispensary must maintain the following inventory data in its electronic tracking system:

12.1.a. Medical cannabis received from a grower/processor.

12.1.b. Medical cannabis dispensed to a patient or caregiver.

12.1.c. Damaged, defective, expired, or contaminated medical cannabis awaiting return to a grower/processor or disposal.

12.2. A dispensary must establish inventory controls and procedures to conduct monthly inventory reviews and annual comprehensive inventories of medical cannabis at its facility.

12.3. A written record must be created and maintained of each inventory which includes the date of the inventory, a summary of the inventory findings, and the names, signatures, and titles or positions of the individuals who conducted the inventory.

§64-112-13. Storage requirements.

13.1. A dispensary must have separate locked limited access areas for storage of medical cannabis that is expired, damaged, deteriorated, mislabeled, contaminated, recalled, or whose containers or packaging have been opened or breached until the medical cannabis is returned to a grower/processor, destroyed or otherwise disposed of as required under 64CSR110.22.

13.2. A dispensary must maintain all storage areas in a clean and orderly condition and free from infestation by insects, rodents, birds and pests.

§64-112-14. Sanitation and safety in a facility.

14.1. A dispensary must maintain its facility in a sanitary condition to limit the potential for contamination or adulteration of the medical cannabis stored in or dispensed at the facility. The following apply:

14.1.a. Trash must be properly removed.

14.1.b. Floors, walls and ceilings must be kept in good repair.

14.1.c. Adequate protection against pests must be provided through the use of integrated pest management practices and techniques that identify and manage pest problems, and the regular disposal of trash to prevent infestation.

14.1.d. Toxic cleaning compounds, sanitizing agents, solvents, and pesticide chemicals must be labeled and stored in a manner that prevents contamination of medical cannabis and in a manner that otherwise complies with other applicable laws and rules.

14.2. An employee must conform to sanitary practices while on duty, including the following:

14.2.a. Maintaining adequate personal hygiene.

14.2.b. Washing hands thoroughly in an adequate hand-washing area before starting work and at any other time when hands may have become soiled or contaminated and at all times before dispensing medical cannabis to a patient or caregiver.

14.3. A dispensary must provide its employees and visitors with adequate and convenient hand-washing facilities furnished with running water at a temperature suitable for sanitizing hands. The following apply:

14.3.a. Hand-washing facilities must be located where good sanitary practices require employees to wash and sanitize their hands.

14.3.b. Effective nontoxic sanitizing cleansers and sanitary towel service or suitable hand drying devices must be provided.

14.4. A dispensary must provide its employees and visitors with adequate, readily accessible lavatories that are maintained in a sanitary condition and in good repair.

14.5. A dispensary must comply with all other applicable state and local building code requirements.

§64-112-15. Transportation of medical cannabis.

15.1. A dispensary may transport and deliver medical cannabis to a medical cannabis organization in this state in accordance with this section. The following apply:

15.1.a. A dispensary may deliver medical cannabis to a medical cannabis organization only between 7:00 a.m. and 9:00 p.m. for the purposes of transferring medical cannabis among the permittee's dispensary locations and returning medical cannabis to a grower/processor.

15.1.b. A dispensary may contract with a third-party contractor for delivery so long as the contractor complies with this section.

15.1.c. A dispensary may not transport medical cannabis to any location outside of this state.

15.1.d. A dispensary must use a global positioning system to ensure safe, efficient delivery of the medical cannabis to a medical cannabis organization.

15.2. Vehicles permitted to transport medical cannabis must:

15.2.a. Be equipped with a secure lockbox or locking cargo area.

15.2.b. Have no markings that would either identify or indicate that the vehicle is being used to transport medical cannabis.

15.2.c. Be capable of being temperature-controlled for perishable medical cannabis, as appropriate.

15.2.d. Display current state inspection stickers and maintain a current state vehicle registration.

15.2.e. Be insured in an amount that is commercially reasonable and appropriate.

15.3. A transport vehicle must be staffed with a delivery team consisting of at least two individuals and comply with the following:

15.3.a. At least one delivery team member must remain with the vehicle at all times that the vehicle contains medical cannabis.

15.3.b. Each delivery team member must have access to a secure form of communication with the dispensary, such as a cellular telephone, at all times that the vehicle contains medical cannabis.

15.3.c. Each delivery team member must carry an identification badge or card at all times and must, upon demand, produce it to the bureau or its authorized agents, law enforcement or other federal or state government officials if necessary, to perform the government officials' functions and duties.

15.3.d. Each delivery team member must have a valid driver's license.

15.3.e. While on duty, a delivery team member may not wear any clothing or symbols that may indicate ownership or possession of medical cannabis.

15.4. Medical cannabis stored inside the transport vehicle may not be visible from the outside of the transport vehicle.

15.5. Except as provided in subsection 15.8., a delivery team must proceed in a transport vehicle from the dispensary, where the medical cannabis is loaded, directly to the medical cannabis organization,

where the medical cannabis is unloaded, without unnecessary delays. Notwithstanding the foregoing, a transport vehicle may make stops at multiple facilities, as appropriate, to deliver medical cannabis.

15.6. A dispensary must immediately report to the bureau, either through a designated phone line established by the bureau or by electronic communication with the bureau in a manner prescribed by the bureau, any vehicle accidents, diversions, losses, or other reportable events that occur during transport of medical cannabis.

15.7. A dispensary must notify the bureau daily of its delivery schedule, including routes and delivery times, either through a designated phone line established by the bureau or by electronic communication with the bureau in a manner prescribed by the bureau.

15.8. A transport vehicle is subject to inspection by the bureau or its authorized agents, law enforcement, or other federal or state officials, if necessary to perform the government officials' functions and duties. A transport vehicle may be stopped and inspected along its delivery route or at any medical cannabis organization.

§64-112-16. Transport manifest.

16.1. A dispensary must generate a printed or electronic transport manifest that accompanies every transport vehicle and contains the following information:

16.1.a. The name, address, and permit number of the dispensary, and the name of and contact information for a representative of the dispensary who has direct knowledge of the transport.

16.1.b. The name, address, and permit number of the medical cannabis organization receiving the delivery, and the name of and contact information for a representative of the medical cannabis organization.

16.1.c. The quantity, by weight or unit, of each medical cannabis batch or lot contained in the transport, along with the identification number for each batch or lot.

16.1.d. The date and approximate time of departure.

16.1.e. The date and approximate time of arrival.

16.1.f. The transport vehicle's make and model and license plate number.

16.1.g. The identification number of each member of the delivery team accompanying the transport.

16.2. When a delivery team delivers medical cannabis to multiple medical cannabis organizations, the transport manifest must correctly reflect the specific medical cannabis in transit. Each recipient must provide the dispensary with a printed receipt for the medical cannabis received.

16.3. All medical cannabis being transported must be packaged in shipping containers and labeled in accordance with 64CSR110.16 and section 8 of this rule.

16.4. A dispensary must provide a copy of the transport manifest to the recipient receiving the medical cannabis described in the transport manifest. To maintain confidentiality, a dispensary may prepare separate manifests for each recipient.

16.5. A dispensary must, if requested, provide a copy of the printed transport manifest, and any printed receipts for medical cannabis being transported, to the bureau or its authorized agents, law enforcement, or other federal or state government officials if necessary to perform the government officials' functions and duties.

§64-112-17. Evidence of adverse loss during transport.

17.1. If a dispensary receiving a delivery of medical cannabis from a medical cannabis organization discovers a discrepancy in the transport manifest upon delivery, the dispensary must refuse acceptance of the delivery and immediately report the discrepancy to the bureau either through a designated phone line established by the bureau or by electronic communication with the bureau in a manner prescribed by the bureau, and to the appropriate law enforcement authorities.

17.2. If a dispensary discovers evidence of, or reasonably suspects, a theft or diversion of medical cannabis during transport, the dispensary must immediately report its findings or suspicions to the bureau either through a designated phone line established by the bureau or by electronic communication with the bureau in a manner prescribed by the bureau, and to law enforcement.

17.3. If a dispensary discovers a discrepancy in the transport manifest, the dispensary must:

17.3.a. Conduct an investigation.

17.3.b. Amend the dispensary's standard plan of operation, if necessary, to prevent future discrepancies between the quantity or description of inventory listed in the transport manifest and the quantity or description of inventory delivered.

17.3.c. Submit a report of the investigation to the bureau. The following apply:

17.3.c.1. A written preliminary report of the investigation must be submitted to the bureau within seven days of discovering the discrepancy.

17.3.c.2. A final written report of the investigation must be submitted to the bureau within 30 days of discovering the discrepancy.

§64-112-18. Complaints about or recall of medical cannabis.

18.1. A dispensary must notify the bureau and the grower/processor immediately upon becoming aware of any complaint made to the dispensary by a patient, caregiver or practitioner who reports an adverse event from using medical cannabis dispensed by the dispensary.

18.2. Upon notification by the grower/processor under 64CSR110.23, the dispensary must cease dispensing the affected medical cannabis.

18.3. A dispensary must coordinate the return of the recalled medical cannabis with the grower/processor.

§64-112-19. Electronic tracking system.

A dispensary must use the electronic tracking system prescribed by the bureau containing the requirements in W. Va. Code §16A-7-1. The bureau will publish notice of the electronic tracking system to be utilized by a dispensary in the State Register 60 days prior to the implementation date of the system.

§64-112-20. Application for additional dispensary locations.

20.1. An applicant for a dispensary permit must include at least one specified dispensary facility location in its initial permit application and may file an application under this section for additional dispensary facility locations at a later date.

20.2. A dispensary must submit an application for additional dispensary locations on a form prescribed by the bureau.

20.3. A dispensary submitting an application for additional dispensary locations must include with the application the following fees:

20.3.a. An application fee of \$2,500, which is nonrefundable.

20.3.b. A permit fee of \$10,000 for each dispensary location being proposed. The permit fee must be submitted with the application for additional dispensary locations and will be refunded if the application is not granted.

20.4. A dispensary may not begin operations at an additional location until the bureau approves the application for additional dispensary locations, in writing, under this section.

20.5. A dispensary submitting an application for additional dispensary locations must follow the requirements in 64CSR109 and this rule.



WEST VIRGINIA SECRETARY OF STATE
MAC WARNER
ADMINISTRATIVE LAW DIVISION

eFILED

4/21/2020 9:45:57 AM

Office of West Virginia
Secretary Of State

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED
BY THE WEST VIRGINIA LEGISLATURE**

AGENCY: Health TITLE-SERIES: 64-113

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: medical cannabis program-safe harbor letter

CITE STATUTORY AUTHORITY: 16A-3-1(b)

The above rule has been authorized by the West Virginia Legislature.

Authorization is cited in (house or senate bill number) SB 339

Section 64-5-1(k) Passed On 3/5/2020 12:00:00 AM

This rule is filed with the Secretary of State. This rule becomes effective on the following date:

April 21, 2020

This rule shall terminate and have no further force or effect from the following date:

April 21, 2025

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

April L Robertson -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

**TITLE 64
LEGISLATIVE RULE
BUREAU FOR PUBLIC HEALTH**

**SERIES 113
MEDICAL CANNABIS PROGRAM – SAFE HARBOR LETTER**

§64-113-1. General

1.1. Scope. The provisions of these rules include provisions for obtaining a safe harbor letter from the bureau that authorizes a terminally ill cancer patient to use medical cannabis purchased in another state that has entered into a reciprocity agreement with the bureau.

1.2. Authority. W. Va. Code §16A-3-1(b) and §16A-3-5.

1.3. Filing Date. April 21, 2020.

1.4. Effective Date. April 21, 2020.

1.5. Sunset Provision. These rules will terminate and have no further force or effect on April 21, 2025.

1.6. Applicability. These rules apply to a person who is a terminally ill cancer patient who desires to use medical cannabis purchased in another state that has entered into a reciprocity agreement with the bureau.

§64-113-2. Definitions.

2.1. "Act" means the West Virginia Medical Cannabis Act (W. Va. Code §16A-1-1 *et seq.*).

2.2. "Applicant" means an applicant who wishes to submit or submits an application to the bureau for a Safe Harbor letter.

2.3. "Bureau" means the West Virginia Bureau for Public Health within the Department.

2.4. "Caregiver" means the individual designated by a patient or, if the patient is under 18 years of age, an individual authorized under W. Va. Code §16A-5-1 *et seq.*, to deliver medical cannabis.

2.5. "Certified medical use" means the acquisition, possession, use, or transportation of medical cannabis by an applicant, or the acquisition, possession, delivery, transportation, or administration of medical cannabis by a caregiver, for use as part of the treatment of the applicant's serious medical condition, as authorized in an applicant certification issued under the Act, including enabling the applicant to tolerate treatment for the serious medical condition.

2.6. "Department" means the Department of Health and Human Resources.

2.7. "Medical cannabis" means cannabis that is grown and sold pursuant to the provisions for certified medical use as set forth in the Act and in a form set forth in the provisions of §64-110-10.

2.8. "Medical cannabis program" means the program authorized under the Act and implemented by the bureau.

2.9. "Patient" means an individual who:

2.9.a. Is a terminally ill cancer patient.

2.9.b. Has met the requirements for certification under the Act.

2.9.c. Is a resident of the state of West Virginia.

2.10. "Safe Harbor Letter" means a letter provided by the bureau to an applicant under W. Va. Code §16A-3-5 that allows the applicant to administer to him or herself medical cannabis purchased in another state with which the state has entered into a reciprocity agreement.

2.11. "Terminally ill cancer patient" means a person with a diagnosis of cancer and a medical prognosis of life expectancy of approximately one year or less if the illness runs its normal course.

§64-113-3. Medical cannabis from outside this State.

3.1. Application for Safe Harbor Letter. An applicant may apply to the bureau for a Safe Harbor Letter authorizing the applicant to use medical cannabis in this state that was obtained from a state with which bureau has entered into a reciprocity agreement.

§64-113-4. Application.

4.1. An applicant must submit an application for a Safe Harbor Letter under these rules on a form provided by the bureau, and must include the following information and any other information deemed necessary by the bureau:

4.1.a. The name, address and date of birth of the applicant.

4.1.b. The name, address, and date of birth of a caregiver, if applicable;

4.1.c. The applicant's proof of residency by submitting one of the following:

4.1.c.1. A West Virginia driver's license.

4.1.c.2. Department of Motor Vehicles-issued identification card.

4.1.c.3. Another form of identification that contains a photo and is approved by the bureau in the application.

4.1.d. The caregiver's criminal history record information obtained from the West Virginia State Police or its authorized agent, if applicable.

4.1.e. A written statement from a licensed physician in this state confirming that the applicant is a terminally ill cancer patient, the physician's name, address of practice, telephone number, and state license number.

