



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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10/4/2019 12:16:08 PM

Office of West Virginia
Secretary Of State

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Health

RULE TYPE: Legislative

TITLE-SERIES: 64-111

RULE NAME: MEDICAL CANNABIS PROGRAM
LABORATORIES

CITE AUTHORITY: . Authority. W. Va. Code §16A-3-1(b)
and §16A-7-3.

The above proposed Legislative rules, following review by the Legislative Rule Making Review Committee, is hereby modified as a result of review and comment by the Legislative Rule Making Review Committee. The attached modifications are filed with the Secretary of State.

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

Yes

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

TITLE 64
LEGISLATIVE RULE
BUREAU FOR PUBLIC HEALTH

SERIES 111
MEDICAL CANNABIS PROGRAM – LABORATORIES

§64-111-1. General.

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

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

1.3. Filing Date.

1.4. Effective Date.

1.5. Sunset Provision. This rule will 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.

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

2.2. “Accreditation body” means an organization which:

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

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

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

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

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

2.4. “Bureau” means the West Virginia Bureau for Public Health within the West Virginia Department of Health and Human Resources.

2.5. “Certificate of accreditation” means a document issued by an accreditation body evidencing that

a laboratory is in compliance with International Organization for Standardization Standard ISO/IEC 17025 and other requirements relevant to the operation of laboratories conducting tests on medical cannabis and other items used in the growing, processing, or dispensing of medical cannabis.

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

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

2.8. "Dispensary" means:

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

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

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

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

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

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

2.10. "Grower/processor means:

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

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

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

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

2.13. "Health care medical cannabis organization" means a vertically integrated health system

approved by the bureau to dispense medical cannabis or grow and process medical cannabis, or both, in accordance with a research study under W. Va. Code §16A-13-1 et seq.

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

2.15. “Medical cannabis” means cannabis for certified medical use as set forth in the Act.

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

2.17. “Medical cannabis organization” means:

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

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

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

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

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

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

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

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

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

§64-111-3. Laboratories generally.

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

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

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

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

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

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

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

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

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

§64-111-4. Approval of laboratories.

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

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

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

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

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

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

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

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

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

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

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

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

4.2.k. Other information required by the bureau.

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

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

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

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

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

5.1.a. Maintain proper standards of accuracy.

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

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

5.2.a. Dishonest reporting.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8.2. The sampling policies must at a minimum be:

8.2.a. Appropriate to the matrix being sampled.

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

8.3. The sampling procedures must include the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

9.3.a. Samples at the time of harvest.

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

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

§64-111-10. Testing requirements.

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

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

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

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

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

another medical cannabis organization.

10.4. The samples identified in subsection 10.3. of this rule must be tested, at a minimum, for the following:

10.4.a. Pesticides;

10.4.b. Solvents;

10.4.c. Water activity and moisture content;

10.4.d. THC and CBD concentration; and

10.4.e. Microbiological contaminants.

10.5. Sampling and testing under this rule must be conducted with a statistically significant number and size of samples and with methodologies acceptable to the bureau to ensure that all harvest batches, harvest lots and medical cannabis products are adequately tested for contaminants and that the cannabinoid profile is consistent throughout.

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

10.7. An approved laboratory must enter into the electronic tracking system and, under 64CSR110 (Management and disposal of medical cannabis waste) properly dispose of all tested and untested samples and test samples.

§64-111-11. Standards for testing.

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

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

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

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

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

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

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

12.3.a. The approved laboratory that performed the initial test may re-test the sample upon a

request from the grower/processor in accordance with subsection 12.4. of this rule.

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

12.3.c. If the bureau does not agree to accept the results from the approved laboratory, the sample must be disposed of by the approved laboratory under 64CSR110.22 (Management and disposal of medical cannabis waste).

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

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

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

12.5.a.1. Tetrahydrocannabinol (THC).

12.5.a.2. Tetrahydrocannabinol acid (THCA).

12.5.a.3. Tetrahydrocannabivarin (THCV).

12.5.a.4. Cannabidiol (CBD).

12.5.a.5. Cannabinadiolic acid (CBDA).

12.5.a.6. Cannabidivarine (CBDV).

12.5.a.7. Cannabinol (CBN).

12.5.a.8. Cannabigerol (CBG).

12.5.a.9. Cannabichromene (CBC).

12.5.a.10. Any other cannabinoid component at > 0.1percent.

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

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

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

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

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

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

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

12.5.b.3.D. Aspergillus spp.

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

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

12.5.b.3.G. Ochratoxin A.

12.5.b.3.H. Pesticide residue.

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

12.5.b.4.A. Odor.

12.5.b.4.B. Appearance.

12.5.b.4.C. Fineness.

12.5.b.4.D. Moisture content.

§64-111-13. Quality assurance program.

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

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

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

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

13.2.c. Appropriate chain of custody protocols.

13.2.d. Analytical procedures.

13.2.e. Data reduction and validation procedures.

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

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

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

§64-111-14. Transporting samples.

14.1. An employee of an approved laboratory, grower/processor, or third-party contractor must follow the transportation requirements under 64CSR110.17 and 64CSR110.18 (Transportation of medical

cannabis; and Transport manifest) when transporting a sample or test sample under this rule.

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

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

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

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

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

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

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

§64-111-16. Laboratory reporting.

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

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

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

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

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

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

16.1.f. The date the test was completed.

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

16.1.h. A description of each test performed.

16.1.i. The results from the certificate of analysis issued under section 12 of this rule.

16.1.j. The date the testing results were provided to the grower/processor under section 12 of this rule or the bureau under section 15 of this rule.

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

by the bureau.

§64-111-17. Advertising.

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

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

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

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

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

§64-111-18. Ownership prohibition.

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

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

18.1.b. A practitioner.

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

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