WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

eFILED
4/21/2020 8:59:48 AM

Office of West Virginia
Secretary Of State

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

AGENCY: Health

TITLE-SERIES: 64-110

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

RULE NAME: medical cannabis program-grower/processors

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

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

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

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

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

April 21, 2020

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

April 21, 2025

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

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

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

SERIES 110
MEDICAL CANNABIS PROGRAM – GROWER/PROCESSORS

§64-110-1. General.

1.1. Scope. The provisions of this rule include general provisions related to grower/processors pursuant to the West Virginia Medical Cannabis Act (W. Va. Code §16A-1-1 *et seq.*)

1.2. Authority. W. Va. Code §16A-3-1(b), §16A-7-3, and §16A-13-7.

1.3. Filing Date. April 21, 2020.

1.4. Effective Date. April 21, 2020.

1.5. Sunset Provision. This rule will terminate and have no further force or effect on April 21, 2025.

1.6. Applicability. This rule applies to a person or entity that desires to hold a permit as a medical cannabis organization in the state.

§64-110-2. Definitions.

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

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

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

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

2.5. "Approved laboratory" means a laboratory that has applied for, and received, the approval of the bureau to identify, collect, handle, and conduct tests on samples from a grower/processor and test samples from the bureau used in the growing, processing, or dispensing of medical cannabis as required by the Act and this rule.

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

2.7. "CBD" means Cannabidiol.

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

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

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

2.11. "Clinical Registrant" means an entity that:

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

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

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

2.13. "Dispensary" means:

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

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

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

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

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

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

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

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

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

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

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

2.20. "Grower/processor means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2.28.e. Surveillance system devices are stored.

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

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

2.31. "Medical cannabis organization" means:

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

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

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

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

2.34. "Medical cannabis waste" means:

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

2.34.b. The term includes:

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

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

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

2.34.b.3. Spent hydroponic nutrient solution.

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

2.34.b.5. Unused fertilizers and pesticides.

2.34.b.6. Unused excipients.

2.34.b.7. Wastewater.

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

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

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

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

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

2.40. "Patient" means an individual who:

2.40.a. Has a serious medical condition.

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

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

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

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

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

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

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

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

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

2.47.a. Cancer;

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

2.47.c. Amyotrophic lateral sclerosis;

2.47.d. Parkinson's disease;

2.47.e. Multiple sclerosis;

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

2.47.g. Epilepsy;

2.47.h. Neuropathies;

2.47.i. Huntington's disease;

2.47.j. Crohn's disease;

2.47.k. Post-traumatic stress disorder;

2.47.l. Intractable seizures;

2.47.m. Sickle cell anemia;

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

2.47.o. Terminally ill.

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

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

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

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

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

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

2.54. "THC" means Tetrahydrocannabinol.

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

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

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

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

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

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

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

§64-110-4. Plans of operation.

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

4.1.a. Employment policies and procedures;

4.1.b. Security policies and protocols including:

4.1.b.1. Staff identification measures;

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

4.1.b.3. Alarm systems;

4.1.b.4. Video surveillance;

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

4.1.b.6. Personal security.

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

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

4.1.e. Contamination protocols.

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

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

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

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

4.1.j. Inventory maintenance and reporting procedures.

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

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

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

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

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

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

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

5.2.b. Nongrowing and non-processing areas.

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

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

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

§64-110-6. Start-up inventory.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§64-110-8. Security and surveillance.

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

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

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

and the perimeter of the facility;

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

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

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

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

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

8.1.a.7. Smoke and fire alarms

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

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

8.1.a.10. Motion detectors; and

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

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

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

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

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

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

8.1.b.1.E. Twenty feet from the exterior of the perimeter of the facility;

8.1.b.2. Auxiliary power sufficient to maintain operation for at least 48 hours following a power outage;

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

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

8.1.c. Ability to clearly and accurately display the date and time. The date and time must be synchronized and set correctly and may not significantly obscure the picture;

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

8.1.d.1. At the facility:

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

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

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

8.1.e. A security alarm system separate from the facility's primary security system covering the limited access area or other room where the recordings under subdivision 8.1.d. are stored. The separate security alarm system must meet the same requirements as the facility's primary security alarm system.

