

TITLE 64
LEGISLATIVE RULE
BUREAU FOR PUBLIC HEALTH

SERIES 111
MEDICAL CANNABIS PROGRAM – LABORATORIES

§64-111-1. General.

1.1. Scope. The provisions of this rule regulate the certification and operation of laboratories that provide testing services to medical cannabis organizations authorized by the West Virginia Medical Cannabis Act (*W.Va. Code §§ 16A-1-1 et seq.*)

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

1.3. Filing Date.

1.4. Effective Date.

1.5. Sunset Provision. This rule shall terminate and have no further force or effect upon the expiration of five years from its effective date.

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

§64-111-2. Definitions. The following words and terms, when used in this rule, have the following meanings, unless the context clearly indicates otherwise:

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

2.2. “Accreditation body” means an organization which:

2.2.a. Certifies the competency, expertise and integrity of a laboratory and operates in conformance with the current version of International Organization Standard ISO/IEC 17011;

2.2.b. Determines a laboratory's compliance with and conformance to the relevant standards established by the International Organization for Standardization, including ISO/IEC 17025;

2.2.c. Is a signatory to the International Accreditation Cooperation Mutual Recognition Arrangement for Testing; and

2.2.d. Is not affiliated with a laboratory applicant for which it has or will issue a certificate of accreditation.

2.3. "Advanced practice registered nurse" has the same meaning as it does in *W.Va. Code §§ 30-7-1 et seq.* (Registered Professional Nurses).

2.4. "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.

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

2.6. "Certificate of accreditation" means a document issued by an accreditation body evidencing that a laboratory is in compliance with International Organization for Standardization Standard ISO/IEC 17025 or other standards relevant to the operation of laboratories conducting tests on medical cannabis and other items used in the growing, processing or dispensing of medical cannabis.

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

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

2.9. "Dispensary" means:

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

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

2.10. "Grower/processor means:

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

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

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

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

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

2.14. "Medical cannabis" means cannabis for certified medical use as set forth in the Act.

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

2.16. "Medical cannabis organization" means:

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

2.16.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.*

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

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

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

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

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

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

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

§64-111-3. Laboratories generally.

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

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

3.3. An approved laboratory shall employ at least one director to oversee and be responsible for the identification, collection, handling, and testing operations of the approved laboratory. A director

shall have earned, from a college or university accredited by a national or regional accrediting authority, at least one of the following:

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

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

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

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

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

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

§64-111-4. Approval of laboratories.

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

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

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

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

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

4.2.d. A copy of the laboratory applicant's most recent certificate of accreditation.

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

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

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

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

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

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

4.2.k. Other information required by the bureau.

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

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

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

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

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

5.1.a. Maintain proper standards of accuracy.

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

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

5.2.a. Dishonest reporting.

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

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

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

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

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

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

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

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

5.3. A laboratory applicant may appeal a determination made by the bureau under this section in accordance with *W.Va. Code R. 64-1-1 et seq.* (Rules of Procedure for Contested Case Hearings and Declaratory Rulings).

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

An approved laboratory intending to renew the approval issued to the laboratory under this rule shall, not more than six months nor less than four months prior to the expiration of the approval, submit an application under section 4 (Approval of laboratories) and update all of the information required to be submitted with the application.

§64-111-7. Stability testing and retention of samples.

7.1. A grower/processor shall request that a sample be identified and collected by an approved laboratory from each harvest batch sufficient to perform stability testing at six-month intervals for a one-year period.

7.2. The stability test shall be performed to ensure product potency and purity and provide support for expiration dating.

7.3. An approved laboratory shall retain a sample from each harvest batch sufficient to provide for stability testing and properly store the sample for one year.

§64-111-8. Sampling procedures for testing.

8.1. An approved laboratory shall ensure that its employees prepare all samples in accordance with policies and procedures that include appropriate information necessary for identifying, collecting and transporting samples in a manner that does not endanger the integrity of the samples for any testing required by this rule.

8.2. The sampling policies must at a minimum be:

8.2.a. Appropriate to the matrix being sampled.

8.2.b. In accordance with guidance provided by the bureau.

8.3. The sampling procedures must include the following:

8.3.a. Surveying the conditions in which the sample is being stored.

8.3.b. Using appropriate sampling equipment and consistent procedures.

8.3.c. Selecting and removing equal portions for each sample.

8.3.d. Random or systematic taking of samples throughout the harvest batch or harvest lot.

8.3.e. Obtaining a minimum number of samples based on harvest batch or harvest lot size.

8.3.f. Checking all parts of the harvest batch when harvest lots are created from that harvest batch.

8.3.g. Recording on a form prescribed by the bureau all observations and procedures used when collecting the sample.

8.3.h. Creating a unique sample identification number that will be linked to the harvest batch or harvest lot number assigned by the grower/processor in the electronic tracking system.

8.3.i. Entering all required information into the electronic tracking system.

§64-111-9. Selection protocols for samples.

