



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

eFILED

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Office of West Virginia
Secretary Of State

NOTICE OF AN EMERGENCY RULE

AGENCY: Health TITLE-SERIES: 64-112

RULE TYPE: Legislative Amendment to Existing Rule: No

RULE NAME: Medical Cannabis Program - Dispensaries

CITE STATUTORY AUTHORITY FOR PROMULGATING EMERGENCY RULE:

W. Va. Code §§16A-3-1(b).

IF THE EMERGENCY RULE WAS PROMULGATED TO COMPLY WITH A TIME LIMIT ESTABLISHED BY CODE OR FEDERAL STATUTE OR REGULATION, CITE THE CODE PROVISION, FEDERAL STATUTE OR REGULATION AND TIME LIMIT ESTABLISHED THEREIN:

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THE ABOVE RULE IS BEING FILED AS AN EMERGENCY RULE TO BECOME EFFECTIVE AFTER APPROVAL BY THE SECRETARY OF STATE OR THE 42ND DAY AFTER FILING, WHICHEVER OCCURS FIRST. THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE AS FOLLOWS:

West Virginia Medical Cannabis Act, passed in SB 386 during 2017 Regular Legislative Session, requires the Bureau for Public Health to propose rules for legislative promulgation as may be necessary to carry out and implement its provisions, including emergency rules. SB 386 states that the Bureau for Public Health has a duty to begin publishing emergency rules in the State Register no later than six months after the effective date of the Act.

DOES THIS EMERGENCY RULE REPEAL A CURRENT RULE? No

HAS THE SAME OR SIMILAR EMERGENCY RULE PREVIOUSLY BEEN FILED AND OR EXPIRED? No

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

Senate Bill 386 passed with no funds allocated for implementation or operation of the Medical Cannabis Program. It is estimated that expenditures will surpass projected revenue by \$472,466 in FY2018, \$1,317,616 in FY2019, and \$1,099,901 upon full implementation in FY2020 and each fiscal year thereafter.

B. ECONOMIC IMPACT ON THE STATE OR ITS RESIDENTS:

C. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2018 Increase/Decrease (use "-")	2019 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	1,077,466.00	1,824,991.00	1,442,276.00
Personal Services	74,716.00	1,023,903.00	1,023,903.00
Current Expenses	107,750.00	801,088.00	418,373.00
Repairs and Alterations			
Assets	895,000.00	0.00	0.00
Other			
2. Estimated Total Revenues	605,000.00	507,375.00	342,375.00

D. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

Estimated Personal Services costs for the remainder of FY2018 is \$74,716 and include salaries of \$53,811 and fringes/employee benefits of \$20,905 for an HHR Office Director II that was hired in January 2018 and an HHR Program Manager I and Administrative Services Assistant III that are estimated to be hired with an effective date of May 5, 2018.

Estimated Current Expense and Equipment costs for FY2018 is \$1,002,750 and include (1) in-state travel (\$26,775) for Advisory Board meetings, speaking engagements, meetings with local and/or county governments, onsite reviews of grower/processor sites, onsite review of laboratory facilities, etc.; (2) out-of-state travel (\$11,312) for attending National Cannabis regulatory meeting and participating in onsite visits of two other state's cannabis programs; (3) contractual (\$46,825) for implementing Phase 1 of a "seed to sale" marijuana tracking system; (4) Hospitality services (\$1,869) to host an Alternative Pain Management conference; (5) testing equipment (\$895,000) for state laboratory testing; and (6) supplies and recurring expenses (\$20,969) to operate the program.

Estimated Personal Services costs for FY2019 is \$1,023,903 and include salaries of \$711,426 and fringes/employee benefits of \$312,477 for 15 FTEs (HHR Office Director II, Attorney II, Administrative Services Assistant III, Administrative Services Assistant II, HHR Program Manager I, HHR Specialist, Chemist II, Microbiologist, Accountant Auditor IV, Inspector Supervisor, two field inspectors, new position to supervise writing and issuance of permit and licenses, and two new positions for writing permits and licenses). New position classifications are being requested from the WV Division of Personnel for inspector and permit/license positions.

