2020 SESSION

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SENATE BILL NO. 885

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the Senate Committee on Education and Health

on January 30, 2020)

(Patron Prior to Substitute—Senator Marsden)

5 6 A BILL to amend and reenact §§ 54.1-3422 and 54.1-3423 of the Code of Virginia and to amend the 7 Code of Virginia by adding a section numbered 18.2-251.1:2, relating to performance of laboratory 8 analysis; cannabidiol oil; THC-A oil; tetrahydrocannabinol; industrial hemp.

9 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 10 11 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, THC-A oil, or industrial hemp; 12 laboratories. 13

14 No person employed by an analytical laboratory to retrieve, deliver, or possess cannabidiol oil, 15 THC-A oil, or industrial hemp samples from a permitted pharmaceutical processor, a licensed industrial hemp grower, or a licensed industrial hemp processor for the purpose of performing required testing 16 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 17 or distribution of cannabidiol oil, THC-A oil, or industrial hemp, or for storing cannabidiol oil, THC-A 18 oil, or industrial hemp for testing purposes in accordance with regulations promulgated by the Board of 19 20 Pharmacy and the Board of Agriculture and Consumer Services.

21 § 54.1-3422. Controlled substances registration certificate required in addition to other 22 requirements; exemptions.

23 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 24 25 such controlled substance except permitted pharmacies, those persons who are licensed pharmacists, 26 those persons who are licensed physician assistants, and those persons who are licensed practitioners of 27 medicine, osteopathy, podiatry, dentistry, optometry, nursing, or veterinary medicine shall obtain 28 annually a controlled substances registration certificate issued by the Board. This registration shall be in 29 addition to other licensing or permitting requirements enumerated in this chapter or otherwise required 30 by law.

31 B. Registration under this section and under all other applicable registration requirements shall entitle 32 the registrant to possess, manufacture, distribute, dispense, perform laboratory analysis, or conduct 33 research with those substances to the extent authorized by this registration and in conformity with the 34 other provisions of this chapter. 35

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

37 1. An agent or employee of any holder of a controlled substance registration certificate or of any 38 practitioner listed in subsection A of this section as exempt from the requirement for registration, if such 39 agent or employee is acting in the usual course of his business or employment;

40 2. A common or contract carrier or warehouseman, or his employee, whose possession is in the usual 41 course of business or employment; or

42 3. An ultimate user or a person in possession of any controlled substance pursuant to a lawful order 43 of a prescriber or in lawful possession of a Schedule V substance.

44 D. A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances. 45

§ 54.1-3423. Board to issue registration unless inconsistent with public interest; authorization to 46 47 conduct research; application and fees.

48 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 49 50 with the public interest. In determining the public interest, the Board shall consider the following 51 factors:

52 1. Maintenance of effective controls against diversion of controlled substances into other than 53 legitimate medical, scientific, or industrial channels; 54

2. Compliance with applicable state and local law;

55 3. Any convictions of the applicant under any federal and state laws relating to any controlled 56 substance;

4. Past experience in the manufacture or distribution of controlled substances, and the existence in 57 the applicant's establishment of effective controls against diversion; 58

5. Furnishing by the applicant of false or fraudulent material in any application filed under this 59

60 chapter;

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

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

64 B. Registration under subsection A does not entitle a registrant to manufacture and distribute 65 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 71 72 Schedules II through VI upon a determination that (i) there is a documented need, (ii) the issuance of 73 the registration is consistent with the public interest, (iii) the possession and subsequent use of the 74 controlled substances complies with applicable state and federal laws and regulations, and (iv) the 75 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 76 veterinary medicine as specified in the Board's regulations. The Board shall consider, at a minimum, the 77 78 factors listed in subsection A of this section in determining whether the registration shall be issued. 79 Notwithstanding the exceptions listed in § 54.1-3422 A, the Board may mandate a controlled substances 80 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 81 requirements or criteria for the issuance of such controlled substances registration, storage, security, 82 83 supervision, and recordkeeping.

84 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 85 86 Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and 87 animals and to purchase, possess, and administer certain Schedule VI drugs and biological products for 88 the purpose of preventing, controlling, and treating certain communicable diseases that failure to control 89 would result in transmission to the animal population in the shelter. Controlled substances used for 90 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 91 92 Schedule VI drugs and biological products used for treatment and prevention of communicable diseases 93 within the shelter shall be determined by the supervising veterinarian of the shelter and the drugs and 94 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 95 96 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 97 98 training records of those persons administering drugs and biological products on the premises of the 99 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 106 diagnostic equipment through which images and medical records may be transmitted electronically for 107 108 the purpose of establishing a bona fide practitioner-patient relationship and is prescribed Schedule II 109 through VI controlled substances when such prescribing is in compliance with federal requirements for 110 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, 111 112 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 113 114 interest.

H. Applications for controlled substances registration certificates and renewals thereof shall be madeon a form prescribed by the Board and such applications shall be accompanied by a fee in an amount tobe 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

- 122 123 124 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.
- 2. That an emergency exists and this act is in force from its passage.