4.1.f. An applicant must verify that the applicant will obtain the medical cannabis lawfully in another state.

4.2. The applicant must complete every required section of the application before it will be considered by the bureau.

4.2.a. If the bureau deems an application submitted by an applicant to be incomplete, the bureau will notify the applicant in writing of the factors for which further documentation is required.

4.2.b. An applicant must have 30 days from the mailing date of the notification to submit the additional material to the bureau or the bureau will deem the application as denied and the applicant will be required to submit a new application.

4.3. The applicant must certify as part of the application that the applicant understands the following:

4.3.a. Cannabis is a prohibited Schedule I controlled substance under federal law.

4.3.b. Participation in the Medical Cannabis Program is permitted only to the extent provided by the Act and these rules.

4.3.c. An activity not sanctioned by the Act or rules promulgated under the Act is a violation of state law.

4.3.d. Growing, distributing, or possessing cannabis in any capacity, except through a federally approved research program, is a violation of federal law.

4.3.e. Improper use or acquisition of medical cannabis may be a violation of state or federal law.

4.3.f. Participation in the Medical Cannabis Program does not authorize a person to violate federal or state law and does not provide immunity from or affirmative defense to arrest or prosecution under federal or state law except as provided under the Act.

4.3.g. Notwithstanding anything herein to the contrary, that civil or criminal penalties may result from the applicant's participation in the Medical Cannabis Program, including obtaining medical cannabis from outside this state as set forth in W. Va. Code §16A-3-5.

4.4. An application for a Safe Harbor Letter must be obtained and submitted as required by the bureau, which shall include notice that a false statement by the applicant is punishable under the applicable provisions of the Uniform Controlled Substances Act, W. Va. Code §60A-1-101 *et seq.*

§64-113-5. Validity of Safe Harbor Letter.

5.1. The Safe Harbor Letter will be valid from the date of issuance by the bureau until August 1, 2022, or unless any of the following occurs:

5.1.a. The applicant dies.

5.1.b. The applicant changes physicians.

5.1.c. The applicant's physician knows or has reason to know that the applicant no longer suffers from terminal cancer and that use of medical cannabis would not be medically indicated.

5.1.d. The applicant's residency in another state.

5.1.e. The applicant receives notice under subsection 5.6.

5.2. The applicant or physician, or both, must notify the bureau in writing immediately upon

knowledge of any change in the information in the original application and upon the occurrence of an event listed in subsection 5.1. The applicant must return the invalid Safe Harbor Letter to the bureau.

5.3. A new application must be submitted to the bureau under the following circumstances:

5.3.a. The applicant changes physicians. The application must include a written statement from the new physician that the applicant is a terminally ill cancer patient.

5.3.b. The applicant has not submitted information within 30 days under subdivision 4.2.b (relating to application).

5.4. The new application must be submitted to the bureau within a reasonable time period of the occurrence of the triggering event.

5.5. The submission of a new application will not be considered to be effective notice under subsection 5.2.

5.6. In the event that the Medical Cannabis Program becomes effective prior to the expiration of Safe Harbor Letters, the bureau will publish notice in the State Register that Safe Harbor Letters will be invalid as of a certain date. Individuals wishing to participate in the Medical Cannabis Program must obtain the requisite identification cards and registrations under the Act and these rules.

§64-113-6. Penalties and sanctions.

6.1. In addition to the penalties in W. Va. Code §16A-12-1 *et seq.*, the bureau may deny, revoke, or suspend a Safe Harbor Letter if the Bureau has evidence of the following:

6.1.a. Falsified information on the application.

6.1.b. An intentional, knowing, or reckless violation of a provision of the Act or rules promulgated to implement the Act.

6.2. Any person adversely affected by the enforcement of this rule shall seek relief in the manner prescribed by 64CSR1.

§64-113-7. Confidentiality.

7.1. Information obtained by the bureau regarding an applicant under these rules is confidential and not subject to public disclosure, including disclosure under the West Virginia Freedom of Information Act (W. Va. Code §29A-1-1 *et seq.*), including the following:

7.1.a. Individual identifying information of applicant.

7.1.b. Information regarding the applicant's medical condition, including the physician's written statements.

WEST VIRGINIA LEGISLATURE

2020 REGULAR SESSION

Enrolled

Committee Substitute

for

Senate Bill 339

OFFICE OF THE
SECRETARY OF STATE

MAR 24 A 10:37

FILED

SENATOR MAYNARD, *original sponsor*

[Passed March 5, 2020; in effect from passage]

SB 339

WEST VIRGINIA LEGISLATURE

2020 REGULAR SESSION

Enrolled

Committee Substitute

for

Senate Bill 339

SENATOR MAYNARD, *original sponsor*

[Passed March 5, 2020; in effect from passage]

FILED

2020 WVA 24 A 0 07
OFFICE OF THE SECRETARY OF STATE
SECRETARIAT OF STATE

1 AN ACT to amend and reenact §64-5-1 *et seq.* of the Code of West Virginia, 1931, as amended,
2 relating generally to authorizing certain agencies of the Department of Health and Human
3 Resources to promulgate legislative rules; authorizing the rules as filed, as modified by
4 the Legislative Rule-Making Review Committee, and as amended by the Legislature;
5 authorizing the Department of Health and Human Resources to promulgate a legislative
6 rule relating to public water systems; authorizing the Department of Health and Human
7 Resources to promulgate a legislative rule relating to fees for permits; authorizing the
8 Department of Health and Human Resources to promulgate a legislative rule relating to
9 vital statistics; authorizing the Department of Health and Human Resources to promulgate
10 a legislative rule relating to emergency medical services; authorizing the Department of
11 Health and Human Resources to promulgate a legislative rule relating to primary care
12 support program; authorizing the Department of Health and Human Resources to
13 promulgate a legislative rule relating to primary care seed money grants; authorizing the
14 Department of Health and Human Resources to promulgate a legislative rule relating to
15 medical cannabis program—general provisions; authorizing the Department of Health and
16 Human Resources to promulgate a legislative rule relating to medical cannabis program—
17 grower/processors; authorizing the Department of Health and Human Resources to
18 promulgate a legislative rule relating to medical cannabis program—laboratories;
19 authorizing the Department of Health and Human Resources to promulgate a legislative
20 rule relating to medical cannabis program—dispensaries; authorizing the Department of
21 Health and Human Resources to promulgate a legislative rule relating to medical cannabis
22 program—safe harbor letter; authorizing the Department of Health and Human Resources
23 to promulgate a legislative rule relating to the collection and exchange of data related to
24 overdoses; authorizing the Department of Health and Human Resources to promulgate a
25 legislative rule relating to minimum licensing requirements for residential child care and
26 treatment facilities for children and transitioning adults in West Virginia; authorizing the

27 Department of Health and Human Resources to promulgate a legislative rule relating to
28 qualifications for a provisional license to practice as a social worker within the Department
29 of Health and Human Resources; authorizing the Department of Health and Human
30 Resources to promulgate a legislative rule relating to pilot program for drug screening of
31 applicants for cash assistance; and authorizing the Health Care Authority to promulgate a
32 legislative rule relating to critical access hospitals.

Be it enacted by the Legislature of West Virginia:

**ARTICLE 5. AUTHORIZATION FOR DEPARTMENT OF HEALTH AND HUMAN
RESOURCES TO PROMULGATE LEGISLATIVE RULES.**

§64-5-1. Department of Health and Human Resources.

1 (a) The legislative rule filed in the State Register on July 16, 2019, authorized under the
2 authority of §16-1-4 of this code, modified by the Department of Health and Human Resources to
3 meet the objections of the Legislative Rule-Making Review Committee and refiled in the State
4 Register on November 4, 2019, relating to the Department of Health and Human Resources
5 (public water systems, 64 CSR 03), is authorized.

6 (b) The legislative rule filed in the State Register on July 16, 2019, authorized under the
7 authority of §16-1-11(d) of this code, modified by the Department of Health and Human Resources
8 to meet the objections of the Legislative Rule-Making Review Committee and refiled in the State
9 Register on December 19, 2019, relating to the Department of Health and Human Resources
10 (fees for permits, 64 CSR 30), is authorized.

11 (c) The legislative rule filed in the State Register on July 16, 2019, authorized under the
12 authority of §16-5-3 of this code, modified by the Department of Health and Human Resources to
13 meet the objections of the Legislative Rule-Making Review Committee and refiled in the State
14 Register on November 4, 2019, relating to the Department of Health and Human Resources (vital
15 statistics, 64 CSR 32), is authorized.

16 (d) The legislative rule filed in the State Register on July 16, 2019, authorized under the
17 authority of §16-4C-23 of this code, modified by the Department of Health and Human Resources
18 to meet the objections of the Legislative Rule-Making Review Committee and refiled in the State
19 Register on November 4, 2019, relating to the Department of Health and Human Resources
20 (emergency medical services, 64 CSR 48), is authorized.

21 (e) The legislative rule filed in the State Register on July 25, 2019, authorized under the
22 authority of §16-2H-2(d) of this code, modified by the Department of Health and Human
23 Resources to meet the objections of the Legislative Rule-Making Review Committee and refiled
24 in the State Register on December 19, 2019, relating to the Department of Health and Human
25 Resources (primary care support program, 64 CSR 70), is authorized, with the following
26 amendment:

27 On page 4, by striking subsection 4.2.

28 (f) The legislative rule filed in the State Register on July 26, 2019, authorized under the
29 authority of §16-2H-2(d) of this code, relating to the Department of Health and Human Resources
30 (primary care seed money grants, 64 CSR 71), is authorized.

31 (g) The legislative rule filed in the State Register on July 25, 2019, authorized under the
32 authority of §16A-3-1(b) of this code, modified by the Department of Health and Human
33 Resources to meet the objections of the Legislative Rule-Making Review Committee and refiled
34 in the State Register on October 4, 2019, relating to the Department of Health and Human
35 Resources (medical cannabis program—general provisions, 64 CSR 109), is authorized, with the
36 following amendment:

37 On page 5, by striking subsection 2.36 and inserting a new subsection 2.36 to read as
38 follows: 2.36 “Medical cannabis” means cannabis that is grown and sold pursuant to the
39 provisions for certified medical use as set forth in the Act and in a form set forth in the provisions
40 of §64-110-10.

41 (h) The legislative rule filed in the State Register on July 25, 2019, authorized under the
42 authority of §16A-3-1(b) of this code, modified by the Department of Health and Human
43 Resources to meet the objections of the Legislative Rule-Making Review Committee and refiled
44 in the State Register on October 4, 2019, relating to the Department of Health and Human
45 Resources (medical cannabis program—grower/processors, 64 CSR 110), is authorized, with the
46 following amendments:

47 On page 4, by striking subsection 2.29 and inserting a new subsection 2.29 to read as
48 follows: 2.29 “Medical cannabis” means cannabis that is grown and sold pursuant to the
49 provisions for certified medical use as set forth in the Act and in a form set forth in the provisions
50 of §64-110-10.;

51 On page 12, subdivision 8.1.d., after the words “minimum of”, by deleting the words “four
52 years” and inserting in lieu thereof the words “two years”; and

53 On page 13, subparagraph 8.2.f.2., after the words “recording for”, by deleting the words
54 “four years” and inserting in lieu thereof the words “two years”.

55 And,

56 On page 15, by striking section §64-110-10 and inserting in lieu thereof a new §64-110-
57 10 to read as follows:

58 **“§64-110-10. Forms of medical cannabis.”**

59 10.1. A grower/processor may only process medical cannabis for dispensing to a patient
60 or caregiver in the following forms:

61 10.1.a. Pill;

62 10.1.b. Oil;

63 10.1.c. Topical forms, including gel, creams, and ointments;

64 10.1.d. A form medically appropriate for administration by vaporization or nebulization;

65 10.1.e. Liquid;

66 10.1.f. Dermal patch; or

67 10.1.g. Dry leaf or plant form.

68 10.2. A grower/processor may not manufacture, produce, or assemble any medical
69 cannabis product, instrument, or device without prior written approval of the bureau.

70 (i) The legislative rule filed in the State Register on July 25, 2019, authorized under the
71 authority of §16A-3-1(b) of this code, modified by the Department of Health and Human
72 Resources to meet the objections of the Legislative Rule-Making Review Committee and refiled
73 in the State Register on October 4, 2019, relating to the Department of Health and Human
74 Resources (medical cannabis program—laboratories, 64 CSR 111), is authorized, with the
75 following amendment:

76 On page 3, by striking subsection 2.15 and inserting a new subsection 2.15 to read as
77 follows: 2.15 “Medical cannabis” means cannabis that is grown and sold pursuant to the
78 provisions for certified medical use as set forth in the Act and in a form set forth in the provisions
79 of §64-110-10.

80 (j) The legislative rule filed in the State Register on July 25, 2019, authorized under the
81 authority of §16A-3-1(b) of this code, modified by the Department of Health and Human
82 Resources to meet the objections of the Legislative Rule-Making Review Committee and refiled
83 in the State Register on October 4, 2019, relating to the Department of Health and Human
84 Resources (medical cannabis program—dispensaries, 64 CSR 112), is authorized, with the
85 following amendments:

86 On page 3, by striking subsection 2.19 and inserting a new subsection 2.19 to read as
87 follows: 2.19 “Medical cannabis” means cannabis that is grown and sold pursuant to the
88 provisions for certified medical use as set forth in the Act and in a form set forth in the provisions
89 of §64-110-10.; and

90 On page 12, subdivision 11.1.d., after the words “minimum of”, by deleting the words “four
91 years” and inserting in lieu thereof the words “two years”.

92 (k) The legislative rule filed in the State Register on July 24, 2019, authorized under the
93 authority of §16A-3-1(b) of this code, modified by the Department of Health and Human
94 Resources to meet the objections of the Legislative Rule-Making Review Committee and refiled
95 in the State Register on December 19, 2019, relating to the Department of Health and Human
96 Resources (medical cannabis program—safe harbor letter, 64 CSR 113), is authorized, with the
97 following amendment:

98 On page 1, by striking subsection 2.7 and inserting a new subsection 2.7 to read as
99 follows: 2.7 “Medical cannabis” means cannabis that is grown and sold pursuant to the provisions
100 for certified medical use as set forth in the Act and in a form set forth in the provisions of §64-110-
101 10.

102 (l) The legislative rule filed in the State Register on July 22, 2019, authorized under the
103 authority of §16-5T-5 of this code, modified by the Department of Health and Human Resources
104 to meet the objections of the Legislative Rule-Making Review Committee and refiled in the State
105 Register on November 21, 2019, relating to the Department of Health and Human Resources
106 (collection and exchange of data related to overdoses, 69 CSR 14), is authorized.