Estimated Current Expense for FY2019 is \$801,088 and include (1) in-state travel (\$53,550) for Advisory Board meetings, speaking engagements, meetings with local and/or county governments, onsite reviews of grower/processor sites, onsite review of laboratory facilities, etc.; (2) out-of-state travel (\$19,701) for attending National Cannabis regulatory meeting and participating in onsite visits of three other state's cannabis programs; (3) contractual (\$623,800) for full implementation of a "seed to sale" marijuana tracking system, preventive maintenance contracts on laboratory equipment, maintaining the Medical Cannabis website, and developing a public awareness campaign; and (4) supplies and recurring expenses (\$104,037) to manage and operate the program.

Estimated Personal Services costs upon full implementation in FY2020 and ongoing fiscal years is \$1,023,903 and include salaries of \$711,426 and fringes/employee benefits of \$312,477 for 15 FTEs (HHR Office Director II, Attorney II, Administrative Services Assistant III, Administrative Services Assistant II, HHR Program Manager I, HHR Specialist, Chemist II, Microbiologist, Accountant Auditor IV, Inspector Supervisor, two field inspectors, new position to supervise writing and issuance of permit and licenses, and two new positions for writing permits and licenses). New position classifications are being requested from the WV Division of Personnel for inspector and permit/license positions.

Estimated Current Expense upon full implementation in FY2020 and ongoing fiscal years is \$418,373 and include (1) in-state travel (\$53,550) for Advisory Board meetings, speaking engagements, meetings with local and/or county governments, onsite reviews of grower/processor sites, onsite review of laboratory facilities, etc.; (2) out-of-state travel (\$5,466) for attending National Cannabis regulatory meeting; (3) contractual (\$275,000) for maintaining a "seed to sale" marijuana tracking system, preventive maintenance contracts on laboratory equipment, maintaining the Medical Cannabis website, and developing a public awareness campaign; and (4) supplies and recurring expenses (\$84,357) to manage and operate the program.

Estimated revenue for FY2018 includes application fees for 10 Growers and 10 Processors at \$5,000 each (\$100,000) and permit fees for 10 Growers and 10 Processors at \$50,000 each (\$1,000,000) for a total of \$1,100,000. The Department's percentage of the total estimated revenue will be 55% (\$605,000).

Estimated revenue for FY2019 includes application renewal fees for 10 Growers and 10 Processors at \$5,000 each (\$100,000); application fees for 30 Dispensaries at \$2,500 each (\$75,000); permit fees for 30 Dispensaries at \$10,000 each (\$300,000); application fees for 6,000 patients at \$50 each (\$300,000); and a conservative tax revenue projection of \$147,500 for a total of \$922,500. The Department's percentage of the total estimated revenue will be 55% (\$507,375).

Estimated revenue upon full implementation of the Medical Cannabis Program in FY2020 and ongoing fiscal years includes application renewal fees for 10 Growers and 10 Processors at \$5,000 each (\$100,000); application renewal fees for 30 Dispensaries at \$2,500 each (\$75,000); application renewal fees for 6,000 patients at \$50 each (\$300,000); and a conservative tax revenue projection of \$147,500 for a total of \$622,500. The Department's percentage of the total estimated revenue will be 55% (\$342,375).

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

Yes

Heather J Mcdaniel--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 these rules 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).

1.3. Filing Date.

1.4. Effective Date.

1.5. Sunset Provision. These rules will terminate and have no further force or effect upon the expiration of five years from its effective date.

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

§64-112-2. Definitions. The following words and terms, when used in these rules, have the following meanings, unless the context clearly indicates otherwise:

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 an individual over 21 years of age, or if the patient is under 18 years of age, an individual who is designated by a patient under *W.Va. Code §16A-5-6(2)*.

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.

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 sections 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 these rules, 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. "Pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacist care pursuant to "The Larry W. Border Pharmacy Practice Act" (W.Va. Code §§ 30-5-1 et seq.).

2.29. "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.).

2.30. "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.

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

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

2.32.a. Cancer.

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

2.32.c. Amyotrophic lateral sclerosis.

2.32.d. Parkinson's disease.

2.32.e. Multiple sclerosis.

