WEST VIRGINIA LEGISLATURE

2020 REGULAR SESSION

Introduced

House Bill 4368

BY DELEGATES HIGGINBOTHAM AND HORNBUCKLE

[Introduced January 16, 2020; Referred to the Committee on Health and Human Resources then the Judiciary]

A BILL to amend and reenact §16A-2-1 of the Code of West Virginia, 1931, as amended; to amend and reenact §16A-3-1 and §16A-3-5 of said code; and to amend and reenact §16A-13-3 of said code, all relating to the Medical Cannabis Act; adding definitions to "serious medical condition"; requiring rules related to use of edible medical cannabis; protecting patients from another state with medical cannabis in possession from arrest; and clarifying that colleges and private businesses shall be included in medical cannabis research programs.

Be it enacted by the Legislature of West Virginia:

ARTICLE 2. DEFINITIONS.

§16A-2-1. Definitions.

The following words and phrases when used in this chapter ~~shall~~ have the meanings given to them in this section unless the context clearly indicates otherwise:

~~(1)~~ "Act" means the West Virginia Medical Cannabis Act and the provisions contained in §60A-1-101 *et seq.* of this code.

~~(2)~~ "Advisory board" means the advisory board established under §16A-11-1 *et seq.* of this code.

~~(3)~~ "Bureau" means the Bureau for Public Health within the West Virginia Department of Health and Human Resources.

~~(4)~~ "Caregiver" means the individual designated by a patient or, if the patient is under 18 years of age, an individual authorized under §16A-5-1 *et seq.* of this code, to deliver medical cannabis.

~~(5)~~ "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 certification under this act, including enabling the patient to tolerate treatment for the serious medical condition.

~~(6)~~ "Change in control" means the acquisition by a person or group of persons acting in

concert of a controlling interest in an applicant or permittee either all at one time or over the span of a 12-consecutive-month period.

~~(7)~~ "Commissioner" means the Commissioner of the Bureau for Public Health.

~~(8)~~ "Continuing care" means treating a patient, in the course of which the practitioner has completed a full assessment of the patient's medical history and current medical condition, including an in-person consultation with the patient, and is able to document and make a medical diagnosis based upon the substantive treatment of the patient.

~~(9)~~ "Controlling interest" means:

(A) For a publicly traded entity, voting rights that entitle a person to elect or appoint one or more of the members of the board of directors or other governing board or the ownership or beneficial holding of five percent or more of the securities of the publicly traded entity.

(B) For a privately held entity, the ownership of any security in the entity.

~~(10)~~ "Dispensary" means a person, including a natural person, corporation, partnership, association, trust, or other entity, or any combination thereof, which holds a permit issued by the bureau to dispense medical cannabis. The term does not include a health care medical cannabis organization as defined in §16A-13-1 *et seq.* of this code.

~~(11)~~ "Family or household member" means the same as defined in §48-27-204 of this code.

~~(12)~~ "Financial backer" means an investor, mortgagee, bondholder, note holder, or other source of equity, capital, or other assets, other than a financial institution.

~~(13)~~ "Financial institution" means a bank, a national banking association, a bank and trust company, a trust company, a savings and loan association, a building and loan association, a mutual savings bank, a credit union, or a savings bank.

~~(14)~~ "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.

~~(15)~~ "Fund" means the Medical Cannabis Program Fund established in §16A-9-2 of this code.

~~(16)~~ "Grower" means a person, including a natural person, corporation, partnership, association, trust, or other entity, or any combination thereof, which holds a permit from the bureau under this act to grow medical cannabis. The term does not include a health care medical cannabis organization as defined in §16-13-1 *et seq*. of this code.

~~(17)~~ "Grower/processor" means either a grower or a processor.

~~(18)~~ "Identification card" means a document issued under §16A-5-1 *et seq.* of this code that authorizes access to medical cannabis under this act.

~~(19)~~ "Individual dose" means a single measure of medical cannabis.

~~(20)~~ "Medical cannabis" means cannabis for certified medical use as set forth in this act.

~~(21)~~ "Medical cannabis organization" means a dispensary, grower, or processor. The term does not include a health care medical cannabis organization as defined in §16A-13-1 *et seq.* of this code.

~~(22)~~ "Patient" means an individual who:

(A) Has a serious medical condition;

(B) Has met the requirements for certification under this act; and

(C) Is a resident of this state.

~~(23)~~ "Permit" means an authorization issued by the bureau to a medical cannabis organization to conduct activities under this act.

