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SENATE BILL NO. 1090

Offered January 11, 2023

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A *BILL to amend and reenact § 54.1-3442.6 of the Code of Virginia, relating to the Board of Pharmacy; permit to operate pharmaceutical processor or cannabis dispensing facility.*

Patron—Ebbin

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3442.6 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3442.6. Permit to operate pharmaceutical processor or cannabis dispensing facility.

A. No person shall operate a pharmaceutical processor or a cannabis dispensing facility without first obtaining a permit from the Board. The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmaceutical processor's dispensing area or cannabis dispensing facility. The Board shall establish an application fee and other general requirements for such application.

B. Each permit shall expire annually on a date determined by the Board in regulation. The number of permits that the Board may issue or renew in any year is limited to ~~one~~ *two* pharmaceutical ~~processor~~ *processors* and up to five cannabis dispensing facilities *per pharmaceutical processor* for each health service area established by the Board of Health. *No pharmaceutical processor, or any general partner, any member, any limited partner of 10 percent or more with voting rights, any officer, director, or shareholder owning 10 percent or more of its capital stock, or any member-manager or member owning 10 percent or more of the membership interest shall hold more than one permit.* Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor and cannabis dispensing facility.

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors and cannabis dispensing facilities. Such regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling, including the potency of each botanical cannabis product and the amounts recommended by the practitioner or dispensing pharmacist, and packaging; (vii) routine inspections no more frequently than once annually; (viii) processes for safely and securely dispensing and delivering in person cannabis products to a patient, his registered agent, or, if such patient is a minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) dosage limitations for cannabis oil that provide that each dispensed dose of cannabis oil not exceed 10 milligrams of delta-9-tetrahydrocannabinol; (x) a process for the wholesale distribution of and the transfer of usable cannabis, botanical cannabis, cannabis oil, and cannabis products between pharmaceutical processors, between a pharmaceutical processors and a cannabis dispensing facility, and between cannabis dispensing facilities; (xi) an allowance for the sale of devices for administration of dispensed cannabis products and hemp-based CBD products that meet the applicable standards set forth in state and federal law, including the laboratory testing standards set forth in subsection M; (xii) an allowance for the use and distribution of inert product samples containing no cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility, and not for further distribution or sale, without the need for a written certification; (xiii) a process for acquiring industrial hemp extracts and formulating such extracts into cannabis products; and (xiv) an allowance for the advertising and promotion of the pharmaceutical processor's products and operations, which shall not limit the pharmaceutical processor from the provision of educational material to practitioners who issue written certifications and patients. The Board shall also adopt regulations for pharmaceutical processors that include requirements for (a) processes for safely and securely cultivating Cannabis plants intended for producing cannabis products, (b) the secure disposal of agricultural waste, and (c) a process for registering cannabis oil products.

D. The Board shall require that, after processing and before dispensing any cannabis products, a pharmaceutical processor shall make a sample available from each batch of cannabis product for testing by an independent laboratory located in Virginia meeting Board requirements. A valid sample size for testing shall be determined by each laboratory and may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing or distribution from each homogenized batch of cannabis oil is required to achieve a representative cannabis oil sample for analysis. A minimum sample size, to be determined by the

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59 certified testing laboratory, from each batch of botanical cannabis is required to achieve a representative
60 botanical cannabis sample for analysis. Botanical cannabis products shall only be tested for the
61 following: total cannabidiol (CBD); total tetrahydrocannabinol (THC); terpenes; pesticide chemical
62 residue; heavy metals; mycotoxins; moisture; and microbiological contaminants. Testing thresholds shall
63 be consistent with generally accepted cannabis industry thresholds. The pharmaceutical processor may
64 remediate botanical cannabis or cannabis oil that fails any quality testing standard except pesticides.
65 Following remediation, all remediated botanical cannabis or cannabis oil shall be subject to laboratory
66 testing and approved upon satisfaction of applicable testing standards, which shall not be more stringent
67 than initial testing prior to remediation. If a batch of botanical cannabis fails retesting after remediation,
68 it shall be considered usable cannabis and may be processed into cannabis oil. Stability testing shall not
69 be required for any cannabis product with an expiration date assigned by the pharmaceutical processor
70 of six months or less from the date of the cannabis product registration approval. Stability testing
71 required for assignment of an expiration date longer than six months shall be limited to microbial
72 testing, on a pass/fail basis, and potency testing, on a 10 percent deviation basis, of active ingredients.

73 E. A laboratory testing samples for a pharmaceutical processor shall obtain a controlled substances
74 registration certificate pursuant to § 54.1-3423 and shall comply with quality standards established by
75 the Board in regulation.

76 F. Every pharmaceutical processor's dispensing area or cannabis dispensing facility shall be under the
77 personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor or
78 cannabis dispensing facility. The pharmaceutical processor shall ensure that security measures are
79 adequate to protect the cannabis from diversion at all times, and the pharmacist-in-charge shall have
80 concurrent responsibility for preventing diversion from the dispensing area.