107 (m) The legislative rule filed in the State Register on July 26, 2019, authorized under the
108 authority of §49-2-121 of this code, modified by the Department of Health and Human Resources
109 to meet the objections of the Legislative Rule-Making Review Committee and refiled in the State
110 Register on January 7, 2020, relating to the Department of Health and Human Resources
111 (minimum licensing requirements for residential child care and treatment facilities for children and
112 transitioning adults in West Virginia, 78 CSR 03), is authorized.

113 (n) The legislative rule filed in the State Register on July 24, 2019, authorized under the
114 authority of §30-30-16(c)(2) of this code, modified by the Department of Health and Human
115 Resources to meet the objections of the Legislative Rule-Making Review Committee and refiled
116 in the State Register on November 25, 2019, relating to the Department of Health and Human

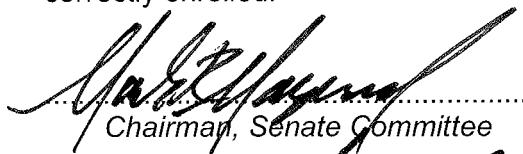
117 Resources (qualifications for a provisional license to practice as a social worker within the
118 Department of Health and Human Resources, 78 CSR 24), is authorized.

119 (o) The legislative rule filed in the State Register on September 4, 2019, authorized under
120 the authority of §9-3-6 of this code, relating to the Department of Health and Human Resources
121 (pilot program for drug screening of applicants for cash assistance, 78 CSR 26), is authorized.

§64-5-2. Health Care Authority.

1 The legislative rule filed in the State Register on July 16, 2019, authorized under the
2 authority of §16-5B-14(d) of this code, modified by the Health Care Authority to meet the
3 objections of the Legislative Rule-Making Review Committee and refiled in the State Register on
4 November 22, 2019, relating to the Health Care Authority (critical access hospitals, 65 CSR 09),
5 is authorized.

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


Matt Hagen
Chairman, Senate Committee


Moore Capito
Chairman, House Committee

2020 MAR 24 A 10:08
OFFICE OF THE GOVERNOR
SECRETARY OF STATE

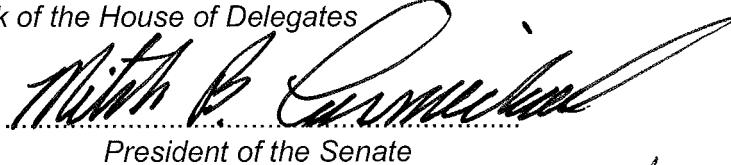
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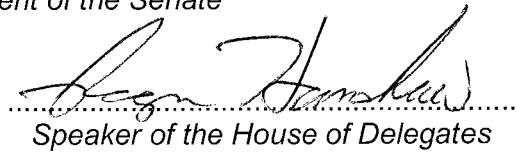
Originated in the Senate.

In effect from passage.

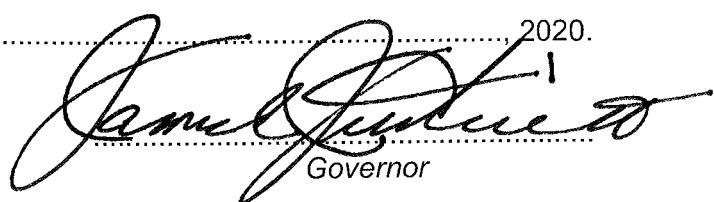

Jeff Lamm
Clerk of the Senate


Steve Warriner
Clerk of the House of Delegates


Mitch B. Gerwick
President of the Senate


Benji Hamlin
Speaker of the House of Delegates

The within is approved this the 24th
Day of March, 2020.


Jim Justice
Governor

PRESENTED TO THE GOVERNOR

MAR 12 2020

Time 3:02pm

WV Code §16A-1

§16A-1-1. Short title.

This chapter is in honor of James William “Bill” Flanigan and Lucile Gillespie and shall be known and cited as the West Virginia Medical Cannabis Act.

WV Code §16A-2

§16A-2-1. Definitions.

(a) The following words and phrases when used in this chapter shall have the meanings given to them in this section unless the context clearly indicates otherwise:

(1) "Act" means the West Virginia Medical Cannabis Act and the provisions contained in §60A-1-101 *et seq.* of this code.

(2) "Advisory board" means the advisory board established under §16A-11-1 *et seq.* of this code.

(3) "Bureau" means the Bureau for Public Health within the Department of Health.

(4) "Caregiver" means the individual designated by a patient or, if the patient is under 18 years of age, an individual authorized under §16A-5-1 *et seq.* of this code, to deliver medical cannabis.

(5) "Certified medical use" means the acquisition, possession, use, or transportation of medical cannabis by a patient, or the acquisition, possession, delivery, transportation, or administration of medical cannabis by a caregiver, for use as part of the treatment of the patient's serious medical condition, as authorized in a certification under this act, including enabling the patient to tolerate treatment for the serious medical condition.

(6) "Change in control" means the acquisition by a person or group of persons acting in concert of a controlling interest in an applicant or permittee either all at one time or over the span of a 12-consecutive-month period.

(7) "Commissioner" means the Commissioner of the Bureau for Public Health.

(8) "Continuing care" means treating a patient, in the course of which the practitioner has completed a full assessment of the patient's medical history and current medical condition, including an in-person consultation with the patient, and is able to document and make a medical diagnosis based upon the substantive treatment of the patient.

(9) "Controlling interest" means:

(A) For a publicly traded entity, voting rights that entitle a person to elect or appoint one or more of the members of the board of directors or other governing board or the ownership or beneficial holding of five percent or more of the securities of the publicly traded entity.

(B) For a privately held entity, the ownership of any security in the entity.

(10) "Dispensary" means a person, including a natural person, corporation, partnership, association, trust, or other entity, or any combination thereof, which holds a permit issued by the

bureau to dispense medical cannabis. The term does not include a health care medical cannabis organization as defined in §16A-13-1 *et seq.* of this code.

(11) "Family or household member" means the same as defined in §48-27-204 of this code.

(12) "Financial backer" means an investor, mortgagee, bondholder, note holder, or other source of equity, capital, or other assets, other than a financial institution.

(13) "Financial institution" means a bank, a national banking association, a bank and trust company, a trust company, a savings and loan association, a building and loan association, a mutual savings bank, a credit union, or a savings bank.

(14) "Form of medical cannabis" means the characteristics of the medical cannabis recommended or limited for a particular patient, including the method of consumption and any particular dosage, strain, variety and quantity, or percentage of medical cannabis or particular active ingredient.

(15) "Fund" means the Medical Cannabis Program Fund established in §16A-9-2 of this code.

(16) "Grower" means a person, including a natural person, corporation, partnership, association, trust, or other entity, or any combination thereof, which holds a permit from the bureau under this act to grow medical cannabis. The term does not include a health care medical cannabis organization as defined in §16A-13-1 *et seq.* of this code.

(17) "Grower/processor" means either a grower or a processor.

(18) "Identification card" means a document issued under §16A-5-1 *et seq.* of this code that authorizes access to medical cannabis under this act.

(19) "Individual dose" means a single measure of medical cannabis.

(20) "Medical cannabis" means cannabis for certified medical use as set forth in this act.

(21) "Medical cannabis organization" means a dispensary, grower, or processor. The term does not include a health care medical cannabis organization as defined in §16A-13-1 *et seq.* of this code.

(22) "Patient" means an individual who:

- (A) Has a serious medical condition;
- (B) Has met the requirements for certification under this act; and
- (C) Is a resident of this state.

(23) "Permit" means an authorization issued by the bureau to a medical cannabis organization to conduct activities under this act.

(24) "Physician" or "practitioner" means a doctor of allopathic or osteopathic medicine who is fully licensed pursuant to the provisions of either §30-3-1 *et seq.* or §30-14-1 *et seq.* of this code to practice medicine and surgery in this state.

(25) "Post-traumatic stress disorder" means a diagnosis made as part of continuing care of a patient by a medical doctor, licensed counselor, or psychologist.

(26) "Prescription drug monitoring program" means the West Virginia Controlled Substances Monitoring Program under §60A-9-101 *et seq.* of this code.

(27) "Principal" means an officer, director, or person who directly owns a beneficial interest in or ownership of the securities of an applicant or permittee, a person who has a controlling interest in an applicant or permittee, or who has the ability to elect the majority of the board of directors of an applicant or permittee, or otherwise control an applicant or permittee, other than a financial institution.

(28) "Processor" means a person, including a natural person, corporation, partnership, association, trust, or other entity, or any combination thereof, which holds a permit from the bureau under this act to process medical cannabis. The term does not include a health care medical cannabis organization as defined in §16A-13-1 *et seq.* of this code.

(29) "Registry" means the registry established by the bureau for practitioners.

(30) "Serious medical condition" means any of the following, as has been diagnosed as part of a patient's continuing care:

(A) Cancer.

(B) Positive status for human immunodeficiency virus or acquired immune deficiency syndrome.

(C) Amyotrophic lateral sclerosis.

(D) Parkinson's disease.

(E) Multiple sclerosis.

(F) Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity.

(G) Epilepsy.

(H) Neuropathies.

- (I) Huntington's disease.
- (J) Crohn's disease.
- (K) Post-traumatic stress disorder.
- (L) Intractable seizures.
- (M) Sickle cell anemia.
- (N) Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain.
- (O) Terminally ill.

(31) "Terminally ill" means a medical prognosis of life expectancy of approximately one year or less if the illness runs its normal course.

WV Code §16A-3

§16A-3-1. Establishment of program.

(a) A medical cannabis program for patients suffering from serious medical conditions is established. The program shall be implemented and administered by the bureau. The bureau shall:

- (1) Issue permits to medical cannabis organizations to authorize them to grow, process or dispense medical cannabis and ensure their compliance with this act.
- (2) Register practitioners and ensure their compliance with this act.
- (3) Have regulatory and enforcement authority over the growing, processing, sale and use of medical cannabis in this state.
- (4) Establish and maintain an electronic database to include activities and information relating to medical cannabis organizations, certifications and identification cards issued, practitioner registration and electronic tracking of all medical cannabis as required under this act to include:
 - (A) Ensurance that medical cannabis is not diverted or otherwise used for unlawful purposes by a practitioner or medical cannabis organization.
 - (B) Ability to establish the authenticity of identification cards.
 - (C) Recording recommended forms of medical cannabis provided in a certification filed by the practitioner.
 - (D) Monitoring all growth, transfer, possession, processing, testing and dispensing of medical cannabis in this state.
 - (E) The tracking system under article seven of this chapter must include information under section one, article eight of this chapter and any other information required by the bureau to be used by the bureau and dispensaries to enable a dispensary to lawfully provide medical cannabis. The tracking system and database shall be capable of providing information in real time. The database shall be capable of receiving information from a dispensary regarding the disbursement of medical cannabis to patients and caregivers. This information shall be immediately accessible to the bureau and other dispensaries to inhibit diversion and ensure compliance with this act.
- (5) Maintain a directory of patients and caregivers approved to use or assist in the administration of medical cannabis within the bureau's database.
- (6) Develop a four-hour training course for physicians regarding the latest scientific research on medical cannabis, including the risks and benefits of medical cannabis and other information

deemed necessary by the bureau. Successful completion of the course shall be approved as continuing education credits as determined by:

- (A) The State Board of Medicine.
- (B) The State Board of Osteopathic Medicine.

(7) Develop a two-hour course for the principals and employees of a medical cannabis organization who either have direct contact with patients or caregivers or who physically handle medical cannabis. Employees must successfully complete the course no later than ninety days after commencing employment. Principals must successfully complete the course prior to commencing initial operation of the medical cannabis organization. The subject matter of the course shall include the following:

- (A) Methods to recognize and report unauthorized activity, including diversion of medical cannabis for unlawful purposes and falsification of identification cards.
- (B) Proper handling of medical cannabis and recordkeeping.
- (C) Any other subject required by the bureau.

(8) Develop enforcement procedures, including announced and unannounced inspections of facilities of the grower/processors and dispensaries and all records of the medical cannabis organizations.

(9) Establish a program to authorize the use of medical cannabis to conduct medical research relating to the use of medical cannabis to treat serious medical conditions, including the collection of data and the provision of research grants.

(10) Establish and maintain public outreach programs about the medical cannabis program, including:

- (A) A dedicated telephone number for patients, caregivers and members of the public to obtain basic information about the dispensing of medical cannabis under this act.
- (B) A publicly accessible Internet website with similar information.

(11) Collaborate as necessary with other state agencies or contract with third parties as necessary to carry out the provisions of this act.

(12) Determine the number and type of medical cannabis products to be produced by a grower/processor and dispensed by a dispensary.

(13) Develop recordkeeping requirements for all books, papers, any electronic database or tracking system data and other information of a medical cannabis organization. Information shall be retained for a minimum period of four years unless otherwise provided by the bureau.

(14) Restrict the advertising and marketing of medical cannabis, which shall be consistent with the Federal rules and regulations governing prescription drug advertising and marketing.

(b) The bureau shall propose rules for legislative promulgation pursuant to the provisions of article three, chapter twenty-nine-a of this code as may be necessary to carry out and implement the provisions of this act. The bureau shall also have the power to propose and promulgate emergency rules as may be necessary to carry out and implement the provisions of this act.

§16A-3-2. Lawful use of medical cannabis.

(a) Notwithstanding any provision of law to the contrary, the use or possession of medical cannabis as set forth in this act is lawful within this state, subject to the following conditions:

(1) Medical cannabis may only be dispensed to:

(A) a patient who receives a certification from a practitioner and is in possession of a valid identification card issued by the bureau; and

(B) a caregiver who is in possession of a valid identification card issued by the bureau.

(2) Subject to rules promulgated under this act, medical cannabis may only be dispensed to a patient or caregiver in the following forms:

(A) Pill;

(B) Oil;

(C) Topical forms, including gels, creams or ointments;

(D) A form medically appropriate for administration by vaporization or nebulization, excluding dry leaf or plant form until dry leaf or plant forms become acceptable under rules adopted by the bureau;

(E) Tincture;

(F) Liquid; or

(G) Dermal patch.

(3) Unless otherwise provided in rules adopted by the bureau under section two, article eleven of this chapter, medical cannabis may not be dispensed to a patient or a caregiver in dry leaf or plant form.

(4) An individual may not act as a caregiver for more than five patients.

(5) A patient may designate up to two caregivers at any one time.

(6) Medical cannabis that has not been used by the patient shall be kept in the original package in which it was dispensed.

(7) A patient or caregiver shall possess an identification card whenever the patient or caregiver is in possession of medical cannabis.

