WEST VIRGINIA CODE CHAPTER 16A ARTICLE 13

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§16A-13-1. Definitions.

(a) 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) “Health care medical cannabis organization”. 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 this chapter.

(2) “Vertically integrated health system”. A health delivery system in which the complete spectrum of care, including primary and specialty care, hospitalization and pharmaceutical care, is provided within a single organization.

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§16A-13-2. Establishment of medical cannabis research program.

(a) Program to be established. — The bureau shall establish and develop a research program to study the impact of medical cannabis on the treatment and symptom management of serious medical conditions. The program shall not include a clinical registrant or academic clinical research center under article fourteen of this chapter.

(b) Bureau duties. — The bureau shall:

(1) Review all serious medical conditions which are cited by a practitioner upon the practitioner's certification that a patient be granted an identification card.

(2) Create a database of all serious medical conditions, including comorbidities, which are cited by practitioners in the certifications of patients. The database shall also include the form of medical cannabis certified to treat each serious medical condition.

(3) When the database contains twenty-five or more patients with the same serious medical condition, petition the United States Food and Drug Administration and the United States Drug Enforcement Administration for approval to study the condition and the impact of medical cannabis on the condition.

(4) Concurrent with the request to the United States Food and Drug Administration and United States Drug Enforcement Administration, publicly announce the formation of a research study to which a vertically integrated health system and a university within this state may submit a request to participate.

(5) Upon approval of a research study by the United States Food and Drug Administration and the United States Drug Enforcement Administration, select a vertically integrated health system or systems to conduct the research study and designate the form or forms of medical cannabis which will be used to treat the serious medical condition.

(6) Notify a patient who has been issued an identification card:

(A) that the patient has been selected to participate, at the patient's option, in a research study to study medical cannabis as a treatment; and

(B) where the patient may secure medical cannabis through a health care medical cannabis organization at no cost to the patient in accordance with subsection (c).

(7) If the United States Food and Drug Administration and the United States Drug Enforcement Administration reject the proposal for the research study, take all reasonable steps to collect and collate data on the serious medical condition and the use of medical cannabis as a treatment for the serious medical condition and consider submitting an additional request to the United States Food and Drug Administration and United States Drug Enforcement Administration for a research study on the same condition.

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(c) Costs. — The cost of the medical cannabis which is dispensed to patients in accordance with an approved research study shall be paid for by the fund.

(d) Geographic accessibility. — The bureau shall take into consideration the geographic location of the health care medical cannabis organization when assigning a patient to a health care medical cannabis organization. The bureau shall make an effort to assign a patient to a health care medical cannabis organization that is located within fifty miles of the patient's residence.

(e) Data. — Data collected by the health care medical cannabis organization shall be provided to the university participating in the research study for analysis.

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

(a) The bureau may establish a research study for each serious medical condition. The bureau may engage universities 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 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), shall be submitted to the bureau and made publicly available within one hundred eighty 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.

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§16A-13-4. Approval.

A vertically integrated health system located in this state may petition the bureau to participate in a research study to study a serious medical condition. Approval of the vertically integrated health system as a health care medical cannabis organization by the bureau shall authorize access within a region under subsection (d), section three, article six of this chapter to medical cannabis for all patients included in an approved research study.

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§16A-13-5. Requirements.

(a) Dispensing. — A health care medical cannabis organization that dispenses medical cannabis shall:

(1) Maintain licensure with the bureau.

(2) Secure the medical cannabis within the associated pharmacies of the health care medical cannabis organization in a manner and method prescribed by the bureau.

(3) Keep a daily log of the medical cannabis dispensed and the research study with which the patient and the medical cannabis are associated. Reports shall be delivered to the bureau and the university participating in the research study on a weekly basis.

(4) Report the utilization rates of those patients participating in the research of medical cannabis and treatment options.

(5) Only dispense medical cannabis received from a grower, processor or a health care medical cannabis organization that is approved to grow and process medical cannabis.

(6) Provide all patients or caregivers with the safety insert, prepared by the bureau, which includes potential dangers, recognition and correction of problematic dosage and any other information required by the bureau or which the bureau deems relevant for patient safety.

(b) Growing and processing. — A health care medical cannabis organization that grows and processes medical cannabis shall:

(1) Maintain licensure with the bureau.

(2) Only make available medical cannabis to health care medical cannabis organizations that dispense medical cannabis.

(3) Keep a daily log of medical cannabis intended for ultimate use by patients participating in a research study.

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§16A-13-6. Restrictions.

A health care medical cannabis organization may not participate in a research study of any kind, including the program established under this article, or dispense or grow and process medical cannabis if it has violated its licensure requirements or conditions.

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§16A-13-7. Rules.

The bureau shall, by rule, establish the procedure to be used by a health care medical cannabis organization that grows and processes medical cannabis with respect to:

(1) Real time inventory tracking, including a seed-to-dispensing tracking system that tracks medical cannabis from seed or immature plant stage until the medical cannabis is provided to a patient in a research study.

(2) Security, recordkeeping, record retention and surveillance systems relating to every stage of growing and processing medical cannabis.

(3) A daily log of each day's beginning inventory, acquisitions, disbursements, disposals and ending inventory.

(4) A system to recall defective medical cannabis.

(5) A system to track the plant waste resulting from the growth of medical cannabis.

(6) Testing of medical cannabis by an independent laboratory to test the medical cannabis produced by the health care medical cannabis organization, including requiring a test at harvest and a test at final processing.

(7) Any other procedure deemed necessary by the bureau.

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§16A-13-8. Nonentitlement.

Nothing in this chapter shall be construed to create an entitlement or right of a patient to receive medical cannabis or to participate in a research study.

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