



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF PUBLIC COMMENT PERIOD

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: W. Va. Code §16A-3-1(b)

COMMENTS LIMITED TO:

Written

DATE OF PUBLIC HEARING:

LOCATION OF PUBLIC HEARING:

DATE WRITTEN COMMENT PERIOD ENDS: 08/26/2024 5:00 PM

COMMENTS MAY BE MAILED OR EMAILED TO:

NAME: Virginia M. Payne
ADDRESS: 350 Capitol Street, Room 702
Charleston, WV 25301
EMAIL: virginia.m.payne@wv.gov

PLEASE INDICATE IF THIS FILING INCLUDES:

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

INCORPORATED BY REFERENCE: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

PROVIDE A BRIEF SUMMARY OF THE CONTENT OF THE RULE:

This rule includes general provisions related to the permitting of medical cannabis organizations.

SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN THE RULE AND A STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE:

The rule is sunseting, and contains a sunset extension and technical cleanup along with minor edits to language for clarification.

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

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

None

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

None

C. ECONOMIC IMPACT OF THE RULE ON THE STATE OR ITS RESIDENTS:

None

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2024 Increase/Decrease (use "-")	2025 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Assets	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

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

N/A

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

Yes

Virginia M Payne -- 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
BUREAU FOR PUBLIC HEALTH

SERIES 109
MEDICAL CANNABIS PROGRAM – GENERAL PROVISIONS

§64-109-1. General.

1.1. Scope. ~~The provisions of these rules include~~ This rule includes 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~~ This rule shall terminate and have no further force or effect on ~~April 21, 2025~~ August 1, 2030.

1.6. Applicability. ~~These rules apply~~ This rule applies 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, or 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~~ 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. "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.~~ 2.13.1. Holds a permit as both a grower/processor and a dispensary; and

~~2.13.b.~~ 2.13.2. 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.~~ 2.15.1. 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.~~ 2.15.2. For a privately held entity, the ownership of any security in the entity.

2.16. "Dispensary" means:

~~2.16.a.~~ 2.16.1. A person who holds a permit issued by the Bureau to dispense medical cannabis.

~~2.16.b.~~ 2.16.2. 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.~~ 2.17.1. 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.~~ 2.17.2. 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.~~ 2.17.3. 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.~~ 2.23.1. Any bank or savings association;

~~2.23.b.~~ 2.23.2. 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.~~ 2.23.3. Any federal credit union or state-chartered credit union, including an institution-affiliated party of a credit union; and

~~2.23.d.~~ 2.23.4. 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.~~ 2.26.1. A person who holds a permit from the Bureau under the Act to grow or process medical cannabis.

~~2.26.b.~~ 2.26.2. 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~~ in a site or within a facility where:

~~2.35.a.~~ 2.35.1. Immature medical cannabis plants or seeds are stored, or medical cannabis plants are growing or being processed into medical cannabis;

~~2.35.b.~~ 2.35.2. 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.~~ 2.35.3. Medical cannabis is packaged for sale or stored;

~~2.35.d.~~ 2.35.4. Medical cannabis waste is processed, stored, or destroyed; and

~~2.35.e.~~ 2.35.5. 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~~ 64CSR110-10 (Forms of medical cannabis).

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.~~ 2.38.1. A dispensary or a grower/processor.

~~2.38.b.~~ 2.38.2. 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.~~ 2.41.1. Solid, liquid, semi-solid, or contained gaseous materials that are generated by a grower/processor or an approved laboratory.

~~2.41.b.~~ 2.41.2. The term includes:

~~2.41.b.1.~~ 2.41.2.a. Unused, surplus, returned, recalled, contaminated, or expired medical cannabis;

~~2.41.b.2.~~ 2.41.2.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;

~~2.41.b.3.~~ 2.41.2.c. Spent hydroponic nutrient solution;

~~2.41.b.4.~~ 2.41.2.d. 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.~~ 2.41.2.e. Unused fertilizers and pesticides;

~~2.41.b.6.~~ 2.41.2.f. Unused excipients; and

~~2.41.b.7.~~ 2.41.2.g. 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"~~ "Operational" 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~~ this rule.