9.1. An employee of an approved laboratory may only enter a facility operated by a grower/processor for the purpose of identifying and collecting samples and shall have access to limited access areas in the facility for these purposes.

9.2. An employee identifying and collecting samples under subsection 9.1 shall follow the chain of custody procedures included in the approved laboratory's application and approved by the bureau.

9.3. While at a facility operated by a grower/processor, an employee of an approved laboratory shall identify and collect the following for testing:

9.3.a. Samples at the time of harvest.

9.3.b. Samples of medical cannabis product before being sold or provided to a dispensary.

9.3.c. Test samples at other times when requested by the bureau.

§64-111-10. Testing requirements.

10.1. Prior to conducting any testing of a sample at the request of a grower/processor, an approved laboratory shall enter into a written contract with the grower/processor for testing services. The approved laboratory shall provide a copy of the contract to the bureau within two days following the bureau's request.

10.2. A grower/processor shall submit through the electronic tracking system a request to the approved laboratory with which it has a written contract under subsection 10.1 for each test to be conducted.

10.3. At a minimum, an approved laboratory shall perform tests as prescribed by the bureau on the following:

10.3.a. Samples from a harvest batch or harvest lot prior to being used to produce a medical cannabis product.

10.3.b. Samples from each process lot before the medical cannabis is sold or offered for sale to another medical cannabis organization.

10.4. The samples identified in subsection 10.3 shall be tested, at a minimum, for the following:

10.4.a. Pesticides.

10.4.b. Solvents.

10.4.c. Water activity and moisture content.

10.4.d. THC and CBD concentration.

10.4.e. Microbiological contaminants.

10.5. Sampling and testing under this rule shall be conducted with a statistically significant number and size of samples and with methodologies acceptable to the bureau to ensure that all harvest

batches, harvest lots and medical cannabis products are adequately tested for contaminants and that the cannabinoid profile is consistent throughout.

10.6. An approved laboratory may not test any samples when there is evidence of improper collection, improper preservation, apparent spoilage, excessive time lapse between collection of the sample and testing, or any other factor sufficient to render the findings of questionable validity.

10.7. An approved laboratory shall enter into the electronic tracking system and, under *W.Va. Code R. § 64-110-22 (Management and disposal of medical cannabis waste)* properly dispose of all tested and untested samples and test samples.

§64-111-11. Standards for testing.

An approved laboratory shall follow the methodologies, ranges and parameters acceptable to the bureau which are contained in the scope of the certificate of accreditation issued to the laboratory.

§64-111-12. Test results and reporting.

12.1. Only the results of the following tests are in compliance with the testing requirements of this rule:

12.1.a. Tests conducted on harvest batch samples or harvest lot samples requested by a grower/processor under section 10 (Testing requirements) and identified and collected by an employee of an approved laboratory.

12.1.b. Tests conducted on process lot samples requested by a grower/processor under section 10 and identified and collected by either an employee of a grower/processor or an employee of an approved laboratory.

12.2. The test results for each sample shall be entered into the electronic tracking system and shall only be accessible to the grower/processor submitting the sample and to the bureau.

12.3. If a sample fails any test required under section 10, the following apply to the sample:

12.3.a. The approved laboratory that performed the initial test may re-test the sample upon a request from the grower/processor in accordance with subsection 12.4.

12.3.b. If the sample passes the re-test, another approved laboratory shall sample the same harvest batch, harvest lot or process lot to confirm the passing test result.

12.3.c. If the bureau does not agree to accept the results from the approved laboratory, the sample shall be disposed of by the approved laboratory under *W.Va. Code R. § 64-110-22* (Management and disposal of medical cannabis waste).

12.4. A grower/processor shall notify the bureau and the approved laboratory through the electronic tracking system of its intent to re-test the sample or test another sample from the same harvest batch, harvest lot or process lot that failed a test.

12.5. An approved laboratory shall issue to a grower/processor a certificate of analysis, including the supporting data, for each harvest batch, harvest lot, or process lot sample that was tested at the request of the grower/processor. The certificate of analysis must include:

12.5.a. Whether the chemical profile of the harvest batch, harvest lot or process lot conforms to the chemical profile of the strain as determined by the bureau for the following compounds:

12.5.a.1. THC.

12.5.a.2. Tetrahydrocannabinolic acid.

12.5.a.3. CBD.

12.5.a.4. Cannabidiolic acid.

12.5.a.5. Cannabigerol.

12.5.a.6. Cannabinol.

12.5.b. That the presence of the following contaminants within the harvest batch, harvest lot or process lot does not exceed the levels as determined by the bureau for the following:

12.5.b.1. Heavy metals, mercury, lead, cadmium or arsenic.

12.5.b.2. Foreign material such as hair, insects, or any similar or related adulterant.

12.5.b.3. Any microbiological impurity, including:

12.5.b.3.A. Total aerobic microbial count.

12.5.b.3.B. Total yeast mold count.

