WEST VIRGINIA LEGISLATURE

2024 REGULAR SESSION

Introduced

House Bill 5511

By Delegates Hardy, Steele, Ward, Westfall, Hite, Marple, Statler, Hott, and Maynor

[Introduced February 07, 2024; Referred to the Committee on Health and Human Resources then the Judiciary]

A BILL to amend and reenact §16A-3-2 and §16A-3-3 of the Code of West Virginia, 1931, as amended; to amend and reenact §16A-8-1 of said code; and to amend and reenact §60A-9-4 of said code, all relating generally to medical cannabis; modifying allowable forms of medical cannabis to include edible form; specifying certain requirements applicable to medical cannabis dispensed in edible form; modifying the unlawful use of medical cannabis; relating to the controlled substance monitoring database; adding the reporting of dispensing medical cannabis to the controlled substance monitoring database; and relating to certain required information for controlled substances monitoring.

Be it enacted by the Legislature of West Virginia:

CHAPTER 16A. MEDICAL CANNABIS ACT.

article 3. medical cannabis program.

§16A-3-2. Lawful use of medical cannabis.

(a) Notwithstanding any provision of law to the contrary, the use or possession of medical cannabis as set forth in this act is lawful within this state, subject to the following conditions:

(1) Medical cannabis may only be dispensed to:

(A) a patient who receives a certification from a practitioner and is in possession of a valid identification card issued by the bureau; and

(B) a caregiver who is in possession of a valid identification card issued by the bureau.

(2) Subject to rules promulgated under this act, medical cannabis may only be dispensed to a patient or caregiver in the following forms:

(A) Pill;

(B) Oil;

(C) Topical forms, including gels, creams or ointments;

(D) A form medically appropriate for administration by vaporization or nebulization, excluding dry leaf or plant form until dry leaf or plant forms become acceptable under rules adopted by the bureau;

(E) Tincture;

(F) Liquid; ~~or~~

(G) Dermal patch; or

(H) Edible: *Provided*, That any medical cannabis product produced or dispensed in edible form in this state must comply with the requirements of subsection (b) of this section.

(3) Unless otherwise provided in rules adopted by the bureau under section two, article eleven of this chapter, medical cannabis may not be dispensed to a patient or a caregiver in dry leaf or plant form.

(4) An individual may not act as a caregiver for more than five patients.

(5) A patient may designate up to two caregivers at any one time.

(6) Medical cannabis that has not been used by the patient shall be kept in the original package in which it was dispensed.

(7) A patient or caregiver shall possess an identification card whenever the patient or caregiver is in possession of medical cannabis.

(8) Products packaged by a grower/processor or sold by a dispensary shall only be identified by the name of the grower/processor, the name of the dispensary, the form and species of medical cannabis, the percentage of tetrahydrocannabinol and cannabinol contained in the product.

(b) Requirements applicable to medical cannabis dispensed in edible form in West Virginia:

(1) A processor that produces edibles must hold a permit to operate as a food establishment pursuant to §64-17-1, *et seq*. of the Code of State Rules of this state and must comply with all of the requirements for food establishments set forth in such rule.

(2) Before producing edibles within this state, a processor must obtain approval from the bureau for each edible product the processor intends to produce. The request for approval of the edible product must demonstrate that the proposed edible, including its packaging and labeling, complies with this section and any applicable legislative rule promulgated by the bureau pursuant to this article. As part of the approval process, the processor must submit a picture of the proposed edible bearing the universal symbol established by the bureau, and the measurements of the edible and universal symbol.

(3) Edibles shall be one of the following shapes (including the three-dimensional form of each shape):

(A) Square;

(B) Circle;

(C) Rectangle;

(D) Triangle;

(E) Parallelogram;

(F) Oval; or

(G) Diamond.

(4) Edibles shall be manufactured in one of the following two forms:

(A) Lozenges. For purposes of this section, a "lozenge" shall mean a hard edible that is held in the mouth and slowly dissolved; or

(B) Gelatins. For purposes of this section, a "gelatin" is a semi-translucent edible made with water-soluble protein derived from collagen, or a plant-based alternative, including but not limited to pectin.

(5) Each single serving edible may not exceed 10 milligrams of tetrahydrocannabinol. Edibles may have a potency variance of no greater than 15 percent.