2.47. "Patient" means an individual who:

~~2.47.a.~~ 2.47.1. Has a serious medical condition;

~~2.47.b.~~ 2.47.2. Has met the requirements for certification under the Act; and

~~2.47.c.~~ 2.47.3. 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~~ this rule.

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.~~ 2.53.1. 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.~~ 2.53.2. 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.~~ 2.53.3. 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.~~ 2.55.1. Cancer;

~~2.55.b.~~ 2.55.2. Positive status for Human Immunodeficiency Virus or Acquired Immune Deficiency Syndrome;

~~2.55.c.~~ 2.55.3. Amyotrophic lateral sclerosis;

~~2.55.d.~~ 2.55.4. Parkinson's disease;

~~2.55.e.~~ 2.55.5. Multiple sclerosis;

~~2.55.f.~~ 2.55.6. Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity;

~~2.55.g.~~ 2.55.7. Epilepsy;

~~2.55.h.~~ 2.55.8. Neuropathies;

~~2.55.i.~~ 2.55.9. Huntington's disease;

~~2.55.j.~~ 2.55.10. Crohn's disease;

~~2.55.k.~~ 2.55.11. Post-traumatic stress disorder;

~~2.55.l.~~ 2.55.12. Intractable seizures;

~~2.55.m.~~ 2.55.13. Sickle cell anemia;

~~2.55.n.~~ 2.55.14. Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain; or

~~2.55.o.~~ 2.55.15. 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.~~ 3.1.1. 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.~~ 3.1.2. The name, business address, and medical credentials of a practitioner; and

~~3.1.c.~~ 3.1.3. 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.~~ 3.2.1. 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.~~ 3.2.2. The name or other personal identifying information of a patient or caregiver who applies for or is issued an identification card;

~~3.2.c.~~ 3.2.3. A patient certification issued by a practitioner;

~~3.2.d.~~ 3.2.4. Any information on an identification card;

~~3.2.e.~~ 3.2.5. 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.~~ 3.2.6. Information regarding a patient's serious medical condition.

~~3.2.g.~~ 3.2.7. 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.~~ 3.2.8. Information regarding the physical features of, and security measures installed in, a facility; and

~~3.2.i.~~ 3.2.9. 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.~~ 4.1.1. An initial permit application;

~~4.1.b.~~ 4.1.2. A permit renewal application;

~~4.1.c.~~ 4.1.3. An application for approval of a change in ownership of a medical cannabis organization authorized by a permit;

~~4.1.d.~~ 4.1.4. An application for approval of a change of location of a facility authorized by a permit;

~~4.1.e.~~ 4.1.5. An application for approval of alteration of a facility authorized by a permit; and

~~4.1.f.~~ 4.1.6. 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.~~ 4.3.1. The payment of the applicable application and permit fees in section 5 (Fees) are submitted with the application;

~~4.3.b.~~ 4.3.2. 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.e.~~ 4.3.3. 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~~ If an application ~~that~~ is rejected by the Bureau, ~~shall be returned to the applicant without further consideration~~ shall be notified by the Bureau ~~along with the refund of~~ and the initial permit fee shall be refunded.

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.~~ 5.1.1. 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 subsection~~ subsection 4.4 and subdivision 6.1.e (initial permit application) 6.1.3;

~~5.1.b.~~ 5.1.2. 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.~~ 5.1.3. 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.~~ 5.2.1. 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.~~ 5.2.2. 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.~~ 5.2.3. 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.~~ 5.3.1. An application for approval of a change in ownership of a medical cannabis organization;

~~5.3.b.~~ 5.3.2. An application for approval of a change of location of a facility authorized by a permit;
or

~~5.3.c.~~ 5.3.3. 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.~~ 6.1.1. An applicant may only use the initial permit application form prescribed by the Bureau made available on its web site.

~~6.1.b.~~ 6.1.2. An applicant must submit an initial permit application to the Bureau in a manner prescribed by the initial permit application instructions.