~~(24)~~ "Physician" or "practitioner" means a doctor of allopathic or osteopathic medicine who is fully licensed pursuant to the provisions of either §30-3-1 *et seq.* or §30-14-1 *et seq.* of this code to practice medicine and surgery in this state.

~~(25)~~ "Post-traumatic stress disorder" means a diagnosis made as part of continuing care of a patient by a medical doctor, licensed counselor, or psychologist.

~~(26)~~ "Prescription drug monitoring program" means the West Virginia Controlled Substances Monitoring Program under §60A-9-101 *et seq.* of this code.

~~(27)~~ "Principal" means an officer, director, or person who directly owns a beneficial interest in or ownership of the securities of an applicant or permittee, 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.

~~(28)~~ "Processor" means a person, including a natural person, corporation, partnership, association, trust, or other entity, or any combination thereof, which holds a permit from the bureau under this act to process medical cannabis. The term does not include a health care medical cannabis organization as defined in §16A-13-1 *et seq.* of this code.

~~(29)~~ "Registry" means the registry established by the bureau for practitioners.

~~(30)~~ "Serious medical condition" means any of the following, as has been diagnosed as part of a patient's continuing care:

(A) Cancer.

(B) Positive status for human immunodeficiency virus or acquired immune deficiency syndrome.

(C) Amyotrophic lateral sclerosis.

(D) Parkinson's disease.

(E) Multiple sclerosis.

(F) Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity.

(G) Epilepsy.

(H) Neuropathies.

(I) Huntington's disease.

(J) Crohn's disease.

(K) Post-traumatic stress disorder.

(L) Intractable seizures.

(M) Sickle cell anemia.

(N) Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain.

(O) Terminally ill.

(P) Migraines.

(Q) Spasms and cramps.

~~(31)~~ "Terminally ill" means a medical prognosis of life expectancy of approximately one year or less if the illness runs its normal course.

ARTICLE 3. MEDICAL CANNABIS PROGRAM.

§16A-3-1. Establishment of program.

(a) A medical cannabis program for patients suffering from serious medical conditions is established. The program shall be implemented and administered by the bureau. The bureau shall:

(1) Issue permits to medical cannabis organizations to authorize them to grow, process or dispense medical cannabis and ensure their compliance with this act.

(2) Register practitioners and ensure their compliance with this act.

(3) Have regulatory and enforcement authority over the growing, processing, sale and use of medical cannabis in this state.

(4) Establish and maintain an electronic database to include activities and information relating to medical cannabis organizations, certifications and identification cards issued, practitioner registration and electronic tracking of all medical cannabis as required under this act to include:

(A) Ensure that medical cannabis is not diverted or otherwise used for unlawful purposes by a practitioner or medical cannabis organization.

(B) Ability to establish the authenticity of identification cards.

(C) Recording recommended forms of medical cannabis provided in a certification filed by the practitioner.

(D) Monitoring all growth, transfer, possession, processing, testing and dispensing of medical cannabis in this state.

(E) The tracking system under article seven of this chapter must include information under §16A-8-1 of this code and any other information required by the bureau to be used by the bureau and dispensaries to enable a dispensary to lawfully provide medical cannabis. The tracking system and database shall be capable of providing information in real time. The database shall be capable of receiving information from a dispensary regarding the disbursement of medical cannabis to patients and caregivers. This information shall be immediately accessible to the bureau and other dispensaries to inhibit diversion and ensure compliance with this act.

(5) Maintain a directory of patients and caregivers approved to use or assist in the administration of medical cannabis within the bureau's database.

(6) Develop a four-hour training course for physicians regarding the latest scientific research on medical cannabis, including the risks and benefits of medical cannabis and other information deemed necessary by the bureau. Successful completion of the course shall be approved as continuing education credits as determined by:

(A) The State Board of Medicine.

(B) The State Board of Osteopathic Medicine.

(7) Develop a two-hour course for the principals and employees of a medical cannabis organization who either have direct contact with patients or caregivers or who physically handle medical cannabis. Employees must successfully complete the course no later than 90 days after commencing employment. Principals must successfully complete the course prior to commencing initial operation of the medical cannabis organization. The subject matter of the course shall include the following:

(A) Methods to recognize and report unauthorized activity, including diversion of medical cannabis for unlawful purposes and falsification of identification cards.

(B) Proper handling of medical cannabis and recordkeeping.

(C) Any other subject required by the bureau.

(8) Develop enforcement procedures, including announced and unannounced inspections of facilities of the grower/processors and dispensaries and all records of the medical cannabis organizations.