(6) A processor shall not produce any edibles that:

(A) Contain any color additives, whether natural or artificial;

(B) Contain or bear a reasonable resemblance to commercially available candy;

(C) Contain any additive that increases potency, toxicity, or psychoactivity of the cannabis oil used to produce the edible (e.g., nicotine, alcohol, and caffeine);

(D) Bear any markings, symbols, images, graphics, or words, other than the universal symbol;

(E) Are decorated with icing, sprinkles, or other toppings of any kind; or

(F) Are a primary or bright color. Edibles shall be produced in a manner to minimize color intensity and other color and visual characteristics attractive to children.

(7) Edibles shall be marked with the universal symbol on at least one side of each edible such that the universal symbol is distinguishable and easily recognizable.

§16A-3-3. Unlawful use of medical cannabis.

(a) Except as provided in section two of this article, section four of article seven, article thirteen or article fourteen of this chapter, the use of medical cannabis is unlawful and shall, in addition to any other penalty provided by law, be deemed a violation of the Uniform Controlled Substances Act under chapter sixty-a of this code.

(b) It shall be unlawful to:

(1) Smoke medical cannabis.

~~(2) Except as provided under subsection (c), incorporate medical cannabis into edible form or sell in edible form~~

~~(3)~~ (2) Grow medical cannabis unless the grower/processor has received a permit from the bureau under this act.

~~(4)~~ (3) Grow or dispense medical cannabis unless authorized as a health care medical cannabis organization under article thirteen of this chapter.

~~(5)~~ (4) Dispense medical cannabis unless the dispensary has received a permit from the bureau under this act.

~~(c)~~*~~Edible medical cannabis~~*~~. -- Nothing in this act shall be construed to preclude the incorporation of medical cannabis into edible form by a patient or a caregiver in order to aid ingestion of the medical cannabis by the patient~~

article 8. dispensaries.

§16A-8-1. Dispensing to patients and caregivers.

(a) *General rule*. — A dispensary that has been issued a permit under §16A-6-1 *et seq.* of this code may lawfully dispense medical cannabis to a patient or caregiver upon presentation to the dispensary of a valid identification card for that patient or caregiver. The dispensary shall provide to the patient or caregiver a receipt, as appropriate. The receipt shall include all of the following:

(1) The name, address, and any identification number assigned to the dispensary by the bureau.

(2) The name and address of the patient and caregiver.

(3) The date the medical cannabis was dispensed.

(4) Any requirement or limitation by the practitioner as to the form of medical cannabis for the patient.

(5) The form and the quantity of medical cannabis dispensed.

(b) *Filing with bureau*. — Prior to dispensing medical cannabis to a patient or caregiver, the dispensary shall file the receipt information with the bureau utilizing the electronic tracking system, and input information in the controlled substance monitoring database. When filing receipts under this subsection, the dispensary shall dispose of any electronically recorded certification information as provided by rule.

(c) *Limitations*. — No dispensary may dispense to a patient or caregiver:

(1) A quantity of medical cannabis greater than that which the patient or caregiver is permitted to possess under the certification; or

(2) A form of medical cannabis prohibited by this act.

(d) *Supply*. — When dispensing medical cannabis to a patient or caregiver, the dispensary may not dispense an amount greater than a 30-day supply until the patient has exhausted all but a seven-day supply provided pursuant to §16A-4-5 of this code.

(e)*Verification*. — Prior to dispensing medical cannabis to a patient or caregiver, the dispensary shall verify the information in subsections (d) and (f) of this section by consulting the electronic tracking system included in the bureau’s electronic database established under §16A-3-1 of this code and the dispensary tracking system under §16A-7-1 of this code.

(f) *Form of medical cannabis*. — Medical cannabis dispensed to a patient or caregiver by a dispensary shall conform to any requirement or limitation set by the practitioner as to the form of medical cannabis for the patient.

(g) *Safety insert*. — When a dispensary dispenses medical cannabis to a patient or caregiver, the dispensary shall provide to that patient or caregiver, as appropriate, a safety insert. The insert shall be developed and approved by the bureau. The insert shall provide the following information:

(1) Lawful methods for administering medical cannabis in individual doses.

(2) Any potential dangers stemming from the use of medical cannabis.

(3) How to recognize what may be problematic usage of medical cannabis and how to obtain appropriate services or treatment for problematic usage.

(4) How to prevent or deter the misuse of medical cannabis by minors or others.

(5) Any other information as determined by the bureau.