~~6.1.c.~~ 6.1.3. 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.~~ 6.2.1. The legal name of the applicant;

~~6.2.b.~~ 6.2.2. 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.~~ 6.2.3. The physical address of the applicant's proposed site and facility, including the following, as applicable:

~~6.2.c.1.~~ 6.2.3.a. Evidence of the applicant's clear legal title to or option to purchase the proposed site and the facility;

~~6.2.c.2.~~ 6.2.3.b. 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.~~ 6.2.3.c. 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.~~ 6.2.4. 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.~~ 6.2.5. The following apply to the proposed facility:

~~6.2.e.1.~~ 6.2.5.a. 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.~~ 6.2.5.b. 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.~~ 6.2.5.c. 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.~~ 6.2.6. 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.~~ 6.2.6.a. A verification of identity that is satisfactory to the Bureau;

~~6.2.f.2.~~ 6.2.6.b. Evidence of good moral character and reputation of each principal, operator, financial backer, or employee; and

~~6.2.f.3.~~ 6.2.6.c. 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.~~ 6.2.6.d. An affidavit from each principal or operator of the applicant setting forth the following:

~~6.2.f.4.A.~~ 6.2.6.d.1. 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.~~ 6.2.6.d.2. Whether the principal, operator, or financial backer has been convicted of a felony criminal offense.

~~6.2.g.~~ 6.2.7. If a principal, operator, or financial backer is a corporation or limited liability company:

~~6.2.g.1.~~ 6.2.7.a. The names, residential addresses, titles, and the curricula vitae of each principal of the corporation or limited liability company;

~~6.2.g.2.~~ 6.2.7.b. 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.~~ 6.2.7.c. 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.~~ 6.2.8. 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.~~ 6.2.8.a. 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.~~ 6.2.8.b. A certified copy of its filed certificate of limited partnership or other formation document, if applicable;

~~6.2.h.3.~~ 6.2.8.c. A certified copy of its partnership agreement; and

~~6.2.h.4.~~ 6.2.8.d. Unless the entity is a publicly traded company, the names, and mailing addresses of each of its partners.

~~6.2.i.~~ 6.2.9. Evidence that the applicant is responsible and capable of successfully establishing and operating a facility, including the following:

~~6.2.i.1.~~ 6.2.9.a. 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.~~ 6.2.9.b. 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.~~ 6.2.9.c. 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.~~ 6.2.9.d. 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 West Virginia State Tax Department and Workforce West Virginia under section 4;

~~6.2.i.5.~~ 6.2.9.e. 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.~~ 6.2.9.f. 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.~~ 6.2.9.g. 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.~~ 6.2.9.h. 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.~~ 6.2.10. A description of the duties, responsibilities, and roles of each principal, operator, financial backer, and employee;

~~6.2.k.~~ 6.2.11. A timetable outlining the steps the applicant will take to become operational;

~~6.2.l.~~ 6.2.12. 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.~~ 6.2.12.a. Security;

~~6.2.l.2.~~ 6.2.12.b. Employee qualifications and training;

~~6.2.l.3.~~ 6.2.12.c. Transportation of medical cannabis;

~~6.2.l.4.~~ 6.2.12.d. Storage of medical cannabis;

~~6.2.l.5.~~ 6.2.12.e. Labeling of medical cannabis;

~~6.2.l.6.~~ 6.2.12.f. Inventory management;

~~6.2.l.7.~~ 6.2.12.g. With respect to a grower/processor's facility, nutrient practice;

~~6.2.l.8.~~ 6.2.12.h. With respect to a grower/processor's facility, quality control and testing of medical cannabis for potential contamination;

~~6.2.l.9.~~ 6.2.12.i. Recordkeeping;

~~6.2.l.10.~~ 6.2.12.j. Preventing unlawful diversion of medical cannabis; and

~~6.2.l.11.~~ 6.2.12.k. 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.~~ 6.2.13. The relevant financial information in section 25 (capital requirements);

~~6.2.n.~~ 6.2.14. Statements that:

~~6.2.n.1.~~ 6.2.14.a. The applicant and each principal, operator, financial backer, and employee are of good moral character;

~~6.2.n.2.~~ 6.2.14.b. 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.~~ 6.2.14.c. 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.~~ 6.2.14.d. 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.~~ 6.2.15. 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.~~ 6.2.16. 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.~~ 6.5.1. 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.~~ 6.5.2. 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.