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

2.32.g. Epilepsy.

2.32.h. Neuropathies.

2.32.i. Huntington's disease.

2.32.j. Crohn's disease.

2.32.k. Post-traumatic stress disorder.

2.32.l. Intractable seizures.

2.32.m. Sickle cell anemia.

2.32.n. Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain in which conventional therapeutic intervention and opiate therapy is contraindicated or ineffective.

2.32.o. Terminally ill.

2.33. "Site" means the total area contained within the property line boundaries in which a facility is operated by a dispensary.

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

2.35. "THC" means Tetrahydrocannabinol.

2.36. "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.

2.37. "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 these rules, 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 *W.Va. Code R. § 64-110-16 (Relating to failure to be operational)*.

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. If a practitioner does not set forth recommendations, requirements, or limitations as to the form or dosage of medical cannabis on the patient certification, the physician or pharmacist employed by the dispensary and working at the facility must consult with the patient or the caregiver regarding the appropriate form and dosage of medical cannabis to be provided.

4.2.b.3. 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 these rules, 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. Licensed medical professionals at facility.

6.1. A dispensary must ensure that a physician or a pharmacist is present at the facility at all times during the hours the facility is open to dispense or offer to dispense medical cannabis to patients and caregivers.

6.2. As required under the Act, a physician or a pharmacist must, prior to assuming any duties at a facility, successfully complete a four-hour training course developed by the bureau. The course must provide instruction in the latest scientific research on medical cannabis, including the risks and benefits of medical cannabis, and other information deemed necessary by the bureau.

6.3. A practitioner or a physician, while at the facility, may not issue a patient certification to a patient.

§64-112-7. Dispensary facilities.

7.1. A dispensary may only dispense medical cannabis to a patient or caregiver in an indoor, enclosed, secure facility as approved by the bureau.

7.2. A dispensary may not be located:

7.2.a. Within 1,000 feet of the property line of a public, private or parochial school, or a day-care center;

7.2.b. At the same site used for growing and processing medical cannabis; or

7.2.c. In the same office space as a practitioner or other physician.

7.3. The bureau may waive or amend the prohibition under subdivision 7.2.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.

7.4. 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.

7.5. The following areas of a dispensary must be clearly marked with proper signage:

7.5.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.**

7.5.b. Areas that are open to patients and caregivers.

7.6. 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.

§64-112-8. Items and services provided at a dispensary.

8.1. A dispensary must dispense the form of medical cannabis under section 4 (dispensing medical cannabis).

8.2. A dispensary must purchase medical cannabis products only from a grower/processor.

8.3. 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.

8.4. 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 *W.Va. Code R. § 64-110-10*. (Forms of medical cannabis).

8.5. A dispensary may not:

8.5.a. Advertise medical cannabis:

8.5.a.1. As a promotional item.

8.5.a.2. As part of a giveaway.

8.5.a.3. As part of a coupon program.

8.5.b. Provide medical cannabis at no cost or free.

8.5.c. Make the dispensing of medical cannabis to a patient or caregiver conditional upon:

8.5.c.1. The purchase of a medical device, instrument, or service provided at a dispensary facility.

8.5.c.2. The purchase of a medical device, instrument, or service provided at a location other than a dispensary facility.

8.5.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.

§64-112-9. Labels and safety inserts.

9.1. 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.

9.2. A dispensary must dispense medical cannabis to a patient or caregiver in a sealed and properly labeled package.

9.3. The dispensary must inspect the label to ensure that the label contains the following:

9.3.a. The information required to be included in the receipt in section 4 (Dispensing medical cannabis).

9.3.b. The packaging date.

9.3.c. A use by or expiration date.

9.3.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.

9.3.e. The number of individual doses contained within the package and the species and percentage of THC and CBD.

9.3.f. A warning that the medical cannabis must be kept in the original container in which it was dispensed.

9.3.g. A warning that unauthorized use is unlawful and will subject the purchaser or user to criminal penalties.

9.3.h. Any other information required by the bureau.

9.4. The dispensary must inspect the label to ensure that the label does not bear:

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

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

9.4.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.

