



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF AN EMERGENCY RULE

AGENCY: Health TITLE-SERIES: 64-113

RULE TYPE: LegislativeExempt Amendment to Existing Rule: No

RULE NAME: Medical Cannabis Program - Safe Harbor Letter

CITE STATUTORY AUTHORITY FOR PROMULGATING EMERGENCY RULE:

W. Va. Code §§ 16A-3-5 & 16A-10-6

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

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

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

DOES THIS EMERGENCY RULE REPEAL A CURRENT RULE? No

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

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

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

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

B. ECONOMIC IMPACT ON THE STATE OR ITS RESIDENTS:

C. FISCAL NOTE DETAIL:

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

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

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

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

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

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

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

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

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

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

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

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

Yes

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

TITLE 64
LEGISLATIVE RULE
BUREAU FOR PUBLIC HEALTH

SERIES 113
MEDICAL CANNABIS PROGRAM – SAFE HARBOR LETTER

§64-113-1. General

1.1. Scope. The provisions of these rules include provisions for obtaining a safe harbor letter from the bureau that authorizes a terminally ill cancer patient to use medical cannabis purchased in another state that has entered into a reciprocity agreement with the bureau.

1.2. Authority. *W. Va. Code §§ 16A-3-5 & 16A-10-6.*

1.3. Filing Date.

1.4. Effective Date.

1.5. Sunset Provision. These rules will terminate and have no further force or effect upon the upon the earlier of the following:

1.5.a. August 1, 2019.

1.5.b. Upon publication of a notice in the State Register.

1.6. Applicability. These rules apply to a person who is a terminally ill cancer patient who desires to use medical cannabis purchased in another state that has entered into a reciprocity agreement with the bureau.

§64-113-2. Definitions. The following words and terms, when used in these rules, have the following meanings, unless the context clearly indicates otherwise:

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

2.2. “Applicant” means an applicant who wishes to submit or submits an application to the bureau for a Safe Harbor letter.

2.3. “Bureau” means the West Virginia Bureau for Public Health within the Department.

2.4. "Caregiver" means an individual over 21 years of age, or if the applicant is under 18 years of age, an individual under *W.Va. Code §16A-5-6(2)*, who is designated by an applicant for certified medical use.

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

2.6. "Department" means the Department of Health and Human Resources.

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

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

2.9. "Patient" means an individual who:

2.9.a. Is a terminally ill cancer patient.

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

2.9.c. Is a resident of the state of West Virginia.

2.10. "Safe Harbor Letter" means a letter provided by the bureau to an applicant under *W.Va. Code § 16A-3-5* that allows the applicant to administer to him or herself medical cannabis purchased in another state with which the state has entered into a reciprocity agreement.

2.11. "Terminally ill cancer patient" means a person with a diagnosis of cancer and a medical prognosis of life expectancy of approximately one year or less if the illness runs its normal course.

§64-113-3. Medical cannabis from outside this State.

3.1. *Application for Safe Harbor Letter.* An applicant may apply to the bureau for a Safe Harbor Letter authorizing the applicant to obtain and use medical cannabis in this state that was obtained from a state with which bureau has entered into a reciprocity agreement.

§64-113-4. Application.

4.1. An applicant must submit an application for a Safe Harbor Letter under these rules on a form provided by the bureau under subsection 4.4, and must include the following information and any other information deemed necessary by the bureau:

4.1.a. The name, address and date of birth of the applicant.

4.1.b. The name, address, and date of birth of a caregiver, if applicable;

4.1.c. The applicant's proof of residency by submitting one of the following:

4.1.c.1. A West Virginia driver's license.

4.1.c.2. Department of Motor Vehicles-issued identification card.

4.1.c.3. Another form of identification that contains a photo and is approved by the bureau in the application.

4.1.d. The caregiver's criminal history record information obtained from the West Virginia State Police or its authorized agent, if applicable.

4.1.e. A written statement from a licensed physician in this state confirming that the applicant is a terminally ill cancer patient, the physician's name, address of practice, telephone number, and state license number.

4.1.f. An applicant must verify that the applicant will obtain the medical cannabis lawfully in another state.

4.2. The applicant must complete every required section of the application before it will be considered by the bureau.

4.2.a. If the bureau deems an application submitted by an applicant to be incomplete, the bureau will notify the applicant in writing of the factors for which further documentation is required.

4.2.b. An applicant must have 30 days from the mailing date of the notification to submit the additional material to the bureau or the bureau will deem the application as denied and the applicant will be required to submit a new application.

4.3. The applicant must certify as part of the application that the applicant understands and agrees to the following:

4.3.a. Cannabis is a prohibited Schedule I controlled substance under federal law.

4.3.b. Participation in the Medical Cannabis Program is permitted only to the extent provided by the Act and these rules.

4.3.c. An activity not sanctioned by the Act or rules promulgated under the Act is a violation of state law.

4.3.d. Growing, distributing, or possessing cannabis in any capacity, except through a federally-approved research program, is a violation of federal law.

4.3.e. Improper use or acquisition of medical cannabis may be a violation of state or federal law.