8.1. 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.~~ 9.3.1. 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.~~ 9.3.1.a. 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.~~ 9.3.1.b. 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.~~ 9.3.1.c. 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.~~ 9.3.1.d. The medical cannabis organization's history of compliance with the Act and ~~these rules~~ the legislative rules promulgated pursuant to the Act.

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~~ the legislative rules promulgated pursuant to the Act.

§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.~~ 10.1.1. 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.~~ 10.1.2. The medical cannabis organization falsified any part of the permit renewal application or any other application submitted to the Bureau under ~~these rules~~ this rule.

~~10.1.c.~~ 10.1.3. 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.~~ 10.4.1. Cease all operations authorized by the permit.

~~10.4.b.~~ 10.4.2. 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.~~ 10.4.3. 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.~~ 11.1.1. 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.~~ 11.1.2. In writing of any proposed modification of its plan of operation at least 30 days prior to the proposed modification.

~~11.1.c.~~ 11.1.3. 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.~~ 11.3.1. Discontinuance of operations.

~~11.3.b.~~ 11.3.2. 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.~~ 13.6.1. 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.~~ 13.6.2. 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.~~ 16.6.3. 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.~~ 14.2.1. An increase or decrease in the total square footage of the facility;

~~14.2.b.~~ 14.2.2. 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.~~ 14.2.3. Any of the following made to enhance activities authorized under the permit:

~~14.2.c.1.~~ 14.2.3.a. Additional electric fixtures or lighting equipment;

~~14.2.c.2.~~ 14.2.3.b. The lowering of a ceiling; and

~~14.2.c.3.~~ 14.2.3.c. 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.~~ 16.3.1. The projected date of closure.

~~16.3.b.~~ 16.3.2. 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.~~ 16.3.3. 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.~~ 16.3.4. 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 (Management and disposal of medical cannabis waste).

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~~ operational 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~~ the legislative rules promulgated pursuant to the Act.

18.2. An investigation or inspection may include:

~~18.2.a.~~ 18.2.1. Inspection of a medical cannabis organization's site, facility, vehicles, books, records, papers, documents, data, and other physical or electronic information.

~~18.2.b.~~ 18.2.2. Questioning of employees, principals, operators, and financial backers of the medical cannabis organization.

~~18.2.c.~~ 18.2.3. 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~~ at the end of each three-month period thereafter:

~~19.1.a.~~ 19.1.1. In the case of a grower/processor:

~~19.1.a.1.~~ 19.1.1.a. The amount of medical cannabis sold by the grower/processor during the period for which the report is being submitted.

~~19.1.a.2.~~ 19.1.1.b. 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.~~ 19.1.2. In the case of a dispensary:

~~19.1.b.1.~~ 19.1.2.a. The amount of medical cannabis purchased by the dispensary during the period for which the report is being submitted.

~~19.1.b.2.~~ 19.1.2.b. 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.~~ 19.1.2.c. 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~~ the legislative rules promulgated pursuant to the Act.

§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 legislative rules promulgated pursuant to the Act, the Bureau may take one or more of the following actions:

~~20.1.a.~~ 20.1.1. Suspend or revoke a permit if any of the following occur:

~~20.1.a.1.~~ 20.1.1.a. 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.~~ 20.1.1.b. The medical cannabis organization violates a provision of the Act or these rules, or an order issued under the Act or ~~these rules~~ the legislative rules promulgated pursuant to the Act;

~~20.1.a.3.~~ 20.1.1.c. The medical cannabis organization violates a provision of other state or local laws regarding the operation of its facility; or

~~20.1.a.4.~~ 20.1.1.d. 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.~~ 20.1.2. 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.~~ 20.1.2.a. The gravity of the violation.

~~20.1.b.2.~~ 20.1.2.b. The potential harm resulting from the violation to patients, caregivers, or the general public.

~~20.1.b.3.~~ 20.1.2.c. The willfulness of the violation.

~~20.1.b.4.~~ 20.1.2.d. Previous violations, if any, by the medical cannabis organization being assessed.