(8) Products packaged by a grower/processor or sold by a dispensary shall only be identified by the name of the grower/processor, the name of the dispensary, the form and species of medical cannabis, the percentage of tetrahydrocannabinol and cannabinol contained in the product.

§16A-3-3. Unlawful use of medical cannabis.

(a) Except as provided in section two of this article, section four of article seven, article thirteen or article fourteen of this chapter, the use of medical cannabis is unlawful and shall, in addition to any other penalty provided by law, be deemed a violation of the Uniform Controlled Substances Act under chapter sixty-a of this code.

(b) It shall be unlawful to:

(1) Smoke medical cannabis.

(2) Except as provided under subsection (c), incorporate medical cannabis into edible form or sell in edible form.

(3) Grow medical cannabis unless the grower/processor has received a permit from the bureau under this act.

(4) Grow or dispense medical cannabis unless authorized as a health care medical cannabis organization under article thirteen of this chapter.

(5) Dispense medical cannabis unless the dispensary has received a permit from the bureau under this act.

(c) Edible medical cannabis. — Nothing in this act shall be construed to preclude the incorporation of medical cannabis into edible form by a patient or a caregiver in order to aid ingestion of the medical cannabis by the patient.

§16A-3-4. Confidentiality.

(a) Patient information. — The bureau shall maintain a confidential list of patients and caregivers to whom it has issued identification cards. All information obtained by the bureau relating to patients, caregivers and other applicants shall be confidential and not subject to public disclosure under chapter twenty-nine-b of this code, including specifically the following:

(1) Individual identifying information about patients and caregivers.

- (2) Certifications issued by practitioners.
 - (3) Information on identification cards.
 - (4) Information provided by the West Virginia State Police under section two, article five of this chapter.
 - (5) Information relating to the patient's serious medical condition.
- (b) Public information. — The following records are public records and shall be subject to the Freedom of Information Act, under chapter twenty-nine-b of this code:
- (1) Applications for permits submitted by medical cannabis organizations.
 - (2) The names, business addresses and medical credentials of practitioners authorized to provide certifications to patients to enable them to obtain and use medical cannabis in this state. All other practitioner registration information shall be confidential and exempt from public disclosure under the Freedom of Information Act.
 - (3) Information relating to penalties or other disciplinary actions taken against a medical cannabis organization or practitioner by the bureau for violation of this act.

§16A-3-5. Reciprocity for terminally ill cancer patients.

The bureau may enter into reciprocity agreements with any states that have comparable requirements for the use and lawful purchase of medical cannabis in a manner consistent with the provisions of this article to allow terminally ill cancer patients to purchase medical cannabis in another state.

WV Code §16A-4

§16A-4-1. Registration.

- (a) Eligibility. — A physician included in the registry is authorized to issue certifications to patients to use medical cannabis. To be eligible for inclusion in the registry:
- (1) A physician must apply for registration in the form and manner required by the bureau.
 - (2) The bureau must determine that the physician is, by training or experience, qualified to treat a serious medical condition. The physician shall provide documentation of credentials, training or experience as required by the bureau.
 - (3) The physician must have successfully completed the course under subsection (a), section one, article three of this chapter.
- (b) Bureau action. —
- (1) The bureau shall review an application submitted by a physician to determine whether to include the physician in the registry. The review shall include information regarding whether the physician has a valid, unexpired, unrevoked, unsuspended license to practice medicine in this state and whether the physician has been subject to discipline.
 - (2) The inclusion of a physician in the registry shall be subject to annual review to determine if the physician's license is no longer valid, has expired or been revoked or the physician has been subject to discipline. If the license is no longer valid, the bureau shall remove the physician from the registry until the physician holds a valid, unexpired, unrevoked, unsuspended state license to practice medicine in West Virginia.
 - (3) The West Virginia Board of Medicine and West Virginia Board of Osteopathic Medicine shall report to the bureau the expiration, suspension or revocation of a physician's license and any disciplinary actions in a timely fashion.
- (c) Practitioner requirements. — A practitioner included in the registry shall have an ongoing responsibility to immediately notify the bureau in writing if the practitioner knows or has reason to know that any of the following is true with respect to a patient for whom the practitioner has issued a certification:
- (1) The patient no longer has the serious medical condition for which the certification was issued.
 - (2) Medical cannabis would no longer be therapeutic or palliative.
 - (3) The patient has died.

§16A-4-2. Practitioner restrictions.

- (a) Practices prohibited. — The following shall apply with respect to practitioners:
 - (1) A practitioner may not accept, solicit or offer any form of remuneration from or to a prospective patient, patient, prospective caregiver, caregiver or medical cannabis organization, including an employee, financial backer or principal, to certify a patient, other than accepting a fee for service with respect to the examination of the prospective patient to determine if the prospective patient should be issued a certification to use medical cannabis.
 - (2) A practitioner may not hold a direct or economic interest in a medical cannabis organization.
 - (3) A practitioner may not advertise the practitioner's services as a practitioner who can certify a patient to receive medical cannabis.
- (b) Unprofessional conduct. — A practitioner who violates subsection (a) of this section shall not be permitted to issue certifications to patients and shall be removed from the registry.
- (c) Discipline. — In addition to any other penalty that may be imposed under this act, a violation of subsection (a) of this section or subsection (f), section three of this article shall be deemed unprofessional conduct under the West Virginia Medical Practice Act, and shall subject the practitioner to discipline by the West Virginia Board of Medicine and West Virginia Board of Osteopathic Medicine, as appropriate.

§16A-4-3. Issuance of certification.

- (a) Conditions for issuance. — A certification to use medical cannabis may be issued by a practitioner to a patient if all of the following requirements are met:
 - (1) The practitioner has been approved by the bureau for inclusion in the registry and has a valid, unexpired, unrevoked, unsuspended license to practice medicine in this state at the time of the issuance of the certification.
 - (2) The practitioner has determined that the patient has a serious medical condition and has included the condition in the patient's health care record.
 - (3) The patient is under the practitioner's continuing care for the serious medical condition.
 - (4) In the practitioner's professional opinion and review of past treatments, the practitioner determines the patient is likely to receive therapeutic or palliative benefit from the use of medical cannabis.
 - (5) The practitioner has determined that the patient has no past or current medical condition(s) or medication use that would constitute a contraindication for the use of cannabis.

(6) The practitioner has determined that the patient is experiencing serious pathophysiological discomfort, disability, or dysfunction that may be attributable to a serious medical condition and may possibly benefit from cannabis treatment when current medical research exhibits a moderate or higher probability of efficacy; and

(7) The practitioner has educated the patient about cannabis and its safe use.

(b) Contents. — The certification shall include:

(1) The patient's name, date of birth, and address.

(2) The specific serious medical condition of the patient.

(3) A statement by the practitioner that the patient has a serious medical condition and the patient is under the practitioner's continuing care for the serious medical condition.

(4) The date of issuance.

(5) The name, address, telephone number, and signature of the practitioner.

(6) Any requirement or limitation concerning the appropriate form of medical cannabis and limitation on the duration of use, if applicable, including whether the patient is terminally ill.

(7) A statement by the practitioner attesting that he or she has performed the requirements contained in subsection (a) of this section on a form to be issued by the West Virginia Department of Health, Bureau for Public Health.

(c) Consultation. —

(1) A practitioner shall review the prescription drug monitoring program prior to:

(A) Issuing a certification to determine the controlled substance history of a patient.

(B) Recommending a change of amount or form of medical cannabis.

(2) The practitioner shall consider and give due consideration to other controlled substances the patient may be taking prior to certifying medical cannabis.

(d) Other access by practitioner. — A practitioner may access the prescription drug monitoring program to do any of the following:

(1) Determine whether a patient may be under treatment with a controlled substance by another physician or other person.

(2) Allow the practitioner to review the patient's controlled substance history as deemed necessary by the practitioner.

(3) Provide to the patient, or caregiver, on behalf of the patient if authorized by the patient, a copy of the patient's controlled substance history.

(e) Duties of practitioner. — The practitioner shall:

(1) Provide the certification to the patient.

(2) Provide a copy of the certification to the bureau, which shall place the information in the patient directory within the bureau's electronic database. The bureau shall permit electronic submission of the certification.

(3) File a copy of the certification in the patient's health care record.

(f) Prohibition. — A practitioner may not issue a certification for the practitioner's own use or for the use of a family or household member.

§16A-4-4. Certification form.

The bureau shall develop a standard certification form, which shall be available to practitioners upon request. The form shall be available electronically. The form shall include a statement that a false statement made by a practitioner is punishable under the applicable provisions of law.

§16A-4-5. Duration.

Receipt of medical cannabis by a patient or caregiver from a dispensary may not exceed a 30-day supply of individual doses. During the last seven days of any 30-day period during the term of the identification card, a patient may obtain and possess a 30-day supply for the subsequent 30-day period. Additional 30-day supplies may be provided in accordance with this section for the duration of the authorized period of the identification card unless a shorter period is indicated on the certification.

WV Code §16A-5

§16A-5-1. Identification cards.

- (a) **Issuance.** — The bureau may issue an identification card to a patient who has a certification approved by the bureau and to a caregiver designated by the patient. An identification card issued to a patient shall authorize the patient to obtain and use medical cannabis as authorized by this act. An identification card issued to a caregiver shall authorize the caregiver to obtain medical cannabis on behalf of the patient.
- (b) **Procedure for issuance.** — The bureau shall develop and implement procedures for:
 - (1) Review and approval of applications for identification cards.
 - (2) Issuance of identification cards to patients and caregivers.
 - (3) Review of the certification submitted by the practitioner and the patient.
- (c) **Application.** — A patient or a caregiver may apply, in a form and manner prescribed by the bureau, for issuance or renewal of an identification card. A caregiver must submit a separate application for issuance or renewal. Each application must include:
 - (1) The name, address and date of birth of the patient.
 - (2) The name, address and date of birth of a caregiver.
 - (3) The certification issued by the practitioner.
 - (4) The name, address and telephone number of the practitioner and documentation from the practitioner that all of the requirements of subsection (a), section three, article four of this chapter have been met.
 - (5) A \$50 processing fee. The bureau may waive or reduce the fee if the applicant demonstrates financial hardship.
 - (6) The signature of the applicant and date signed.
 - (7) Other information required by the bureau.
- (d) **Forms.** — Application and renewal forms shall be available on the bureau's publicly accessible Internet website.
- (e) **Expiration.** — An identification card of a patient or caregiver shall expire within one year from the date of issuance, upon the death of the patient, or as otherwise provided in this section.

(f) Separate cards to be issued. — The bureau shall issue separate identification cards for patients and caregivers as soon as reasonably practicable after receiving completed applications, unless it determines that an application is incomplete or factually inaccurate, in which case it shall promptly notify the applicant.

(g) Change in name or address. — A patient or caregiver who has been issued an identification card shall notify the bureau within ten days of any change of name or address. In addition, the patient shall notify the bureau within ten days if the patient no longer has the serious medical condition noted on the certification.

(h) Lost or defaced card. — In the event of a lost, stolen, destroyed or illegible identification card, the patient or caregiver shall apply to the bureau within ten business days of discovery of the loss or defacement of the card for a replacement card. The application for a replacement card shall be on a form furnished by the bureau and accompanied by a \$25 fee. The bureau may establish higher fees for issuance of second and subsequent replacement identification cards. The bureau may waive or reduce the fee in cases of demonstrated financial hardship. The bureau shall issue a replacement identification card as soon as practicable. A patient or caregiver may not obtain medical cannabis until the bureau issues the replacement card.

§16A-5-2. Caregivers.

(a) Requirements. —

(1) If the patient designates a caregiver, the application shall include the name, address and date of birth of the caregiver, and other individual identifying information required by the bureau and the following:

(A) Federal and state criminal history record information as set forth in subsection (b) of this section.

(B) If the caregiver has an identification card for the caregiver or another patient, the expiration date of the identification card.

(C) Other information required by the bureau.

(2) The application shall be accompanied by a fee of \$50. The bureau may waive or reduce the fee in cases of demonstrated financial hardship.

(3) The bureau may require additional information for the application.

(4) The application shall be signed and dated by the applicant.

(b) Criminal history. — A caregiver shall submit fingerprints for the purpose of obtaining criminal history record checks, and the West Virginia State Police or its authorized agent shall submit the fingerprints to the Federal Bureau of Investigation for the purpose of verifying the identity of the applicant and obtaining a current record of any criminal arrests and convictions.

Any criminal history record information relating to a caregiver obtained under this section by the bureau may be interpreted and used by the bureau only to determine the applicant's character, fitness and suitability to serve as a caregiver under this act. The bureau shall also review the prescription drug monitoring program relating to the caregiver. The bureau shall deny the application of a caregiver who has been convicted of a criminal offense that occurred within the past five years relating to the felony sale or possession of drugs, narcotics or controlled substances, or conspiracy thereof. The bureau may deny an application if the applicant has a history of drug abuse or of diverting controlled substances or illegal drugs.

§16A-5-3. Notice.

An application for an identification card shall include notice that a false statement made in the application is punishable under the applicable provisions of law.

§16A-5-4. Verification.

The bureau shall verify the information in a patient or caregiver's application and on any renewal form.

§16A-5-5. Special conditions.

The following apply:

(1) If the practitioner states in the certification that, in the practitioner's professional opinion, the patient would benefit from medical cannabis only until a specified earlier date, then the identification card shall expire on that date.

(2) If the certification so provides, the identification card shall state any requirement or limitation by the practitioner as to the form of medical cannabis for the patient.

§16A-5-6. Minors.

If a patient is under eighteen years of age, the following shall apply:

(1) The patient shall have a caregiver.

(2) A caregiver must be one of the following:

(A) A parent or legal guardian of the patient.

(B) An individual designated by a parent or legal guardian.

(C) An appropriate individual approved by the bureau upon a sufficient showing that no parent or legal guardian is appropriate or available.

§16A-5-7. Caregiver authorization and limitations.

- (a) Age. — An individual who is under twenty-one years of age may not be a caregiver unless a sufficient showing, as determined by the bureau, is made to the bureau that the individual should be permitted to serve as a caregiver.
- (b) Changing caregiver. — If a patient wishes to change or terminate the designation of the patient's caregiver, for whatever reason, the patient shall notify the bureau as soon as practicable. The bureau shall issue a notification to the caregiver that the caregiver's identification card is invalid and must be promptly returned to the bureau.
- (c) Denial in part. — If an application of a patient designates an individual as a caregiver who is not authorized to be a caregiver, that portion of the application shall be denied by the bureau. The bureau shall review the balance of the application and may approve that portion of it.

§16A-5-8. Contents of identification card.