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

8.2.a. The systems must be inspected, and all devices tested once every year by a qualified alarm system vendor and a qualified surveillance system vendor, as approved by the bureau;

8.2.b. The grower/processor must conduct maintenance inspections once every month to ensure that any repairs, alterations, or upgrades to the security and surveillance systems are made for the proper operation of the systems;

8.2.c. The grower/processor must retain at the facility, for at least four years, records of all inspections, servicing, alterations, and upgrades performed on the systems and must make the records available to the bureau and its authorized agents within two business days following a request;

8.2.d. In the event of a mechanical malfunction of the security or surveillance system that a

grower/processor anticipates will exceed an eight-hour period, the grower/processor must notify the bureau immediately and, with bureau approval, provide alternative security measures that may include closure of the facility;

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

8.2.f. The following apply regarding records retention:

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

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

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

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

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

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

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

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

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

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

9.1. A grower/processor must use only pesticides, fungicides or herbicides that are approved by the United States Department of Agriculture for use on medical cannabis plants and listed in Appendix A

(Acceptable pesticide active ingredients for use). The bureau will periodically publish a notice in the State Register updating the list of pesticides, fungicides or herbicides.

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

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

9.4. A grower/processor must:

9.4.a. Use appropriate nutrient practices;

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

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

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

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

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

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

9.8.a. Are free of seeds and stems;

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

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

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

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

9.9.b. Proper sanitation must be maintained; and

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

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

9.10.a. Temperature;

9.10.b. Humidity;

9.10.c. Ventilation;

9.10.d. Lighting; and

9.10.e. Water supply.

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

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

10.1.a. Pill;

10.1.b. Oil;

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

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

10.1.e. Liquid;

10.1.f. Dermal patch; or

10.1.g. Dry leaf or plant form.

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

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

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

11.1.a. Tetrahydrocannabinol (THC);

11.1.b. Tetrahydrocannabinol acid (THCA);

11.1.c. Tetrahydrocannabivarin (THCV);

11.1.d. Cannabidiol (CBD);

11.1.e. Cannabinadiolic acid (CBDA);

11.1.f. Cannabidivarine (CBDV);

11.1.g. Cannabinol (CBN);

11.1.h. Cannabigerol (CBG);

11.1.i. Cannabichromene (CBC); and

11.1.j. Any other cannabinoid component at > 0.1percent.

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

§64-110-12. Inventory data.

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

12.1.a. The number, weight, and type of seeds;

12.1.b. The number of immature medical cannabis plants;

12.1.c. The number of medical cannabis plants;

12.1.d. The number of medical cannabis products ready for sale; and

12.1.e. The number of damaged, defective, expired, or contaminated seeds, immature medical cannabis plants, medical cannabis plants, and medical cannabis products awaiting disposal.

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

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

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

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

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

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

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

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

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

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

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

13.2.b.1. Maintenance of equipment;

13.2.b.2. Cleaning of equipment; and

13.2.b.3. Calibration of equipment.

§64-110-14. Storage requirements.

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

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

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

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

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

15.1.b. Trash must be properly removed.

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

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

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

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

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

15.2.a. Maintaining adequate personal hygiene;

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

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

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

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

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

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

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

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

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

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

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

16.2.a. Child-resistant;

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

16.2.c. Light-resistant and opaque; and

16.2.d. Resealable.

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

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

16.4.a. Be easily readable;

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

16.4.c. Be conspicuously placed on the package;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16.5.b. Any statement, artwork, or design that could reasonably lead an individual to believe that

the package contains anything other than medical cannabis;

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

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

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

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

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

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

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

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

17.2. Vehicles permitted to transport medical cannabis must:

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

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

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

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

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

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

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

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

17.3.c. Each delivery team member must carry an identification badge or card at all times and must, upon demand, produce it to the bureau or its authorized agents, law enforcement, or other federal

or state government officials if necessary, to perform the government officials' functions and duties;

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

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

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

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

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

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

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

§64-110-18. Transport manifest.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20.3.a. Conduct an investigation;

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

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

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

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

§64-110-21. Electronic tracking system.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23.2. The following apply to voluntary recalls:

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

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

23.3. The following apply to mandatory recalls:

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

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

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

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

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

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

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

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

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

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

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

23.4.e. Procedures for notifying the bureau; and

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

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

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

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

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

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

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

23.7.d. The names of the recall coordinators;

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

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

23.7.g. The reason for the recall;

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

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

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

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

23.7.i.3. The method of disposal;

23.7.i.4. The date of disposal;

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

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

§64-110-24. Pesticides.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24.6.d. "Plant regulator" means:

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

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

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

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

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

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

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

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

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

Appendix A. Acceptable Pesticide Active Ingredients for Use

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

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

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

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