~~20.1.b.5.~~ 20.1.2.e. The economic benefit to the person being assessed for failing to comply with the requirements of the Act, ~~these rules~~ the legislative rules promulgated pursuant to the Act, or an order issued under the Act or ~~these~~ those rules.

~~20.1.c.~~ 20.1.3. 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.~~ 20.1.4. Order the restitution of funds or property unlawfully obtained or retained by a medical cannabis organization;

~~20.1.e.~~ 20.1.5. 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.~~ 20.1.5.a. 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.~~ 20.1.5.b. 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.~~ 20.1.5.c. An order may include:

~~20.1.e.3.A.~~ 20.1.5.c.1. An immediate evacuation of the site and facility, and the sealing of the entrances to the facility;

~~20.1.e.3.B.~~ 20.1.5.c.2. A quarantine of some or all of the medical cannabis found at the facility; and

~~20.1.e.3.C.~~ 20.1.5.c.3. The suspension of the sale or shipment of some or all of the medical cannabis found at the facility.

~~20.1.f.~~ 20.1.6. Issue a written warning if the Bureau determines that either:

~~20.1.f.1.~~ 20.1.6.a. The public interest will be adequately served under the circumstances by the issuance of the warning; or

~~20.1.f.2.~~ 20.1.6.b. 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~~ the legislative rules promulgated pursuant to the Act, or an order issued under the Act, or ~~these~~ those 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 legislative rules promulgated pursuant to the Act, 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.~~ 21.1.1. Each principal of a medical cannabis organization, prior to starting initial operation of a facility.

~~21.1.b.~~ 21.1.2. 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.~~ 21.2.1. The provisions of the Act and legislative rules relevant to the responsibilities of principals and employees of grower/processors.

~~21.2.b.~~ 21.2.2. Proper handling of medical cannabis.

~~21.2.c.~~ 21.2.3. Proper recordkeeping.

~~21.2.d.~~ 21.2.4. How to prevent and detect the diversion of medical cannabis.

~~21.2.e.~~ 21.2.5. Best practice security procedures.

~~21.2.f.~~ 21.2.6. Best practice safety procedures, including responding to the following:

~~21.2.f.1.~~ 21.2.6.a. A medical emergency.

~~21.2.f.2.~~ 21.2.6.b. A fire.

~~21.2.f.3.~~ 21.2.6.c. A chemical spill.

~~21.2.f.4.~~ 21.2.6.d. A threatening event including:

~~21.2.f.4.A.~~ 21.2.6.d.1. An armed robbery.

~~21.2.f.4.B.~~ 21.2.6.d.2. A burglary.

~~21.2.f.4.C.~~ 21.2.6.d.3. 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.~~ 23.2.1. Medical cannabis advertising may not:

~~23.2.a.1.~~ 23.2.1.a. Contain statements that are deceptive, false, or misleading;

~~23.2.a.2.~~ 23.2.1.b. 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.~~ 23.2.1.c. Specifically encourages the transportation of medical cannabis items across state lines or otherwise encourages illegal activity;

~~23.2.a.4.~~ 23.2.1.d. Display consumption of medical cannabis items;

~~23.2.a.5.~~ 23.2.1.e. 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.~~ 23.2.2. 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.~~ 23.2.2.a. "Do not operate a vehicle or machinery under the influence of this drug."; and

~~23.2.b.2.~~ 23.2.2.b. "Keep out of the reach of children."

23.3. Advertising Media, Coupons, and Promotions.

~~23.3.a.~~ 23.3.1. Advertising through handbills that are passed out in public areas such as parking lots and publicly owned property is prohibited.

~~23.3.b.~~ 23.3.2. 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.~~ 23.3.3. 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.~~ 23.3.4. 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.~~ 23.4.1. A medical cannabis organization must remove any sign, display, or advertisement if the Bureau finds it violates these rules.

~~23.4.b.~~ 23.4.2. 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.

24.1. 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 a grower/processor permit must provide an affidavit that the applicant has at least ~~two million dollars~~ \$2,000,000 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.

§64-109-26. Administrative Due Process.

26.1 Those persons adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests or privileges shall do so in accordance with 645CSR1, Rules of Procedure for Contested Case Hearings and Declaratory Rulings.