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SENATE BILL NO. 885

Offered January 8, 2020 Prefiled January 8, 2020

A BILL to amend and reenact §§ 54.1-3422 and 54.1-3423 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 18.2-251.1:2, relating to performance of laboratory analysis; cannabidiol oil; THC-A oil; tetrahydrocannabinol.

Patron—Marsden

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3422 and 54.1-3423 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 18.2-251.1:2 as follows:

§ 18.2-251.1:2. Possession or distribution of cannabidiol oil or THC-A oil; laboratories.

No person employed by an analytical laboratory to retrieve, deliver, or possess cannabidiol oil or THC-A oil samples from a permitted pharmaceutical processor for performing required testing shall be prosecuted under § 18.2-248, 18.2-248.1, 18.2-250, 18.2-250.1, or 18.2-255 for the possession or distribution of cannabidiol oil or THC-A oil for storing cannabidiol oil or THC-A oil for testing purposes in accordance with regulations promulgated by the Board of Pharmacy.

§ 54.1-3422. Controlled substances registration certificate required in addition to other requirements; exemptions.

A. Every person who manufactures, distributes or dispenses any substance that is controlled in Schedules I through V or who proposes to engage in the manufacture, distribution or dispensing of any such controlled substance except permitted pharmacies, those persons who are licensed pharmacists, those persons who are licensed pharmacists, those persons who are licensed practitioners of medicine, osteopathy, podiatry, dentistry, optometry, nursing, or veterinary medicine shall obtain annually a controlled substances registration certificate issued by the Board. This registration shall be in addition to other licensing or permitting requirements enumerated in this chapter or otherwise required by law.

B. Registration under this section and under all other applicable registration requirements shall entitle the registrant to possess, manufacture, distribute, dispense, *perform laboratory analysis*, or conduct research with those substances to the extent authorized by this registration and in conformity with the other provisions of this chapter.

C. The following persons need not register and may possess controlled substances listed on Schedules I through VI:

1. An agent or employee of any holder of a controlled substance registration certificate or of any practitioner listed in subsection A of this section as exempt from the requirement for registration, if such agent or employee is acting in the usual course of his business or employment;

2. A common or contract carrier or warehouseman, or his employee, whose possession is in the usual course of business or employment; or

3. An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a prescriber or in lawful possession of a Schedule V substance.

D. A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

§ 54.1-3423. Board to issue registration unless inconsistent with public interest; authorization to conduct research; application and fees.

A. The Board shall register an applicant to manufacture or distribute controlled substances included in Schedules I through V unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the Board shall consider the following factors:

1. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

2. Compliance with applicable state and local law;

- 3. Any convictions of the applicant under any federal and state laws relating to any controlled substance;
- 4. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;
 - 5. Furnishing by the applicant of false or fraudulent material in any application filed under this

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59 chapter;

6. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and

7. Any other factors relevant to and consistent with the public health and safety.

- B. Registration under subsection A does not entitle a registrant to manufacture and distribute controlled substances in Schedule I or II other than those specified in the registration.
- C. Practitioners must be registered to conduct research *or laboratory analysis* with controlled substances in Schedules II through VI, *tetrahydrocannabinol*, *or marijuana*. Practitioners registered under federal law to conduct research with Schedule I substances, *other than tetrahydrocannabinol*, may conduct research with Schedule I substances within this Commonwealth upon furnishing the evidence of that federal registration.
- D. The Board may register other persons or entities to possess controlled substances listed on Schedules II through VI upon a determination that (i) there is a documented need, (ii) the issuance of the registration is consistent with the public interest, (iii) the possession and subsequent use of the controlled substances complies with applicable state and federal laws and regulations, and (iv) the subsequent storage, use, and recordkeeping of the controlled substances will be under the general supervision of a licensed pharmacist, practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as specified in the Board's regulations. The Board shall consider, at a minimum, the factors listed in subsection A of this section in determining whether the registration shall be issued. Notwithstanding the exceptions listed in § 54.1-3422 A, the Board may mandate a controlled substances registration for sites maintaining certain types and quantities of Schedules II through VI controlled substances as it may specify in its regulations. The Board shall promulgate regulations related to requirements or criteria for the issuance of such controlled substances registration, storage, security, supervision, and recordkeeping.
- E. The Board may register a public or private animal shelter as defined in § 3.2-6500 to purchase, possess, and administer certain Schedule II through VI controlled substances approved by the State Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and animals and to purchase, possess, and administer certain Schedule VI drugs and biological products for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter. Controlled substances used for euthanasia shall be administered only in accordance with protocols established by the State Veterinarian and only by persons trained in accordance with instructions by the State Veterinarian. The list of Schedule VI drugs and biological products used for treatment and prevention of communicable diseases within the shelter shall be determined by the supervising veterinarian of the shelter and the drugs and biological products shall be administered only pursuant to written protocols established or approved by the supervising veterinarian of the shelter and only by persons who have been trained in accordance with instructions established or approved by the supervising veterinarian. The shelter shall maintain a copy of the approved list of drugs and biological products, written protocols for administering, and training records of those persons administering drugs and biological products on the premises of the shelter.
- F. The Board may register a crisis stabilization unit established pursuant to § 37.2-500 or 37.2-601 and licensed by the Department of Behavioral Health and Developmental Services to maintain a stock of Schedule VI controlled substances necessary for immediate treatment of patients admitted to the crisis stabilization unit, which may be accessed and administered by a nurse pursuant to a written or oral order of a prescriber in the absence of a prescriber. Schedule II through Schedule V controlled substances shall only be maintained if so authorized by federal law and Board regulations.
- G. The Board may register an entity at which a patient is treated by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is prescribed Schedule II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration. In determining whether the registration shall be issued, the Board shall consider (i) the factors listed in subsection A, (ii) whether there is a documented need for such registration, and (iii) whether the issuance of the registration is consistent with the public interest.
- H. Applications for controlled substances registration certificates and renewals thereof shall be made on a form prescribed by the Board and such applications shall be accompanied by a fee in an amount to be determined by the Board.
- I. Upon (i) any change in ownership or control of a business, (ii) any change of location of the controlled substances stock, (iii) the termination of authority by or of the person named as the responsible party on a controlled substances registration, or (iv) a change in the supervising practitioner, if applicable, the registrant or responsible party shall immediately surrender the registration. The

- registrant shall, within 14 days following surrender of a registration, file a new application and, if applicable, name the new responsible party or supervising practitioner.
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- 2. That an emergency exists and this act is in force from its passage.