An identification card shall contain the following:

- (1) The name of the caregiver or the patient, as appropriate. The identification card shall also state whether the individual is designated as a patient or as a caregiver.
- (2) The date of issuance and expiration date.
- (3) An identification number for the patient or caregiver, as appropriate.
- (4) A photograph of the individual to whom the identification card is being issued, whether the individual is a patient or a caregiver. The method of obtaining the photograph shall be specified by the bureau by rule. The bureau shall provide reasonable accommodation for a patient who is confined to the patient's home or is in inpatient care.
- (5) Any requirement or limitation set by the practitioner as to the form of medical cannabis.
- (6) Any other requirements determined by the bureau, except the bureau may not require that an identification card disclose the patient's serious medical condition.

§16A-5-9. Suspension.

If a patient or caregiver intentionally, knowingly or recklessly violates any provision of this act as determined by the bureau, the identification card of the patient or caregiver may be suspended or revoked. The suspension or revocation shall be in addition to any criminal or other penalty that may apply.

§16A-5-10. Prohibitions.

The following prohibitions shall apply:

(1) A patient may not operate or be in physical control of any of the following while under the influence with a blood content of more than three nanograms of active tetrahydrocannabis per milliliter of blood in serum:

(A) Chemicals which require a permit issued by the Federal Government or a state government or an agency of the Federal Government or a state government.

(B) High-voltage electricity or any other public utility.

(C) Vehicle, aircraft, train, boat or heavy machinery.

(2) A patient may not perform any employment duties at heights or in confined spaces, including, but not limited to, mining while under the influence of medical cannabis.

(3) A patient may be prohibited by an employer from performing any task which the employer deems life-threatening, to either the employee or any of the employees of the employer, while under the influence of medical cannabis. The prohibition shall not be deemed an adverse employment decision even if the prohibition results in financial harm for the patient.

(4) A patient may be prohibited by an employer from performing any duty which could result in a public health or safety risk while under the influence of medical cannabis. The prohibition shall not be deemed an adverse employment decision even if the prohibition results in financial harm for the patient.

WV Code §16A-6

§16A-6-1. Authorized medical cannabis organizations.

The following entities shall be authorized to receive a permit to operate as a medical cannabis organization to grow, process or dispense medical cannabis:

- (1) Growers.
- (2) Processors.
- (3) Dispensaries.

§16A-6-2. Permits.

(a) Application. — An application for a grower, processor or dispensary permit to grow, process or dispense medical cannabis shall be in a form and manner prescribed by the bureau and shall include:

- (1) Verification of all principals, operators, financial backers or employees of a medical cannabis grower/processor or dispensary.
- (2) A description of responsibilities as a principal, operator, financial backer or employee.
- (3) Any release necessary to obtain information from governmental agencies, employers and other organizations.
- (4) A criminal history record check. Medical cannabis organizations applying for a permit shall submit fingerprints of principals, financial backers, operators and employees to the West Virginia State Police for the purpose of obtaining criminal history record checks and the West Virginia State Police or its authorized agent shall submit the fingerprints to the Federal Bureau of Investigation for the purpose of verifying the identity of the principals, financial backers, operators and employees and obtaining a current record of any criminal arrests and convictions. Any criminal history record information relating to principals, financial backers, operators and employees obtained under this section by the bureau may be interpreted and used by the bureau only to determine the principal's, financial backer's, operator's and employee's character, fitness and suitability to serve as a principal, financial backer, operator and employee under this act. This subdivision shall not apply to an owner of securities in a publicly traded corporation if the bureau determines that the owner of the securities is not substantially involved in the activities of the medical cannabis organization.
- (5) Details relating to a similar license, permit or other authorization obtained in another jurisdiction, including any suspensions, revocations or discipline in that jurisdiction.

(6) A description of the business activities in which it intends to engage as a medical cannabis organization.

(7) A statement that the applicant:

(A) Is of good moral character. For purposes of this subparagraph, an applicant shall include each financial backer, operator, employee and principal of the medical cannabis organization.

(B) Possesses the ability to obtain in an expeditious manner the right to use sufficient land, buildings and other premises and equipment to properly carry on the activity described in the application and any proposed location for a facility.

(C) Is able to maintain effective security and control to prevent diversion, abuse and other illegal conduct relating to medical cannabis.

(D) Is able to comply with all applicable State laws and rules relating to the activities in which it intends to engage under this act.

(8) The name, residential address and title of each financial backer and principal of the applicant. Each individual, or lawful representative of a legal entity, shall submit an affidavit with the application setting forth:

(A) Any position of management or ownership during the preceding ten years of a controlling interest in any other business, located inside or outside this state, manufacturing or distributing controlled substances.

(B) Whether the person or business has been convicted of a criminal offense graded higher than a summary offense or has had a permit relating to medical cannabis suspended or revoked in any administrative or judicial proceeding.

(9) Any other information the bureau may require.

(b) Notice. — An application shall include notice that a false statement made in the application is punishable under the applicable provisions of law.

§16A-6-3. Granting of permit

(a) The bureau may grant or deny a permit to a grower, processor, or dispensary. In making a decision under this subsection, the bureau shall determine that:

(1) The applicant will maintain effective control of and prevent diversion of medical cannabis.

(2) The applicant will comply with all applicable laws of this state.

(3) The applicant is ready, willing, and able to properly carry on the activity for which a permit is sought.

- (4) The applicant possesses the ability to obtain in an expeditious manner sufficient land, buildings, and equipment to properly grow, process, or dispense medical cannabis.
 - (5) It is in the public interest to grant the permit.
 - (6) The applicant, including the financial backer or principal, is of good moral character and has the financial fitness necessary to operate.
 - (7) The applicant is able to implement and maintain security, tracking, recordkeeping, and surveillance systems relating to the acquisition, possession, growth, manufacture, sale, delivery, transportation, distribution, or the dispensing of medical cannabis as required by the bureau: *Provided*, That the bureau may require that a medical cannabis organization maintain motion activated video surveillance at a dispensary, grower or processor facility and that a medical cannabis organization retain the recordings therefrom onsite or offsite for a period not to exceed 180 days, unless otherwise required for investigative or litigation purposes.
 - (8) The applicant satisfies any other conditions as determined by the bureau.
- (b) *Nontransferability*. — A permit issued under this chapter shall be nontransferable.
- (c) *Privilege*. — The issuance or renewal of a permit shall be a revocable privilege.
- (d) *Dispensary location*. — The bureau shall consider the following when issuing a dispensary permit:
- (1) Geographic location;
 - (2) Regional population;
 - (3) The number of patients suffering from serious medical conditions;
 - (4) The types of serious medical conditions;
 - (5) Access to public transportation;
 - (6) Approval by local health departments;
 - (7) Whether the county has disallowed the location of a grower, processor, or dispensary; and
 - (8) Any other factor the bureau deems relevant.
- (e) *Application procedure*. — The bureau shall establish a procedure for the fair and objective evaluation of all applications for all medical cannabis organization permits. The evaluations shall score each applicant numerically according to standards set forth in this chapter.

§16A-6-4. Notice.

When the boundaries under subsection (d), section three of this article are established, the bureau shall publish notice of the determination in the State Register. The bureau may adjust the boundaries as necessary every two years. Notice of any adjustment to the boundaries shall be published in the State Register.

§16A-6-5. Application and issuance.

(a) Duty to report. — An applicant to be a grower/processor or to operate a dispensary is under a continuing duty to:

- (1) Report to the bureau any change in facts or circumstances reflected in the application or any newly discovered or occurring fact or circumstance which is required to be included in the application, including a change in control of the medical cannabis organization.
- (2) Report to law enforcement, within twenty-four hours, any loss or theft of medical cannabis.
- (3) Submit to announced or unannounced inspections by the bureau of the facilities for growing, processing, dispensing or selling medical cannabis, including all records of the organization.

(b) Additional information. — If the bureau is not satisfied that the applicant should be issued a permit, the bureau shall notify the applicant in writing of the factors for which further documentation is required. Within thirty days of the receipt of the notification, the applicant may submit additional material to the bureau.

§16A-6-6. Fees and other requirements.

The following apply:

(1) For a grower or processor:

- (A) An initial application fee in the amount of \$5,000 shall be paid. The fee is nonrefundable.
- (B) A fee for a permit as a grower/processor in the amount of \$50,000 shall be paid. The permit shall be valid for one year. Applicants shall submit the permit fee at the time of submission of the application. The fee shall be returned if the permit is not granted.
- (C) A renewal fee for the permit as a grower/processor in the amount of \$5,000 shall be paid and shall cover renewal for all locations. The renewal fee shall be returned if the renewal is not granted.
- (D) An application to renew a permit must be filed with the bureau not more than six months nor less than four months prior to expiration.
- (E) All fees shall be paid by certified check or money order.

(2) For a dispensary:

- (A) An initial application fee in the amount of \$2,500 shall be paid. The fee is nonrefundable.
 - (B) A permit fee for a dispensary shall be \$10,000 for each location. The period of the permit is one year. An applicant shall submit the permit fee at the time of submission of the application. The fee shall be returned if the application is not granted.
 - (C) A renewal fee for the permit as a dispensary in the amount of \$2,500 shall be paid. The fee shall be returned if the renewal is not granted and shall cover renewal for all locations.
 - (D) An application to renew a permit must be filed with the bureau not more than six months nor less than four months prior to expiration.
 - (E) All fees shall be paid by certified check or money order.
- (3) A fee of \$250 shall be required when amending the application to indicate relocation within this state or the addition or deletion of approved activities by the medical cannabis organization.
- (4) Fees payable under this section shall be deposited into the fund.

§16A-6-7. Issuance.

A permit issued by the bureau to a medical cannabis organization shall be effective only for that organization and shall specify the following:

- (1) The name and address of the medical cannabis organization.
- (2) The activities of the medical cannabis organization permitted under this act.
- (3) The land, buildings, facilities or location to be used by the medical cannabis organization.
- (4) Any other information required by the bureau.

§16A-6-8. Relocation.

The bureau may approve an application from a medical cannabis organization to relocate within this state or to add or delete activities or facilities.

§16A-6-9. Terms of permit.

A permit issued by the bureau shall be valid for one year from the date of issuance.

§16A-6-10. Permit renewals.

- (a) Renewal. — An application for renewal shall include the following information:

- (1) Any material change in the information provided by the medical cannabis organization in a prior application or renewal of a permit.
 - (2) Any charge or initiated, pending or concluded investigation, during the period of the permit, by any governmental or administrative agency with respect to:
 - (A) Any incident involving the theft, loss or possible diversion of medical cannabis grown, processed or dispensed by the applicant; and
 - (B) Compliance by the applicant with the laws of this state with respect to any substance listed under article two, chapter sixty-a of this code.
- (b) Approval. — The bureau shall renew a permit unless the bureau determines that:
- (1) The applicant is unlikely to maintain or be able to maintain effective control against diversion of medical cannabis.
 - (2) The applicant is unlikely to comply with all laws of this state applicable to the activities in which it may engage under the permit.
- (c) Nonrenewal decision. — The denial or nonrenewal shall specify in detail how the applicant has not satisfied the bureau's requirements for renewal. Within thirty days of the bureau's decision, the applicant may submit additional material to the bureau or demand a hearing, or both. If a hearing is demanded, the bureau shall fix a date as soon as practicable.

§16A-6-11. Suspension or revocation.

The bureau may suspend or revoke a medical cannabis organization permit if:

- (1) The bureau has evidence that the medical cannabis organization has failed to maintain effective control against diversion of medical cannabis.
- (2) The organization violates any provision of this act or a rule of the bureau.
- (3) The organization has intentionally, knowingly, recklessly or negligently failed to comply with applicable laws of this State relating to medical cannabis.

§16A-6-12. Convictions prohibited.

- (a) The following individuals may not hold volunteer positions or positions with remuneration in or be affiliated with a medical cannabis organization, including a clinical registrant under article fourteen of this chapter, in any way if the individual has been convicted of any felony criminal offense related to the sale or possession of illegal drugs, narcotics or controlled substances, or conspiracy thereof:
- (1) Financial backers.

(2) Principals.

(3) Employees.

(b) If an individual seeking to hold a volunteer position or position with remuneration in or be affiliated with a dispensary is otherwise prohibited under subsection (a) of this section, such individual may seek a waiver from the bureau in order to hold such a position with a dispensary. The allowance of the waiver, including any additional restrictions or conditions as part of the waiver, shall be in the discretion of the bureau.

§16A-6-13. Limitations on permits.

(a) The following limitations apply to approval of permits for growers, processors, and dispensaries, subject to the limitations in subsection (b) of this section:

(1) The bureau may not issue permits to more than 10 growers: Provided, That each grower may have up to two locations per permit.

(2) The bureau may not issue permits to more than 10 processors.

(3) The bureau may not issue permits to more than 100 dispensaries.

(4) The bureau may not issue more than 10 individual dispensary permits to one person.

(5) The bureau may not issue more than one individual grower permit to one person.

(6) The bureau may not issue more than one individual processor permit to one person.

(7) A dispensary may only obtain medical cannabis from a grower or processor holding a valid permit under this act.

(8) A grower or processor may only provide medical cannabis to a dispensary holding a valid permit under this act.

(9) A person may hold a grower permit, a processor permit, and a dispensary permit, or any combination thereof, concurrently.

(b) Before a permit may be issued, the bureau shall obtain the following:

(1) A written approval from the board of health for the county in which the permit is to be located and operate business.

(2) **A written statement from the county commission for the county in which the permit is to be located and conduct business that the county has not voted, pursuant to §16A-7-6 of this code, to disapprove a medical cannabis organization to be located or operate within the county.**

WV Code §16A-7

§16A-7-1. Electronic tracking.

(a) Requirement. — A medical cannabis organization must implement an electronic inventory tracking system which shall be directly accessible to the bureau through its electronic database that electronically tracks all medical cannabis on a daily basis. The system shall include tracking of all of the following:

(1) For a grower or processor, a seed-to-sale tracking system that tracks the medical cannabis from seed to plant until the medical cannabis is sold to a dispensary.

(2) For a dispensary, medical cannabis from purchase from the grower/processor to sale to a patient or caregiver and that includes information that verifies the validity of an identification card presented by the patient or caregiver.

(3) For a medical cannabis organization, a daily log of each day's beginning inventory, acquisitions, amounts purchased and sold, disbursements, disposals and ending inventory. The tracking system shall include prices paid and amounts collected from patients and caregivers.

(4) For a medical cannabis organization, a system for recall of defective medical cannabis.

(5) For a medical cannabis organization, a system to track the plant waste resulting from the growth of medical cannabis or other disposal, including the name and address of any disposal service.