(9) Establish a program to authorize the use of medical cannabis to conduct medical research relating to the use of medical cannabis to treat serious medical conditions, including the collection of data and the provision of research grants.

(10) Establish and maintain public outreach programs about the medical cannabis program, including:

(A) A dedicated telephone number for patients, caregivers and members of the public to obtain basic information about the dispensing of medical cannabis under this act.

(B) A publicly accessible Internet website with similar information.

(11) Collaborate as necessary with other state agencies or contract with third parties as necessary to carry out the provisions of this act.

(12) Determine the number and type of medical cannabis products to be produced by a grower/processor and dispensed by a dispensary.

(13) Develop recordkeeping requirements for all books, papers, any electronic database or tracking system data and other information of a medical cannabis organization. Information shall be retained for a minimum period of four years unless otherwise provided by the bureau.

(14) Restrict the advertising and marketing of medical cannabis, which shall be consistent with the Federal rules and regulations governing prescription drug advertising and marketing.

(b) The bureau shall propose rules for legislative promulgation pursuant to ~~the provisions of~~ §29A-3-1 *et seq.* of this code as may be necessary to carry out and implement the provisions

of this act. The bureau ~~shall also have the power to~~ may propose and promulgate emergency rules as may be necessary to carry out and implement the provisions of this act.

(c) Rules proposed and promulgated necessary to carry out and implement the provisions of this act shall include:

(1) Specific identification of edible medical cannabis and safe quantities of medical cannabis that may be used in edible medical cannabis products;

(2) Requirements that sales of edible medical cannabis products fully inform patients or caregivers of specific safe amounts of medical cannabis that may be used in recipes, with warnings of adverse health effects that may occur if directions are not followed; and

(3) Required distribution of written explanations, to patients and caregivers who prefer to incorporate medical cannabis into edible form, of the percentage of tetrahydrocannabinol and cannabinol contained in the product and how using the product in an edible form may affect the patient.

§16A-3-5. Reciprocity for terminally ill cancer patients.

(a) The bureau may enter into reciprocity agreements with any states that have comparable requirements for the use and lawful purchase of medical cannabis in a manner consistent with the provisions of this article to allow terminally ill cancer patients to purchase medical cannabis in another state.

(b) Persons, who are residents and patients of another state, who possess an identification card issued by that state and are in possession of medical cannabis while in West Virginia, have the same protections from arrest as West Virginia resident patients.

ARTICLE 13. RESEARCH PROGRAM.

§16A-13-3. Medical cannabis research program administration.

(a) The bureau may establish a research study for each serious medical condition. The bureau ~~may~~ shall engage universities, colleges and private businesses within this state to participate in the collection, collation, analysis and conclusive findings of the research studies.

The bureau shall, by rule, establish the procedure to be used by health care medical cannabis organizations with respect to:

(1) Real time inventory tracking.

(2) Real time tracking of the medical cannabis dispensed.

(3) Recall of defective medical cannabis.

(b) *Request for distributions.* — The bureau shall establish a form and procedure for universities, colleges and private businesses selected to participate in a research study to request distributions from the fund to conduct research on medical cannabis, including administrative costs. These distributions shall also be used to pay for the cost of the medical cannabis so that it is not borne by the patient participating in the research study. The forms shall include, at a minimum, the following:

(1) The form or forms of medical cannabis to be studied.

(2) The serious medical condition to be studied.

(c) *Research reports*. —

(1) A vertically integrated health system shall report on the effectiveness of the use of medical cannabis for the treatment of the serious medical condition studied and all counterindications and noted side effects.

(2) The bureau shall notify the vertically integrated health system and the university participating in the research study of the data which is required to meet the United States Food and Drug Administration’s and the United States Drug Enforcement Administration’s approval for the research study.

(3) The first report, including the data required under subdivision (2) of this section, shall be submitted to the bureau and made publicly available within 180 days of the initiation of a research study for a specific serious medical condition.

(4) An annual report of the data required under subdivision (2) shall be submitted to the bureau beginning one year after the initiation of a research study for a specific serious medical

condition and each year thereafter.

NOTE: The purpose of this bill is to amend certain provisions of the Medical Cannabis Act. The bill adds definitions to “serious medical condition”. The bill requires rules promulgated relating to use of edible medical cannabis. It protects patients from another state with medical cannabis in possession from arrest. And the bill clarifies that colleges and private businesses shall be included in medical cannabis research programs.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.