(h) *Sealed and labeled package*. — Medical cannabis shall be dispensed by a dispensary to a patient or caregiver in a sealed, properly labeled, and child-resistant package. The labeling shall contain the following:

(1) The information required to be included in the receipt provided to the patient or caregiver, as appropriate, by the dispensary.

(2) The packaging date.

(3) Any applicable date by which the medical cannabis should be used.

(4) A warning stating:

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

(5) The amount of individual doses contained within the package and the species and percentage of tetrahydrocannabinol and cannabidiol.

(6) A warning that the medical cannabis must be kept in the original container in which it was dispensed.

(7) A warning that unauthorized use is unlawful and will subject the person to criminal penalties.

(8) Any other information required by the bureau.

CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.

ARTICLE 9. CONTROLLED SUBSTANCES MONITORING.

§60A-9-4. Required information.

(a) The following individuals shall report the required information to the Controlled Substances Monitoring Program Database when:

(1) A medical services provider dispenses a controlled substance listed in Schedule II, III, IV, or V;

(2) A prescription for the controlled substance or opioid antagonist is filled by:

(A) A pharmacist or pharmacy in this state;

(B) A hospital, or other health care facility, for outpatient use; or

(C) A pharmacy or pharmacist licensed by the Board of Pharmacy, but situated outside this state for delivery to a person residing in this state; ~~and~~

(3) A person dispenses medical cannabis to a patient or caregiver; and

(4) A pharmacist or pharmacy sells an opioid antagonist.

(b) The above individuals shall in a manner prescribed by rules promulgated by the Board of Pharmacy pursuant to this article, report the following information, as applicable:

(1) The name, address, pharmacy prescription number, and Drug Enforcement Administration controlled substance registration number of the dispensing pharmacy or the dispensing physician or dentist;

(2) The full legal name, address, and birth date of the person for whom the prescription is written;

(3) The name, address, and Drug Enforcement Administration controlled substances registration number of the practitioner writing the prescription;

(4) The name and national drug code number of the Schedule II, III, IV, and V controlled substance or opioid antagonist dispensed;

(5) The quantity and dosage of the Schedule II, III, IV, and V controlled substance or opioid antagonist dispensed;

(6) The date the prescription was written and the date filled;

(7) The number of refills, if any, authorized by the prescription;

(8) If the prescription being dispensed is being picked up by someone other than the patient on behalf of the patient, information about the person picking up the prescription as set forth on the person's government-issued photo identification card shall be retained in either print or electronic form until such time as otherwise directed by rule promulgated by the Board of Pharmacy; and

(9) The source of payment for the controlled substance dispensed.

(c) Whenever a medical services provider treats a patient for an overdose that has occurred as a result of illicit or prescribed medication, the medical service provider shall report the full legal name, address, and birth date of the person who is being treated, including any known ancillary evidence of the overdose. The Board of Pharmacy shall coordinate with the Division of Justice and Community Services and the Office of Drug Control Policy regarding the collection of overdose data.

(d) The Board of Pharmacy may prescribe by rule promulgated pursuant to this article the form to be used in prescribing a Schedule II, III, IV, and V substance or opioid antagonist if, in the determination of the Board of Pharmacy, the administration of the requirements of this section would be facilitated.

(e) Products regulated by the provisions of §60A-10-1 *et seq.* of this code shall be subject to reporting pursuant to the provisions of this article to the extent set forth in said article.

(f) Reporting required by this section is not required for a drug administered directly to a patient by a practitioner. Reporting is, however, required by this section for a drug dispensed to a patient by a practitioner. The quantity dispensed by a prescribing practitioner to his or her own patient may not exceed an amount adequate to treat the patient for a maximum of 72 hours with no greater than two 72-hour cycles dispensed in any 15-day period of time.

(g) The Board of Pharmacy shall notify a physician prescribing buprenorphine or buprenorphine/naloxone within 60 days of the availability of an abuse deterrent or a practitioner-administered form of buprenorphine or buprenorphine/naloxone if approved by the Food and Drug Administration as provided in FDA Guidance to Industry. Upon receipt of the notice, a physician may switch his or her patients using buprenorphine or buprenorphine/naloxone to the abuse deterrent or a practitioner-administered form of the drug.

NOTE: The purpose of this bill is to improve patient safety in the medical cannabis program by authorizing permitted, regulated medical cannabis processors to manufacture medical cannabis in edible form for dispensing to certified patients in the state; to specify certain requirements applicable to medical cannabis dispensed in edible form; and to require information relating to the dispensing of medical cannabis be input into the controlled substance monitoring database.

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