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HOUSE BILL NO. 2473

Offered January 13, 2025

Prefiled January 8, 2025

A BILL to amend and reenact § 54.1-3423 of the Code of Virginia, relating to Board of Pharmacy; long-acting injectable or extended-release prescription drugs; correctional facilities.

Patron—Sickles

Referred to Committee on Health and Human Services

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3423 of the Code of Virginia is amended and reenacted as follows:

§ 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 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 or marijuana. Practitioners registered under federal law to conduct research with Schedule I substances, other than marijuana, may conduct research with Schedule I controlled substances within the 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 in determining whether the registration shall be issued. Notwithstanding the exceptions listed in *subsection A of* § 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. *Notwithstanding the provisions of this subsection or Board regulations, the Board may register a correctional facility to maintain a floor stock of long-acting injectable or extended-release prescription drugs for the treatment of mental illness or substance use disorder. Such long-acting injectable or extended-release prescription drugs shall be stored in an area accessible only to persons who are licensed to administer such prescription drugs, regardless of whether the prescriber is on site. Each correctional facility shall maintain an ongoing perpetual inventory of all such drugs in Schedules II through V. Such perpetual inventory shall (a) accurately indicate the physical count of each drug on hand at the time the inventory is performed and (b) no less than once per month, include a reconciliation of each drug with a written explanation for any difference between the physical count and the theoretical count.*

E. The Board may register a public or private animal shelter as defined in § 3.2-6500 to purchase, possess, and administer certain Schedules 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 facility, as defined in § 37.2-100, that provides crisis stabilization services and is licensed by the Department of Behavioral Health and Developmental Services. Such facility may maintain a stock of Schedules II through VI controlled substances necessary for immediate treatment of patients admitted to such facility, which may be accessed and administered by a person licensed to administer drugs pursuant to a written or oral order of a prescriber in the absence of a prescriber.

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 Schedules 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.