81 Every pharmaceutical processor shall designate a person who shall have oversight of the cultivation
82 and production areas of the pharmaceutical processor and shall provide such information to the Board.
83 The Board shall direct all communications related to enforcement of requirements related to cultivation
84 and production of cannabis oil products by the pharmaceutical processor to such designated person.

85 G. The Board shall require the material owners of an applicant for a pharmaceutical processor or
86 cannabis dispensing facility permit to submit to fingerprinting and provide personal descriptive
87 information to be forwarded along with his fingerprints through the Central Criminal Records Exchange
88 to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information
89 regarding the applicant's material owners. The cost of fingerprinting and the criminal history record
90 search shall be paid by the applicant. The Central Criminal Records Exchange shall forward the results
91 of the criminal history background check to the Board or its designee, which shall be a governmental
92 entity. A pharmaceutical processor shall maintain evidence of criminal background checks for all
93 employees and delivery agents of the pharmaceutical processor. Criminal background checks of
94 employees and delivery agents may be conducted by any service sufficient to disclose any federal and
95 state criminal convictions.

96 H. In addition to other employees authorized by the Board, a pharmaceutical processor may employ
97 individuals who may have less than two years of experience (i) to perform cultivation-related duties
98 under the supervision of an individual who has received a degree in a field related to the cultivation of
99 plants or a certification recognized by the Board or who has at least two years of experience cultivating
100 plants, (ii) to perform extraction-related duties under the supervision of an individual who has a degree
101 in chemistry or pharmacology or at least two years of experience extracting chemicals from plants, and
102 (iii) to perform duties at the pharmaceutical processor and cannabis dispensing facility upon certification
103 as a pharmacy technician.

104 I. A pharmaceutical processor to whom a permit has been issued by the Board may establish up to
105 five cannabis dispensing facilities for the dispensing of cannabis products that have been cultivated and
106 produced on the premises of a pharmaceutical processor permitted by the Board. Each cannabis
107 dispensing facility shall be located within the same health service area as the pharmaceutical processor.

108 J. No person who has been convicted of a felony under the laws of the Commonwealth or another
109 jurisdiction within the last five years shall be employed by or act as an agent of a pharmaceutical
110 processor or cannabis dispensing facility.

111 K. Every pharmaceutical processor or cannabis dispensing facility shall adopt policies for
112 pre-employment drug screening and regular, ongoing, random drug screening of employees.

113 L. A pharmacist at the pharmaceutical processor's dispensing area and the cannabis dispensing facility
114 shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees
115 who can be safely and competently supervised at one time; however, no pharmacist shall supervise more
116 than six persons performing the duties of a pharmacy technician at one time in the pharmaceutical
117 processor's dispensing area or cannabis dispensing facility.

118 M. A pharmaceutical processor may acquire industrial hemp extracts grown and processed in
119 Virginia, and in compliance with state or federal law, from a registered industrial hemp dealer or
120 processor. A pharmaceutical processor may process and formulate such extracts into an allowable dosage

of cannabis product. Industrial hemp extracts acquired and formulated by a pharmaceutical processor are subject to the same third-party testing requirements that may apply to cannabis plant extract. Testing shall be performed by a laboratory located in Virginia and in compliance with state law governing the testing of cannabis products. The industrial hemp dealer or processor shall provide such third-party testing results to the pharmaceutical processor before industrial hemp extracts may be acquired.

N. With the exception of § 2.2-4031, neither the provisions of the Administrative Process Act (§ 2.2-4000 et seq.) nor public participation guidelines adopted pursuant thereto shall apply to the adoption of any regulation pursuant to this section. Prior to adopting any regulation pursuant to this section, the Board of Pharmacy shall publish a notice of opportunity to comment in the Virginia Register of Regulations and post the action on the Virginia Regulatory Town Hall. Such notice of opportunity to comment shall contain (i) a summary of the proposed regulation; (ii) the text of the proposed regulation; and (iii) the name, address, and telephone number of the agency contact person responsible for receiving public comments. Such notice shall be made at least 60 days in advance of the last date prescribed in such notice for submittals of public comment. The legislative review provisions of subsections A and B of § 2.2-4014 shall apply to the promulgation or final adoption process for regulations pursuant to this section. The Board of Pharmacy shall consider and keep on file all public comments received for any regulation adopted pursuant to this section.

O. The Board shall register all cannabis products that meet testing, labeling, and packaging standards.

2. That the provisions of this act prohibiting a pharmaceutical processor from holding more than one permit shall not apply to any pharmaceutical processor that has received a permit in accordance with § 54.1-3442.6 of the Code of Virginia, as amended by this act, from the Board of Pharmacy prior to July 1, 2023.