4.3.f. Participation in the Medical Cannabis Program does not authorize a person to violate federal or state law and does not provide immunity from or affirmative defense to arrest or prosecution under federal or state law except as provided under the Act.

4.3.g. An applicant or physician must indemnify, hold harmless and defend the state for any and all civil or criminal penalties resulting from participation in the Medical Cannabis Program, including obtaining medical cannabis from outside this state as set forth in *W.Va. Code § 16A-3-5*.

4.4. The applicant must agree to and accept the limitations of liability and the requirements to indemnify, hold harmless and defend the state by certifying that the applicant understands and agrees to the following:

4.4.a. Limitation of liability. The state is not liable to the state or entity from which the applicant or caregiver obtained medical cannabis, the physician who provided a statement listing the medical condition of the applicant for any damage, injury, accident, loss, compensation or claim, based on, arising out of or resulting from the growing, processing, dispensing, transportation, or sale of medical cannabis to the applicant, including, but not limited to, the following:

4.4.a.1. Arrest.

4.4.a.2. Seizure of persons or property, or both.

4.4.a.3. Prosecution under state or federal law by state or federal prosecutors.

4.4.a.4. Fire, robbery, theft, mysterious disappearance or any other casualty.

4.4.a.5. The actions of any other permittees, registrants or persons.

4.4.b. Criminal prosecution. The United States Congress has determined that cannabis is a controlled substance. Growing, distributing, transporting, possessing, and using cannabis in any capacity, except as part of a federally-authorized research program, is a violation of federal law. The West Virginia Legislature has placed cannabis in Schedule I of The Uniform Controlled Substance Act (*W.Va. Code §§ 60A-1-1 et seq.*). Growing, distributing, transporting, possessing, and using cannabis is a violation of state law, except as specifically set forth in the Act and these rules.

4.5. An application must be obtained and submitted as required by the bureau.

4.6. The application must include a notice that a false statement by the applicant is punishable under the application provisions of *W.Va. Code § 61-3-37*.

§64-113-5. Validity of Safe Harbor Letter.

5.1. The Safe Harbor Letter will be valid from the date of issuance by the bureau until August 1, 2019, or unless any of the following occurs:

5.1.a. The applicant dies.

5.1.b. The applicant changes physicians.

5.1.c. The applicant's physician knows or has reason to know that the applicant no longer suffers from terminal cancer and that use of medical cannabis would not be medically indicated.

5.1.d. The applicant's residency in another state.

5.1.e. The applicant receives notice under subsection 5.6.

5.2. The applicant or physician, or both, must notify the bureau in writing immediately upon knowledge of any change in the information in the original application and upon the occurrence of an event listed in subsection 5.1. The applicant must return the invalid Safe Harbor Letter to the bureau.

5.3. A new application must be submitted to the bureau under the following circumstances:

5.3.a. The applicant changes physicians. The application must include a written statement from the new physician that the applicant is a terminally ill cancer patient.

5.3.b. The applicant has not submitted information within 30 days under subdivision 4.2.b (relating to application).

5.4. The new application must be submitted to the bureau within a reasonable time period of the occurrence of the triggering event.

5.5. The submission of a new application will not be considered to be effective notice under subsection 5.2.

5.6. In the event that the Medical Cannabis Program becomes effective prior to the expiration of Safe Harbor Letters, the bureau will publish notice in the State Register that Safe Harbor Letters will be invalid as of the effective date of the appropriate rules. Individuals wishing to participate in the Medical Cannabis Program must obtain the requisite identification cards and registrations under the Act and these rules.

§64-113-6. Penalties and sanctions.

6.1. In addition to the penalties in *W.Va. Code* §§ 16A-12-1 *et seq.*, the bureau may deny, revoke, or suspend a Safe Harbor Letter if the Bureau has evidence of the following:

6.1.a. A conviction of a criminal offense that occurred within the 5 years relating to the sale or possession of drugs, narcotics or controlled substances.

6.1.b. A history of drug abuse.

6.1.c. A history of diversion of a controlled substance or illegal drugs.

6.1.d. Falsified information on the application.

6.1.e. A conviction of a crime of moral turpitude, such that the bureau would not be able to find the applicant of good moral character.

6.1.f. An intentional, knowing, or reckless violation of a provision of the Act or rules promulgated to implement the Act.

6.2. An applicant whose Safe Harbor Letter is denied, suspended, or revoked under subsection 6.1.a, or 6.1.(a) or (c) – (f) may be prohibited from participating in the Medical Cannabis Program for five years.

6.3. West Virginia Code of State Rules §§ 64-1-1 et seq. applies to all actions of the bureau under these rules.

§64-113-7. Confidentiality.

7.1. Information obtained by the bureau regarding an applicant under these rules is confidential and not subject to public disclosure, including disclosure under the West Virginia Freedom of Information Act (W.Va. Code §§ 29A-1-1 et seq.), including the following:

7.1.a. Individual identifying information of applicant.

7.1.b. Information regarding the applicant’s medical condition, including the physician’s written statements.