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

9.5. 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:

9.5.a. The method or methods for administering individual doses of medical cannabis.

9.5.b. Any potential dangers stemming from the use of medical cannabis.

9.5.c. How to recognize what may be problematic usage of medical cannabis and how to obtain appropriate services or treatment for problematic usage.

9.5.d. The side effects and contraindications associated with medical cannabis, if any, which may cause harm to the patient.

9.5.e. How to prevent or deter the misuse of medical cannabis by an individual under 18 years of age or others.

9.5.f. Any other information determined by the bureau to be relevant to enhance patient safety.

§64-112-10. Plans of operation.

10.1. 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:

10.1.a. Employment policies and procedures.

10.1.b. Security policies and protocols, including:

10.1.b.1. Staff identification measures.

10.1.b.2. Monitoring of attendance of staff and visitors.

10.1.b.3. Alarm systems.

10.1.b.4. Video surveillance.

10.1.b.5. Monitoring and tracking inventory.

10.1.b.6. Personnel security.

10.1.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.

10.1.d. Workplace safety.

10.1.e. Maintenance, cleaning and sanitation of the site or facility, or both.

10.1.f. Inventory maintenance and reporting procedures.

10.1.g. The investigation of complaints and potential adverse events from other medical cannabis organizations, patients, caregivers, or practitioners.

10.1.h. The use of the electronic tracking system prescribed by the bureau.

10.2. 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.

§64-112-11. Visitor access to dispensary facilities.

11.1. 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.**

11.2. Except as provided in subsection 11.3, only authorized employees of a dispensary may enter a limited access area.

11.3. 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.

11.4. When admitting a visitor under subsection 11.3 to a limited access area, a dispensary must:

11.4.a. Require the visitor to sign a visitor log upon entering and leaving the limited access area.

11.4.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.

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

11.4.d. Escort the visitor while the visitor remains in a limited access area.

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

11.5. The following apply regarding the visitor log required under subsections 11.3 and 11.4:

11.5.a. The dispensary must maintain the log for four years and make the log available to the bureau, state, or local law enforcement and other state, or local government officials upon request if necessary to perform the government officials' functions and duties.

11.5.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.

11.6. 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.

11.7. 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.

§64-112-12. Security and surveillance.

12.1. 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:

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

12.1.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.

12.1.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.

12.1.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.

12.1.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.

12.1.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.

12.1.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.

12.1.a.7. Smoke and fire alarms.

12.1.a.8. Auxiliary power sufficient to maintain security and surveillance systems for at least 48 hours following a power outage.

12.1.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.

12.1.a.10. Motion detectors.

12.1.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:

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

12.1.b.1.A. Any area of the facility where medical cannabis is loaded or unloaded into or from transport vehicles.

12.1.b.1.B. Entrances to and exits from the facility. Entrances and exits must be recorded from both indoor and outdoor vantage points.

12.1.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.

12.1.b.1.D. Five feet from the exterior of the perimeter of the facility.

12.1.b.1.E. All limited access areas.

12.1.b.2. Auxiliary power sufficient to maintain security and surveillance systems for at least 48 hours following a power outage.

12.1.b.3. Ability to operate under the normal lighting conditions of each area under surveillance.

12.1.b.4. Ability to immediately produce a clear, color, still photograph in a digital format that meets the requirements of this subsection.

12.1.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.

12.1.d. Ability to record all images captured by each surveillance camera for a minimum of four years in a format that may be easily accessed for investigative purposes. The recordings must be kept:

12.1.d.1. At the facility:

12.1.d.1.A. In a locked cabinet, closet or other secure place to protect it from tampering or theft; and

12.1.d.1.B. In a limited access area or other room to which access is limited to authorized individuals; or

12.1.d.2. At a secure location other than the location of the facility if approved by the bureau.

12.1.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.

12.2. The following apply regarding the inspection, servicing or alteration of, and the upgrade to, the dispensary facility's security and surveillance systems:

12.2.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.

12.2.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.

12.2.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.

12.2.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.

12.2.e. The dispensary must designate an employee to continuously monitor the security and surveillance systems at the facility.

12.2.f. The following apply regarding records retention:

12.2.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.