(b) Additional requirements. — In addition to the information under subsection (a) of this section, each medical cannabis organization shall track the following:

(1) Security and surveillance.

(2) Recordkeeping and record retention.

(3) The acquisition, possession, growing and processing of medical cannabis.

(4) Delivery and transportation, including amounts and method of delivery.

(5) Dispensing, including amounts, pricing and amounts collected from patients and caregivers.

(c) Access. — (1) Information maintained in electronic tracking systems under subsection (a) of this section shall be confidential and not subject to public disclosure under chapter twenty-nine-b of this code.

(2) Pursuant to conditions and procedures established by the bureau, law enforcement shall be provided access to the tracking system.

(d) Reports. — Within one year of the issuance of the first permit to a medical cannabis organization, and every three months thereafter in a form and manner prescribed by the bureau, the following information shall be provided to the bureau, which shall compile the information and post it on the bureau's publicly accessible Internet website:

- (1) The amount of medical cannabis sold by a grower and a processor during each three-month period.
- (2) The price of amounts of medical cannabis sold by growers and processors as determined by the bureau.
- (3) The amount of medical cannabis purchased by each dispensary in this state.
- (4) The cost of amounts of medical cannabis to each dispensary in amounts as determined by the bureau.
- (5) The total amount and dollar value of medical cannabis sold by each dispensary in the three-month period.

§16A-7-2. Grower/processors.

(a) Authorization. — Subject to subsection (b), a grower or processor may do all of the following in accordance with bureau rules:

- (1) Obtain seed from outside this state to initially grow medical cannabis.
- (2) Obtain seed and plant material from another grower/processor within this state to grow medical cannabis.

(b) Limitations. — A grower or processor may only grow, store, harvest or process medical cannabis in an indoor, enclosed, secure facility which:

- (1) Includes electronic locking systems, electronic surveillance and other features required by the bureau; and
- (2) Is located within this state.

§16A-7-3. Storage and transportation.

The bureau shall develop rules relating to the storage and transportation of medical cannabis among grower/processors, testing laboratories and dispensaries which ensure adequate security to guard against in-transit losses. The tracking system developed by the bureau shall include all transportation and storage of medical cannabis. The rules shall provide for the following:

- (1) Requirements relating to shipping containers and packaging.

- (2) The manner in which trucks, vans, trailers or other carriers will be secured.
- (3) Security systems that include a numbered seal on the trailer.
- (4) Obtaining copies of drivers' licenses and registrations and other information related to security and tracking.
- (5) Use of GPS systems.
- (6) Number of drivers or other security required to ensure against storage or in-transit losses.
- (7) Recordkeeping for delivery and receipt of medical cannabis products.
- (8) Requirements to utilize any electronic tracking system required by the bureau.
- (9) Transporting medical cannabis to a grower/processor, approved laboratory or dispensary.

§16A-7-4. Laboratory.

- (a) A grower and processor shall contract with an independent laboratory to test the medical cannabis produced by the grower or processor. The bureau shall approve the laboratory and require that the laboratory report testing results in a manner as the bureau shall determine, including requiring a test at harvest and a test at final processing. The possession by a laboratory of medical cannabis shall be a lawful use.
- (b) All medical cannabis produced pursuant to this chapter shall be subject to testing as directed by the bureau.
- (c) The bureau shall ensure that there is sufficient testing capacity to meet patient demand.
- (d) All laboratories providing testing pursuant to this section shall be certified to do so by the Office of Laboratory Services.

§16A-7-5. Prices.

The bureau and the Department of Revenue shall monitor the price of medical cannabis sold by growers, processors and by dispensaries, including a per-dose price. If the bureau and the Department of Revenue determine that the prices are unreasonable or excessive, the bureau may implement a cap on the price of medical cannabis being sold for a period of six months. The cap may be amended during the six-month period. If the bureau and the Department of Revenue determine that the prices become unreasonable or excessive following the expiration of a six-month cap, additional caps may be imposed for periods not to exceed six months.

§16A-7-6. County prohibition.

A county may pass an ordinance by vote of the residents of the county to prohibit the operation or location of a medical cannabis organization within that particular county. A prohibition under this section shall remain in effect unless and until changed by a subsequent vote.

WV Code §16A-8

§16A-8-1. Dispensing to patients and caregivers.

(a) General rule. — A dispensary that has been issued a permit under §16A-6-1 et seq. of this code may lawfully dispense medical cannabis to a patient or caregiver upon presentation to the dispensary of a valid identification card for that patient or caregiver. The dispensary shall provide to the patient or caregiver a receipt, as appropriate. The receipt shall include all of the following:

- (1) The name, address, and any identification number assigned to the dispensary by the bureau.
- (2) The name and address of the patient and caregiver.
- (3) The date the medical cannabis was dispensed.
- (4) Any requirement or limitation by the practitioner as to the form of medical cannabis for the patient.
- (5) The form and the quantity of medical cannabis dispensed.

(b) Filing with bureau. — Prior to dispensing medical cannabis to a patient or caregiver, the dispensary shall file the receipt information with the bureau utilizing the electronic tracking system. When filing receipts under this subsection, the dispensary shall dispose of any electronically recorded certification information as provided by rule.

(c) Limitations. — No dispensary may dispense to a patient or caregiver:

- (1) A quantity of medical cannabis greater than that which the patient or caregiver is permitted to possess under the certification; or
- (2) A form of medical cannabis prohibited by this act.

(d) Supply. — When dispensing medical cannabis to a patient or caregiver, the dispensary may not dispense an amount greater than a 30-day supply until the patient has exhausted all but a seven-day supply provided pursuant to §16A-4-5 of this code.

(e) Verification. — Prior to dispensing medical cannabis to a patient or caregiver, the dispensary shall verify the information in subsections (d) and (f) of this section by consulting the electronic tracking system included in the bureau's electronic database established under §16A-3-1 of this code and the dispensary tracking system under §16A-7-1 of this code.

(f) Form of medical cannabis. — Medical cannabis dispensed to a patient or caregiver by a dispensary shall conform to any requirement or limitation set by the practitioner as to the form of medical cannabis for the patient.

(g) Safety insert. — When a dispensary dispenses medical cannabis to a patient or caregiver, the dispensary shall provide to that patient or caregiver, as appropriate, a safety insert. The insert shall be developed and approved by the bureau. The insert shall provide the following information:

- (1) Lawful methods for administering medical cannabis in individual doses.
- (2) Any potential dangers stemming from the use of medical cannabis.
- (3) How to recognize what may be problematic usage of medical cannabis and how to obtain appropriate services or treatment for problematic usage.
- (4) How to prevent or deter the misuse of medical cannabis by minors or others.
- (5) Any other information as determined by the bureau.

(h) Sealed and labeled package. — Medical cannabis shall be dispensed by a dispensary to a patient or caregiver in a sealed, properly labeled, and child-resistant package. The labeling shall contain the following:

- (1) The information required to be included in the receipt provided to the patient or caregiver, as appropriate, by the dispensary.
- (2) The packaging date.
- (3) Any applicable date by which the medical cannabis should be used.
- (4) A warning stating:

"This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the practitioner who issued the certification and, in the case of breastfeeding, the infant's pediatrician. This product might impair the ability to drive or operate heavy machinery. Keep out of reach of children."

- (5) The amount of individual doses contained within the package and the species and percentage of tetrahydrocannabinol and cannabidiol.
- (6) A warning that the medical cannabis must be kept in the original container in which it was dispensed.
- (7) A warning that unauthorized use is unlawful and will subject the person to criminal penalties.
- (8) Any other information required by the bureau.

§16A-8-2. Facility requirements.

(a) General rule. —

- (1) A dispensary may only dispense medical cannabis in an indoor, enclosed, secure facility located within this state, as determined by the bureau.
- (2) A dispensary may not operate on the same site as a facility used for growing and processing medical cannabis.
- (3) A dispensary may not be located within one thousand feet of the property line of a public, private or parochial school or a daycare center.
- (4) A dispensary may, pursuant to bureau conditions and limitations, sell medical devices and instruments which are needed to administer medical cannabis under this act.

(b) Adjustment or waiver of prohibition. — The bureau may amend a prohibition under subsection (a)(3) of this section if it is shown by clear and convincing evidence that the amendment is necessary to provide adequate access to patients. An amendment may include additional security, physical plant of a facility or other conditions necessary to protect children.

§16A-8-3. Posting.

A dispensary shall post a copy of its permit in a location within its facility in a manner that is easily observable by patients, caregivers, law enforcement officers and agents of the bureau.

WV Code §16A-9

§16A-9-1. Tax on medical cannabis.

(a) Tax imposed. — For the privilege of engaging or continuing within this state in the business of a dispensary of medical cannabis, as defined in §16A-2-1 of this code, there is hereby levied upon and collected from every person exercising the privilege a privilege tax.

(b) Rate and measure of tax. — The rate of tax imposed by this section shall be 10 percent of the gross receipts the dispensary receives or accrues during the reporting period, depending upon its method of accounting for federal income tax purposes, from the sale of medical cannabis to a patient or to a caregiver. The tax imposed by this section shall not be added by the dispensary as a separate charge or line item on any sales slip, invoice, receipt, other statement, or memorandum of the price paid by a patient, or caregiver.

(c) Definitions. — For purposes of this article:

(1) "Gross receipts" means and includes the gross receipts, however denominated, derived from the sale, distribution, or transfer of medical cannabis, without any deduction on account of the cost of property sold; the cost of materials used to grow, process, or sell the medical cannabis; labor costs, taxes, royalties paid in cash or in kind, or otherwise; interest or discount paid; or any other expense, however denominated.

(2) "Person" includes any natural person, corporation, partnership, limited liability company, or other business entity as those terms are defined in §11-1-1 et seq. of this code.

(d) Payment of tax and reports. — Every person subject to the tax imposed by this section shall make quarterly payments under this section for each calendar quarter at the rate prescribed in subsection (b) of this section on the gross receipts received or accrued for the calendar quarter, depending upon the person's method of accounting for federal income tax purposes. The tax shall be due and payable on the 20th day of January, April, July, and October for the preceding calendar quarter. When the payment of tax is due, the person shall file a tax return in a form prescribed by the Tax Commissioner. The Tax Commissioner may require such forms, schedules, and returns and impose such filing and remittance requirements as may be necessary or convenient for the efficient administration of taxes imposed by this section.

(e) Electronic filing and payment. — The taxes imposed by this section shall be paid to the Tax Commissioner by electronic funds transfer, unless electronic payment is prohibited by state or federal law. Tax returns required by this section shall be filed electronically with the Tax Commissioner.

(f) Liability for reporting and payment of tax. — If any dispensary does not renew its permit, gives up its permit, loses its permit to operate a dispensary, or otherwise ceases business then any tax, additions to tax, penalties, and interest imposed by this article and by §11-10-1 et seq. of this code shall become due and payable immediately and the dispensary shall make a final return or

returns and pay any tax which is due within 30 days after not renewing its permit, giving up its permit, losing its permit to operate a dispensary, or otherwise ceasing business. The unpaid amount of any tax is a lien upon the property of the dispensary and of its owners.

(g) Deposits of proceeds. — All money received from the tax imposed under this section, including any interest and additions to tax paid under §11-10-1 et seq., less the amount of any refunds, shall be deposited into the Medical Cannabis Program Fund.

(h) Exemption. — Sales of medical cannabis shall not be subject to the taxes imposed by §11-15-1 et seq. and §11-15A-1 et seq. of this code if gross receipts from the sale thereof are included in the measure of tax under this section and the tax has been paid as provided in this section. Additionally, sales of medical cannabis shall not be subject to a special district excise tax imposed by a county or municipality pursuant to this code, or to a county or municipal sales tax.

(i) Information. —

(1) Persons subject to the tax imposed by this section shall provide to the Tax Commissioner any information the Tax Commissioner may require to administer, collect, and enforce the tax imposed by this section.

(2) Notwithstanding any provision of §11-10-1 et seq. of this code or of this article to the contrary, the Tax Commissioner, the bureau, and the Secretary of Health and Human Resources may enter into written agreements pursuant to which the Tax Commissioner will disclose to designated employees of the bureau and the Secretary of Health and Human Resources, whether a particular grower, processor, or dispensary is in good standing with the Tax Commissioner, and the bureau and the secretary will disclose to designated employees of the Tax Commissioner information a grower, processor, or dispensary provides to the bureau and the secretary pursuant to this code. Tax information disclosed pursuant to a written agreement shall remain confidential in the hands of the receiver and shall not be disclosable under §29B-1-1 et seq. of this code. To the extent feasible, this information should be shared or exchanged electronically.

(j) Rules. — The Tax Commissioner may promulgate, in accordance with the provisions of §29A-3-1 et seq. of this code, such procedural, interpretive, or legislative rules, including emergency rules, as the Tax Commissioner may deem necessary or convenient for the efficient administration of taxes imposed by this §16A-9-1 of this code.

§16A-9-2. Medical Cannabis Program Fund.

(a) Fund established. — The Medical Cannabis Program Fund is established as a special fund in the State Treasury. Money in the fund is appropriated as set forth in subsection (c) of this section. Any amount unspent at the end of a fiscal year shall be appropriated to the bureau for its operations.

(b) Source of funds. — Fees and taxes payable under this act shall be deposited into the fund. The money deposited into the fund may only be used for the purposes set forth in this section. Any interest accrued shall be deposited into the fund.

- (c) Use of proceeds. — Money in the fund is allocated in accordance with the following percentages:
- (1) Fifty-five percent of the revenue in the fund shall be allocated to the bureau.
 - (2) The remaining forty-five percent of the revenue in the fund shall be allocated as follows:
 - (A) Fifty percent shall be allocated to the Fight Substance Abuse Fund created by section eight, article nine, chapter sixty-a of the code.
 - (B) Forty percent shall be allocated to the Division of Justice and Community Services, for grants to local law enforcement agencies for training, drug diversion, and other programs focused on crime and addiction, pursuant to and in accordance with the provisions of article nine-a, chapter fifteen of this code.
 - (C) Ten percent shall be allocated to the fund created in section four, article twenty-nine, chapter thirty, to be used for law enforcement professional training and professional development programs.

§16A-9-3. Tax on medical cannabis crimes and penalties.

Notwithstanding any provision in §11-9-1 et seq. of this code to the contrary, each and every provision of the West Virginia Tax Crimes and Penalties Act set forth in §11-9-1 et seq. of this code shall apply to the tax imposed by §16A-9-1 et seq. of this code with like effect as if said act were applicable only to the tax imposed by §16A-9-1 et seq. of this code and were set forth in extenso in §16A-9-1 et seq. of this code.

§16A-9-4. Procedure and administration of the tax on medical cannabis.