12.5.b.3.C. P. aeruginosa.

12.5.b.3.D. Aspergillus spp.

12.5.b.3.E. S. aureus.

12.5.b.3.F. Aflatoxin B1, B2, G1 and G2.

12.5.b.3.G. Ochratoxin A.

12.5.b.3.H. Pesticide residue.

12.5.b.4. Whether the harvest batch, harvest lot or process lot is within the specification for

the strain for the characteristics of:

12.5.b.4.A. Odor.

12.5.b.4.B. Appearance.

12.5.b.4.C. Fineness.

12.5.b.4.D. Moisture content.

§64-111-13. Quality assurance program.

13.1. An approved laboratory shall establish and implement a quality assurance program to ensure that measurements are accurate, errors are controlled, and devices used for testing are routinely and properly calibrated.

13.2. The quality assurance program required under subsection 13.1 must include the following components:

13.2.a. An organizational chart that includes the testing responsibilities of each employee of the approved laboratory named in the chart.

13.2.b. A description of sampling procedures to be utilized.

13.2.c. Appropriate chain of custody protocols.

13.2.d. Analytical procedures.

13.2.e. Data reduction and validation procedures.

13.2.f. A plan for implementing corrective action, when necessary.

13.2.g. A requirement for the provision of quality assurance reports to management.

13.2.h. A description of the internal and external quality control systems.

§64-111-14. Transporting samples.

14.1. An employee of an approved laboratory, grower/processor or third-party contractor shall follow the transportation requirements under *W.Va. Code R. §§ 64-110-17 & 18* (Transportation of medical cannabis; and Transport manifest) when transporting a sample or test sample under this rule.

14.2. An employee of an approved laboratory, grower/processor or third-party contractor who transports process lot samples from a grower/processor to an approved laboratory shall:

14.2.a. Protect the physical integrity of the sample.

14.2.b. Keep the composition of the sample intact.

14.2.c. Protect the sample against factors that will interfere with the validity of testing results, including the factors of time, temperature and other environmental factors that may work to jeopardize the integrity of the sample.

§64-111-15. bureau request for testing.

15.1. The bureau, in its sole discretion, may identify and collect a test sample from a grower/processor at any time and request an approved laboratory to conduct tests.

15.2. The approved laboratory shall provide the bureau with a written report of the test results from a test sample tested under subsection 15.1 within seven days of the collection of the test sample, or sooner if requested by the bureau.

§64-111-16. Laboratory reporting.

16.1. An approved laboratory shall enter into the electronic tracking system the following information for each sample collected and each test conducted:

16.1.a. The unique sample identification number the approved laboratory assigns to the sample.

16.1.b. The name of the grower/processor that supplied the sample.

16.1.c. The employee identification number of the employee of the approved laboratory who identified and collected the sample at the request of the grower/processor.

16.1.d. The date and time the sample was collected from the grower/processor.

16.1.e. The date and time the sample was received by the approved laboratory.

16.1.f. The date the test was completed.

16.1.g. The condition of the sample when it was received by the approved laboratory.

16.1.h. A description of each test performed.

16.1.i. The results from the certificate of analysis issued under section 12 (Test results and reporting).

16.1.j. The date the testing results were provided to the grower/processor under section 12 or the bureau under section 15 (Bureau request for testing).

16.2. An approved laboratory shall keep for four years a paper or electronic copy of the certificate of analysis performed on samples submitted by a grower/processor or test samples submitted by the bureau. The laboratory shall provide a copy of a certificate of analysis within two days of a request made by the bureau.

§64-111-17. Advertising.

17.1. An approved laboratory may not advertise, market or otherwise promote its medical cannabis testing services to the general public. An approved laboratory may advertise, market or otherwise promote its medical cannabis testing services to a grower/processor as provided in this section.

17.2. Advertising, marketing and promotional materials proposed to be used by an approved laboratory under this section shall be reviewed and approved by the bureau prior to circulation or other use.

17.3. Personal solicitation by an employee, representative or agent of an approved laboratory to a grower/processor is considered advertising, marketing or otherwise promoting its medical cannabis testing services for the purposes of this section.

17.4. An approved laboratory may only advertise, market or otherwise promote its medical cannabis testing services that are performed onsite at the location designated in the laboratory's application.

17.5. A sign installed at the location of an approved laboratory that is designed to identify the laboratory or access to the laboratory is permissible as long as the sign meets local zoning requirements and does not violate the provisions of this section.

§64-111-18. Ownership prohibition.

The following individuals may not have a management or a direct or indirect financial or other ownership interest in an approved laboratory:

18.1. A principal, owner, financial backer or employee of a medical cannabis organization.

18.2. A practitioner.

18.3. A physician or pharmacist who is currently employed by a medical cannabis organization.

18.4. Any other person, other than a patient, who may receive a direct or indirect financial benefit from the growing, processing, transporting, dispensing or selling of medical cannabis.