12.2.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 four 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.

12.3. 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.

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

12.5. A dispensary must have an electronic back-up system for all electronic records.

12.6. A dispensary must install lighting to ensure proper surveillance inside and outside of the facility.

12.7. 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:

12.7.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.

12.7.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.

§64-112-13. Inventory data.

13.1. A dispensary must maintain the following inventory data in its electronic tracking system:

13.1.a. Medical cannabis received from a grower/processor.

13.1.b. Medical cannabis dispensed to a patient or caregiver.

13.1.c. Damaged, defective, expired, or contaminated medical cannabis awaiting return to a grower/processor or disposal.

13.2. A dispensary must establish inventory controls and procedures to conduct monthly inventory reviews and annual comprehensive inventories of medical cannabis at its facility.

13.3. 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.

§64-112-14. Storage requirements.

14.1. 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 *W.Va. Code R. § 64-110-22 (Management and disposal of medical cannabis waste)*.

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

§64-112-15. Sanitation and safety in a facility.

15.1. 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:

15.1.a. Trash must be properly removed.

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

15.1.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.

15.1.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.

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. 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.

15.3. 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:

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

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

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

15.5. A dispensary must comply with all other applicable state and local building code requirements.

§64-112-16. Transportation of medical cannabis.

16.1. A dispensary may transport and deliver medical cannabis to a medical cannabis organization in this state in accordance with this section. The following apply:

16.1.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.

16.1.b. A dispensary may contract with a third-party contractor for delivery so long as the contractor complies with this section.

16.1.c. A dispensary may not transport medical cannabis to any location outside of this state.

16.1.d. A dispensary must use a global positioning system to ensure safe, efficient delivery of the medical cannabis to a medical cannabis organization.

16.2. Vehicles permitted to transport medical cannabis must:

16.2.a. Be equipped with a secure lockbox or locking cargo area.

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

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

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

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

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

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

16.3.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.

16.3.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, state, or local government officials if necessary to perform the government officials' functions and duties.

16.3.d. Each delivery team member must have a valid driver's license.

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

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

16.5. Except as provided in subsection 16.8, 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.

16.6. 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.

16.7. 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.

16.8. A transport vehicle is subject to inspection by 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. A transport vehicle may be stopped and inspected along its delivery route or at any medical cannabis organization.

§64-112-17. Transport manifest.

17.1. A dispensary must generate a printed or electronic transport manifest that accompanies every transport vehicle and contains the following information:

17.1.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.

17.1.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.

17.1.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.

17.1.d. The date and approximate time of departure.

17.1.e. The date and approximate time of arrival.

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

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

17.2. 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.

17.3. All medical cannabis being transported must be packaged in shipping containers and labeled in accordance with *W.Va. Code R. § 64-110-16* (packaging and labeling of medical cannabis) and section 9 (labels and safety inserts).

17.4. 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.

17.5. 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, state, or local government officials if necessary to perform the government officials' functions and duties.

§64-112-18. Evidence of adverse loss during transport.

18.1. 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.

18.2. 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.

18.3. If a dispensary discovers a discrepancy in the transport manifest, the dispensary must:

18.3.a. Conduct an investigation.

18.3.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.

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

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

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

§64-112-19. Complaints about or recall of medical cannabis.

19.1. 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.

19.2. Upon notification by the grower/processor under *W.Va. Code R. § 64-110-23* (Complaints about or recall of medical cannabis), the dispensary must cease dispensing the affected medical cannabis.

19.3. A dispensary must coordinate the return of the recalled medical cannabis with the grower/processor.

§64-112-20. 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.

§64-112-21. Application for additional dispensary locations.

21.1. 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.

21.2. A dispensary must submit an application for additional dispensary locations on a form prescribed by the bureau.

21.3. A dispensary submitting an application for additional dispensary locations must include with the application the following fees:

21.3.a. An application fee of \$2,500.00, which is nonrefundable.

21.3.b. A permit fee of \$10,000.00 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.

21.4. 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.

21.5. A dispensary submitting an application for additional dispensary locations must follow the requirements in *W.Va. Code R. § 64-110-7* (Initial permit application) and these rules.