Notwithstanding any provision of §11-10-1 et seq. of this code or any other provision of this code to the contrary, each and every provision of the West Virginia Tax Procedure and Administration Act set forth in §11-10-1 et seq. of this code shall apply to the tax imposed by §16A-9-1 et seq. with like effect as if the said West Virginia Tax Procedure and Administration Act were applicable only to the tax imposed by §16A-9-1 et seq. of this code and were set forth in extenso in §16A-9-1 et seq. of this code.

WV Code §16A-10

§16A-10-1. Administration.

The Commissioner of the Bureau for Public Health may establish and create an Office of Medical Cannabis within the bureau to assist in the administration and enforcement of the provisions of this act.

§16A-10-2. Reports by medical cannabis organizations.

A medical cannabis organization shall periodically file reports related to its activities. The bureau shall determine the information required in and the frequency of filing the reports.

§16A-10-3. Law-enforcement notification.

Notwithstanding any provision of this act or any other law to the contrary, the bureau may notify any appropriate law-enforcement agency of information relating to any violation or suspected violation of this act. In addition, the bureau shall verify to law-enforcement personnel in an appropriate case whether a certification, permit, registration or an identification card is valid, including release of the name of the patient.

§16A-10-4. Evaluation.

The bureau may provide for an analysis and evaluation of the implementation and effectiveness of this act. The bureau may enter into agreements with one or more persons for the performance of an evaluation of the implementation and effectiveness of this act.

§16A-10-5. Report.

(a) Report required. — The bureau shall submit a written report under subsection (b) of this section every two years, beginning two years after the effective date of this section, to the following:

- (1) The Governor.
- (2) The Joint Committee on Government and Finance.
- (3) The Attorney General of the State.

(b) Contents of report. — The following information shall be included in the report:

- (1) An assessment of the use of medical cannabis as a result of the enactment of this act.
- (2) An assessment of the benefits and risks to patients using medical cannabis under this act, including adverse events.

(3) Recommendations for amendments to this act for reasons of patient safety or to aid the general welfare of the citizens of this state.

§16A-10-6. Emergency rules.

(a) Promulgation. — In order to facilitate the prompt implementation of this act, the bureau may promulgate emergency rules that shall expire not later than two years following the publication of the emergency rule.

(b) Expiration. — The bureau's authority to adopt emergency rules under subsection (a) of this section shall expire July 1, 2021. Rules adopted after this period shall be promulgated as provided by law.

(c) Publication. — The bureau shall begin publishing emergency rules in the State Register no later than six months after the effective date of this section.

WV Code §16A-11

§16A-11-1. Advisory board.

(a) The Medical Cannabis Advisory Board is established within the bureau. The advisory board shall consist of the following members:

- (1) The commissioner or a designee.
- (2) The Superintendent of the West Virginia State Police or a designee.
- (3) Four physicians licensed to practice in the state to be appointed by the State Medical Association with one from each of the following specialized medicine:
 - (A) Family Practice/Neurologist/General Practitioner.
 - (B) Pain Management.
 - (C) Oncologist/Palliative Care.
 - (D) Psychiatrist.
- (4) Two physicians who are licensed pursuant to §30-14-1 et seq. of this code appointed by the West Virginia Osteopathic Association.
- (5) One pharmacist licensed to practice in the state, to be designated by the Board of Pharmacy.
- (6) One pharmacologist who has experience in the science of cannabis and a knowledge of the uses, effects, and modes of actions of drugs, to be appointed by the Governor.
- (7) One member who is a horticulturalist, to be designated by the West Virginia Commissioner of Agriculture.
- (8) One member designated by the West Virginia Association of Alcoholism and Drug Counselors.
- (9) An attorney licensed in the state who is knowledgeable about medical cannabis laws.
- (10) One member appointed by the West Virginia Prosecuting Attorneys Institute.
- (11) One member appointed by the Governor, who shall be a patient, a family or household member of a patient, or a patient advocate.

(b) Terms. — Except as provided under subsection (g) of this section, the members shall serve a term of four years or until a successor has been appointed and qualified, but no longer than six months beyond the four-year period.

(c) Chair. — The commissioner, or a designee, shall serve as chair of the advisory board.

(d) Voting; quorum. — A majority of the members shall constitute a quorum for the purpose of organizing the advisory board, conducting its business, and fulfilling its duties. A vote of the majority of the members present shall be sufficient for all actions of the advisory board unless the bylaws require a greater number.

(e) Attendance. — A member of the advisory board who fails to attend three consecutive meetings shall be deemed vacant, unless the commissioner, upon written request from the member, finds that the member should be excused from a meeting for good cause. A member who cannot be physically present may attend meetings via electronic means, including video conference.

(f) Governance. — The advisory board shall have the power to prescribe, amend, and repeal bylaws governing the manner in which the business of the advisory board is conducted and the manner in which the duties granted to it are fulfilled. The advisory board may delegate supervision of the administration of advisory board activities to an administrative commissioner and other employees of the bureau as the commissioner shall appoint.

(g) Initial terms. — The initial terms of members appointed under subsection (a) of this section shall be for terms of one, two, three, or four years, the particular term of each member to be designated by the commissioner at the time of appointment. All other members shall serve for a term of four years.

(h) Vacancy. — In the event that any member appointed under subsection (a) of this section shall die or resign, or otherwise become disqualified during the member's term of office, a successor shall be appointed in the same way and with the same qualifications as set forth in this section and shall hold office for the unexpired term. An appointed member of the advisory board shall be eligible for reappointment.

(i) Expenses. — A member shall receive the amount of reasonable travel, hotel, and other necessary expenses incurred in the performance of the duties of the member in accordance with state rules but shall receive no other compensation for the member's service on the board.

(j) Duties. — The advisory board shall have the following duties:

(1) To examine and analyze the statutory and regulatory law relating to medical cannabis within this state.

(2) To examine and analyze the law and events in other states and the nation with respect to medical cannabis.

- (3) To accept and review written comments from individuals and organizations about medical cannabis.
- (4) To issue, two years after the effective date of this section, a written report to the Governor, the Senate, and the House of Delegates.
- (5) The written report under subdivision (4) of this subsection shall include recommendations and findings as to the following:
 - (A) Whether to change the types of medical professionals who can issue certifications to patients.
 - (B) Whether to change, add, or reduce the types of medical conditions which qualify as serious medical conditions under this act.
 - (C) Whether to change the form of medical cannabis permitted under this act.
 - (D) Whether to change, add, or reduce the number of growers, processors, or dispensaries.
 - (E) How to ensure affordable patient access to medical cannabis.
 - (F) Whether to permit medical cannabis to be dispensed in dry leaf or plant form, for administration by vaporization.
- (6) The final written report under this section shall be adopted at a public meeting.

§16A-11-2. Rules based on recommendations of advisory board.

After receiving the report of the advisory board, at the discretion of the commissioner, the bureau may propose rules for legislative promulgation pursuant to the provisions of article three, chapter twenty-nine-a of this code to effectuate recommendations made by the advisory board. The commissioner shall issue notice in the State Register within twelve months of the receipt of the report of the advisory board. The notice shall include the recommendations of the advisory board and shall state the specific reasons for the decision of the commissioner on whether or not to effectuate each recommendation.

WV Code §16A-12

§16A-12-1. Criminal diversion of medical cannabis by practitioners.

In addition to any other penalty provided by law, a practitioner who intentionally and knowingly certifies a person as being able to lawfully receive medical cannabis or who otherwise provides medical cannabis to a person who is not lawfully permitted to receive medical cannabis, is guilty of a felony, and upon conviction thereof, shall be imprisoned in a state correctional facility for not less than one nor more than five years.

§16A-12-2. Criminal diversion of medical cannabis.

(a) In addition to any other penalty provided by law, any employee, financial backer, operator or principal of any qualifying entities who intentionally and knowingly sells, dispenses, trades, delivers or otherwise provides medical cannabis to a person who is not lawfully permitted to receive medical cannabis, is guilty of a felony, and upon conviction thereof, shall be imprisoned in a state correctional facility for not less than one nor more than five years.

(b) For purposes of this section, “qualifying entity” shall mean:

(1) A medical cannabis organization.

(2) A health care medical cannabis organization or university participating in a research study under article thirteen of this chapter.

(3) A clinical registrant or academic clinical research center under article fourteen of this chapter.

(4) A laboratory utilized to test medical cannabis under section four, article seven of this chapter.

§16A-12-3. Criminal retention of medical cannabis.

In addition to any other penalty provided by law, any patient or caregiver who intentionally and knowingly possesses, stores or maintains an amount of medical cannabis in excess of the amount legally permitted is guilty of a misdemeanor, and upon conviction thereof, shall be confined in jail for not more than six months.

§16A-12-4. Criminal diversion of medical cannabis by patient or caregiver.

In addition to any other penalty provided by law, any patient or caregiver that intentionally and knowingly provides medical cannabis to a person who is not lawfully permitted to receive medical cannabis is guilty of a felony, and upon conviction thereof, shall be imprisoned in a state correctional facility for not less than one nor more than five years.

§16A-12-5. Falsification of identification cards.

In addition to any other penalty provided by law, any person who commits one of the following, knowing he or she is not privileged to hold an identification card;

- (1) possesses an identification card and either attempts to use the card to obtain medical cannabis or obtains medical cannabis;
- (2) possesses an identification card which falsely identifies the person as being lawfully entitled to receive medical cannabis and either attempts to use the card to obtain medical cannabis or obtains medical cannabis; or
- (3) possesses an identification card which contains any false information on the card and the person either attempts to use the card to obtain medical cannabis or obtains medical cannabis, is guilty of a misdemeanor, and upon conviction thereof, shall be confined in jail for not more than twelve months.

§16A-12-6. Adulteration of medical cannabis.

In addition to any other penalty provided by law, any person who adulterates, fortifies, contaminates or changes the character or purity of medical cannabis from that set forth on the patient's or caregiver's identification card, is guilty of a felony, and upon conviction thereof, shall be imprisoned in a state correctional facility for not less than one nor more than five years.

§16A-12-7. Disclosure of information prohibited.

(a) In addition to any other penalty provided by law, any employee, financial backer, operator or principal who discloses, except to authorized persons for official governmental or health care purposes, any information related to the use of medical cannabis:

- (1) A medical cannabis organization.
- (2) A health care medical cannabis organization or university participating in a research study under article thirteen of this chapter.
- (3) A clinical registrant or academic clinical research center under article fourteen of this chapter.
- (4) An employee of the bureau.

(b) Exception. — Subsection (a) of this section shall not apply where disclosure is permitted or required by law or by court order.

§16A-12-8. Additional penalties.

(a) Civil penalties. — In addition to any other remedy available to the bureau, the bureau may assess a civil penalty for a violation of this act, a rule promulgated under this act or an order issued under this act or rule, subject to the following:

(1) The bureau may assess a penalty of not more than \$10,000 for each violation and an additional penalty of not more than \$1,000 for each day of a continuing violation. In determining the amount of each penalty, the bureau shall take the following factors into consideration:

- (A) The gravity of the violation.
- (B) The potential harm resulting from the violation to patients, caregivers or the general public.
- (C) The willfulness of the violation.
- (D) Previous violations, if any, by the person being assessed.
- (E) The economic benefit to the person being assessed for failing to comply with the requirements of this act, a rule promulgated under this act or an order issued under this act or rule.

(2) If the bureau finds that the violation did not threaten the safety or health of a patient, caregiver or the general public and the violator took immediate action to remedy the violation upon learning of it, the bureau may issue a written warning in lieu of assessing a civil penalty.

(3) A person who aids, abets, counsels, induces, procures or causes another person to violate this act, a rule promulgated under this act or an order issued under this act or rule shall be subject to the civil penalties provided under this subsection.

(b) Sanctions. —

(1) In addition to the penalties provided in subsection (a) of this section, and any other penalty authorized by law, the bureau may impose the following sanctions:

(A) Revoke or suspend the permit of a person found to be in violation of this act, a rule promulgated under this act or an order issued under this act or rule.

(B) Revoke or suspend the permit of a person for conduct or activity or the occurrence of an event that would have disqualified the person from receiving the permit.

(C) Revoke or suspend the registration of a practitioner for a violation of this act or a rule promulgated or an order issued under this act or for conduct or activity which would have disqualified the practitioner from receiving a registration.

(D) Suspend a permit or registration of a person pending the outcome of a hearing in a case in which the permit or registration could be revoked.

(E) Order restitution of funds or property unlawfully obtained or retained by a permittee or registrant.

(F) Issue a cease and desist order.

(2) A person who aids, abets, counsels, induces, procures or causes another person to violate this act shall be subject to the sanctions provided under this subsection.

(c) Costs of action. — The bureau may assess against a person determined to be in violation of this act the costs of investigation of the violation.

(d) Minor violations. — Nothing in this section shall be construed to require the assessment of a civil penalty or the imposition of a sanction for a minor violation of this act if the bureau determines that the public interest will be adequately served under the circumstances by the issuance of a written warning.

§16A-12-9. Other restrictions.

This act does not permit any person to engage in and does not prevent the imposition of any civil, criminal or other penalty for the following:

(1) Undertaking any task under the influence of medical cannabis when doing so would constitute negligence, professional malpractice or professional misconduct.

(2) Possessing or using medical cannabis in a state correctional facility or Regional Jail Authority facility, including a facility owned or operated or under contract with the Bureau of Corrections or the Regional Jail Authority, which houses inmates serving a portion of their sentences on parole or other community correction program.

(3) Possessing or using medical cannabis in a youth detention center or other facility which houses children adjudicated delinquent, including the separate, secure state-owned facility or unit utilized for sexually violent delinquent children.

WV Code §16A-13

§16A-13-1. Definitions.

(a) The following words and phrases when used in this chapter shall have the meanings given to them in this section unless the context clearly indicates otherwise:

(1) “Health care medical cannabis organization”. A vertically integrated health system approved by the bureau to dispense medical cannabis or grow and process medical cannabis, or both, in accordance with a research study under this chapter.

(2) “Vertically integrated health system”. A health delivery system in which the complete spectrum of care, including primary and specialty care, hospitalization and pharmaceutical care, is provided within a single organization.

§16A-13-2. Establishment of medical cannabis research program.

(a) Program to be established. — The bureau shall establish and develop a research program to study the impact of medical cannabis on the treatment and symptom management of serious medical conditions. The program shall not include a clinical registrant or academic clinical research center under article fourteen of this chapter.

(b) Bureau duties. — The bureau shall:

(1) Review all serious medical conditions which are cited by a practitioner upon the practitioner’s certification that a patient be granted an identification card.

(2) Create a database of all serious medical conditions, including comorbidities, which are cited by practitioners in the certifications of patients. The database shall also include the form of medical cannabis certified to treat each serious medical condition.

(3) When the database contains twenty-five or more patients with the same serious medical condition, petition the United States Food and Drug Administration and the United States Drug Enforcement Administration for approval to study the condition and the impact of medical cannabis on the condition.

(4) Concurrent with the request to the United States Food and Drug Administration and United States Drug Enforcement Administration, publicly announce the formation of a research study to which a vertically integrated health system and a university within this state may submit a request to participate.

(5) Upon approval of a research study by the United States Food and Drug Administration and the United States Drug Enforcement Administration, select a vertically integrated health system or systems to conduct the research study and designate the form or forms of medical cannabis which will be used to treat the serious medical condition.

- (6) Notify a patient who has been issued an identification card:
- (A) that the patient has been selected to participate, at the patient's option, in a research study to study medical cannabis as a treatment; and
- (B) where the patient may secure medical cannabis through a health care medical cannabis organization at no cost to the patient in accordance with subsection (c).
- (7) If the United States Food and Drug Administration and the United States Drug Enforcement Administration reject the proposal for the research study, take all reasonable steps to collect and collate data on the serious medical condition and the use of medical cannabis as a treatment for the serious medical condition and consider submitting an additional request to the United States Food and Drug Administration and United States Drug Enforcement Administration for a research study on the same condition.
- (c) Costs. — The cost of the medical cannabis which is dispensed to patients in accordance with an approved research study shall be paid for by the fund.
- (d) Geographic accessibility. — The bureau shall take into consideration the geographic location of the health care medical cannabis organization when assigning a patient to a health care medical cannabis organization. The bureau shall make an effort to assign a patient to a health care medical cannabis organization that is located within fifty miles of the patient's residence.
- (e) Data. — Data collected by the health care medical cannabis organization shall be provided to the university participating in the research study for analysis.

§16A-13-3. Medical cannabis research program administration.

- (a) The bureau may establish a research study for each serious medical condition. The bureau may engage universities within this state to participate in the collection, collation, analysis and conclusive findings of the research studies. The bureau shall, by rule, establish the procedure to be used by health care medical cannabis organizations with respect to:
- (1) Real time inventory tracking.
- (2) Real time tracking of the medical cannabis dispensed.
- (3) Recall of defective medical cannabis.
- (b) Request for distributions. — The bureau shall establish a form and procedure for universities selected to participate in a research study to request distributions from the fund to conduct research on medical cannabis, including administrative costs. These distributions shall also be used to pay for the cost of the medical cannabis so that it is not borne by the patient participating in the research study. The forms shall include, at a minimum, the following:
- (1) The form or forms of medical cannabis to be studied.

- (2) The serious medical condition to be studied.
- (c) Research reports.—
 - (1) A vertically integrated health system shall report on the effectiveness of the use of medical cannabis for the treatment of the serious medical condition studied and all counterindications and noted side effects.
 - (2) The bureau shall notify the vertically integrated health system and the university participating in the research study of the data which is required to meet the United States Food and Drug Administration's and the United States Drug Enforcement Administration's approval for the research study.
 - (3) The first report, including the data required under subdivision (2), shall be submitted to the bureau and made publicly available within one hundred eighty days of the initiation of a research study for a specific serious medical condition.
 - (4) An annual report of the data required under subdivision (2) shall be submitted to the bureau beginning one year after the initiation of a research study for a specific serious medical condition and each year thereafter.

§16A-13-4. Approval.

A vertically integrated health system located in this state may petition the bureau to participate in a research study to study a serious medical condition. Approval of the vertically integrated health system as a health care medical cannabis organization by the bureau shall authorize access within a region under subsection (d), section three, article six of this chapter to medical cannabis for all patients included in an approved research study.

§16A-13-5. Requirements.

- (a) Dispensing.—A health care medical cannabis organization that dispenses medical cannabis shall:
 - (1) Maintain licensure with the bureau.
 - (2) Secure the medical cannabis within the associated pharmacies of the health care medical cannabis organization in a manner and method prescribed by the bureau.
 - (3) Keep a daily log of the medical cannabis dispensed and the research study with which the patient and the medical cannabis are associated. Reports shall be delivered to the bureau and the university participating in the research study on a weekly basis.
 - (4) Report the utilization rates of those patients participating in the research of medical cannabis and treatment options.

(5) Only dispense medical cannabis received from a grower, processor or a health care medical cannabis organization that is approved to grow and process medical cannabis.

(6) Provide all patients or caregivers with the safety insert, prepared by the bureau, which includes potential dangers, recognition and correction of problematic dosage and any other information required by the bureau or which the bureau deems relevant for patient safety.

(b) Growing and processing. — A health care medical cannabis organization that grows and processes medical cannabis shall:

(1) Maintain licensure with the bureau.

(2) Only make available medical cannabis to health care medical cannabis organizations that dispense medical cannabis.

(3) Keep a daily log of medical cannabis intended for ultimate use by patients participating in a research study.

§16A-13-6. Restrictions.

A health care medical cannabis organization may not participate in a research study of any kind, including the program established under this article, or dispense or grow and process medical cannabis if it has violated its licensure requirements or conditions.

§16A-13-7. Rules.

The bureau shall, by rule, establish the procedure to be used by a health care medical cannabis organization that grows and processes medical cannabis with respect to:

(1) Real time inventory tracking, including a seed-to-dispensing tracking system that tracks medical cannabis from seed or immature plant stage until the medical cannabis is provided to a patient in a research study.

(2) Security, recordkeeping, record retention and surveillance systems relating to every stage of growing and processing medical cannabis.

(3) A daily log of each day's beginning inventory, acquisitions, disbursements, disposals and ending inventory.

(4) A system to recall defective medical cannabis.

(5) A system to track the plant waste resulting from the growth of medical cannabis.

(6) Testing of medical cannabis by an independent laboratory to test the medical cannabis produced by the health care medical cannabis organization, including requiring a test at harvest and a test at final processing.

(7) Any other procedure deemed necessary by the bureau.

§16A-13-8. Nonentitlement.

Nothing in this chapter shall be construed to create an entitlement or right of a patient to receive medical cannabis or to participate in a research study.

WV Code §16A-14

§16A-14-1. Definitions.

The following words and phrases when used in this chapter shall have the meanings given to them in this section unless the context clearly indicates otherwise:

(1) “Academic clinical research center” means an accredited medical school within this state that operates or partners with an acute care hospital licensed within this state.

(2) “Clinical registrant” means an entity that:

(A) Holds a permit as a grower, processor and a dispensary; and

(B) Has a contractual relationship with an academic clinical research center under which the academic clinical research center or its affiliate provides advice to the entity, regarding, among other areas, patient health and safety, medical applications and dispensing and management of controlled substances.

§16A-14-2. Clinical registrants.

Notwithstanding the limitations in section thirteen, article six of this chapter, the bureau may register up to four clinical registrants, and subject to the following:

(1) A clinical registrant must pay the fees and meet all other requirements under this act for obtaining a permit as a grower, processor and a dispensary.

(2) The clinical registrant must comply with all other requirements of this act regarding growing, processing and dispensing medical cannabis.

§16A-14-3. Research study.

Notwithstanding any provision of this act to the contrary, the bureau may, upon application, approve the dispensing of medical cannabis by a clinical registrant to the academic clinical research center for the purpose of conducting a research study. The bureau shall develop the application and standards for approval of such dispensing by the clinical registrant. The following apply to the research study:

(1) The clinical registrant shall disclose the following information to the bureau in its application:

(i) The reason for the research project, including the reason for the trial.

(ii) The strain of medical cannabis to be used and the strength of the medical cannabis to be used in the research study.

- (iii) The anticipated duration of the study.
 - (iv) Evidence of approval of the trial by an accredited institutional review board, including any other required regulatory approvals.
 - (v) Other information required by the bureau, except that the bureau may not require disclosure of any information that would infringe upon the academic clinical research center's exclusive right to intellectual property or legal obligations for patient confidentiality.
- (2) The academic clinical research center shall provide its findings to the bureau within three hundred sixty-five days of the conclusion of the research study or within three hundred sixty-five days of publication of the results of the research study in a peer-reviewed medical journal, whichever is later.
- (3) The bureau shall allow the exchange of medical cannabis seed between clinical registrants for the conduct of research.

WV Code §16A-15

§16A-15-1. Conflict.

The growth, processing, manufacture, acquisition, transportation, sale, dispensing, distribution, possession and consumption of medical cannabis permitted under this act shall not be deemed to be a violation of the provisions of the Uniform Controlled Substance Act under chapter sixty-a of this code. If a provision of Uniform Controlled Substance Act under chapter sixty-a relating to cannabis conflicts with a provision of this act, this act shall take precedence.

§16A-15-2. Financial and employment interests.

- (a) Financial interests. — A public official, or an immediate family member thereof, shall not intentionally or knowingly hold a financial interest in a medical cannabis organization or in a holding company, affiliate, intermediary or subsidiary thereof, while the individual is a public official and for one year following termination of the individual's status as a public official.
- (b) Employment. — No public official, or an immediate family member thereof, shall be employed by a medical cannabis organization or by any holding company, affiliate, intermediary or subsidiary thereof, while the individual is a public official and for one year following termination of the individual's status as a public official.
- (c) For purposes of this section, "public official" and "immediate family" shall have the same definitions as those phrases are defined in section three, article one, chapter six-b of this code.

§16A-15-3. Insurers.

Nothing in this act shall be construed to require an insurer or a health plan, whether paid for by state funds or private funds, to provide coverage for medical cannabis.

§16A-15-4. Protections for patients and caregivers.

- (a) Licensure. — None of the following shall be subject to arrest, prosecution or penalty in any manner, or denied any right or privilege, including civil penalty or disciplinary action by a state licensing board or commission, solely for lawful use of medical cannabis or manufacture or sale or dispensing of medical cannabis, or for any other action taken in accordance with this act:

- (1) A patient.
- (2) A caregiver.
- (3) A practitioner.
- (4) A medical cannabis organization.

(5) A health care medical cannabis organization or university participating in a research study under article thirteen of this chapter.

(6) A clinical registrant or academic clinical research center under article fourteen of this chapter.

(7) An employee, principal or financial backer of a medical cannabis organization.

(8) An employee of a health care medical cannabis organization or an employee of a university participating in a research study under article thirteen of this chapter.

(9) An employee of a clinical registrant or an employee of an academic clinical research center under article fourteen of this chapter.

(b) Employment. —

(1) No employer may discharge, threaten, refuse to hire or otherwise discriminate or retaliate against an employee regarding an employee's compensation, terms, conditions, location or privileges solely on the basis of such employee's status as an individual who is certified to use medical cannabis.

(2) Nothing in this act shall require an employer to make any accommodation of the use of medical cannabis on the property or premises of any place of employment. This act shall in no way limit an employer's ability to discipline an employee for being under the influence of medical cannabis in the workplace or for working while under the influence of medical cannabis when the employee's conduct falls below the standard of care normally accepted for that position.

(3) Nothing in this act shall require an employer to commit any act that would put the employer or any person acting on its behalf in violation of federal law.

§16A-15-5. Schools.

The Department of Education shall promulgate rules within six months of the effective date of this section regarding the following:

(1) Possession and use of medical cannabis by a student on the grounds of a preschool, primary school and a secondary school.

(2) Possession and use of medical cannabis by an employee of a preschool, primary school and a secondary school on the grounds of such school.

§16A-15-6. Daycare centers.

The Bureau shall promulgate rules within six months of the effective date of this section regarding the following:

- (1) Possession and use of medical cannabis by a child under the care of a child-care or social service center licensed or operated by the Bureau of Family Assistance.
- (2) Possession and use of medical cannabis by an employee of a child-care or social service center licensed or operated by the Bureau of Family Assistance.
- (3) Possession and use of medical cannabis by employees of a youth development center or other facility which houses children adjudicated delinquent.

§16A-15-7. Zoning.

The following apply:

- (1) A grower/processor shall meet the same municipal zoning and land use requirements as other manufacturing, processing and production facilities that are located in the same zoning district.
- (2) A dispensary shall meet the same municipal zoning and land use requirements as other commercial facilities that are located in the same zoning district.
- (3) A municipality may enact an ordinance prohibiting or limiting the number and type of medical cannabis organizations permitted to operate in the municipality, including the time, place, and manner of operation.

§16A-15-8. Notice to bureau.

- (a) A municipality that enacts a restrictive ordinance pursuant to section seven of this article, shall promptly notify the bureau of such action.
- (b) A county commission shall notify the bureau if a county votes to prohibit allowance of a medical cannabis organization pursuant to section six, article seven of this chapter.

§16A-15-9. Applicability.

The issuance of permits and other authorizations shall begin upon publication of a notice by the bureau in the State Register that adequate emergency or permanent rules have been adopted to initiate the program under this act.

§16A-15-10. State employee actions and federal law.

- (a) No cause of action exists against the state officers and employees in their personal capacities, while acting within the scope of duties contemplated by §16A-1-1 et seq. of this code. Any recovery for claims or actions arising from this section is limited solely to the proceeds of available insurance coverage.
- (b) To the extent permitted by law, the State of West Virginia shall defend state officers and employees involved in implementing the provisions of §16A-1-1 et seq. of this code against any

claims, charges, liabilities, or expenses and shall indemnify and hold harmless state officers and employees involved in implementing the provisions of §16A-1-1 et seq. of this code provided they acted within the scope of their duties or employment in accordance with the act, including without limitation, defense in any state, federal, or local court and payment of the amount of any judgment obtained, damages, legal fees, expenses, and any other expenses incurred.

WV Code §16A-16

§16A-16-1. Effective date.

- (a) Unless excepted in subsection (b) or (c) of this section, the provisions of this act shall be effective upon passage.
- (b) The provisions of §16A-12-1 et seq. of this code, and any other criminal provisions or penalties contained in this act, shall not be effective until 90 days from passage of Senate Bill 386 during the 2017 regular session.
- (c) Notwithstanding any provision of this chapter to the contrary, no identification cards may be issued to patients until July 1, 2019. The bureau may take sufficient steps through rule to implement the preliminary provisions in preparation for implementation of the provisions of this act.
- (d) Notwithstanding the prohibition contained in subsection (c) of this section on the issuance of identification cards until July 1, 2019, the bureau may implement a process for the preregistration of patients with a serious medical condition who have been issued a certification approved by the bureau and to a caregiver designated by the patient: Provided, That a patient who is preregistered must nevertheless comply with the provisions of §16A-5-1 of this code and may not be issued an identification card necessary to obtain and use medical cannabis as authorized by this act until July 1, 2019.