25106013D

HOUSE BILL NO. 1989

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on General Laws
on January 28, 2025)

(Patron Prior to Substitute—Delegate Askew)

A BILL to amend and reenact §§ 4.1-1600, 4.1-1602, and 4.1-1603 of the Code of Virginia, relating to medical cannabis program; product labels; delivery.

Be it enacted by the General Assembly of Virginia:

1. That §§ 4.1-1600, 4.1-1602, and 4.1-1603 of the Code of Virginia are amended and reenacted as follows:

§ 4.1-1600. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Botanical cannabis" means cannabis that is composed wholly of usable cannabis from the same parts of the same chemovar of cannabis plant.

"Cannabis dispensing facility" means a facility that (i) has obtained a permit from the Board pursuant to § 4.1-1602; (ii) is owned, at least in part, by a pharmaceutical processor; and (iii) dispenses cannabis products produced by a pharmaceutical processor 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.

"Cannabis oil" means any formulation of processed Cannabis plant extract, which may include industrial hemp extracts, including isolates and distillates, acquired by a pharmaceutical processor pursuant to § 4.1-1602, or a dilution of the resin of the Cannabis plant that contains, except as otherwise provided in this chapter, no more than 10 milligrams of tetrahydrocannabinol per dose. "Cannabis oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, handled, or processed in compliance with state or federal law, unless it has been grown and processed in the Commonwealth by a registered industrial hemp processor and acquired and formulated by a pharmaceutical processor.

"Cannabis product" means a product that (i) is formulated with cannabis oil or botanical cannabis; (ii) is produced by a pharmaceutical processor and sold by a pharmaceutical processor or cannabis dispensing facility; (iii) is registered with the Board; (iv) contains, except as otherwise provided in this chapter, no more than 10 milligrams of tetrahydrocannabinol per dose; and (v) is compliant with testing requirements.

"Designated caregiver facility" means any hospice or hospice facility licensed pursuant to § 32.1-162.3, or home care organization as defined in § 32.1-162.7 that provides pharmaceutical services or home health services, private provider licensed by the Department of Behavioral Health and Developmental Services pursuant to Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title 37.2, assisted living facility licensed pursuant to § 63.2-1701, or adult day center licensed pursuant to § 63.2-1701.

"Dispense" means the same as that term is defined in § 54.1-3300.

"Edible cannabis product" means a cannabis product that is intended to be ingested and (i) is formulated with cannabis oil or botanical cannabis, (ii) is produced by a pharmaceutical processor and sold by a pharmaceutical processor or cannabis dispensing facility, (iii) is registered with the Board, and (iv) is compliant with testing requirements.

"Inhalable cannabis product" means a cannabis product that is intended to be inhaled and (i) is formulated with cannabis oil or botanical cannabis, (ii) is produced by a pharmaceutical processor and sold by a pharmaceutical processor or cannabis dispensing facility, (iii) is registered with the Board, and (iv) is compliant with testing requirements.

"Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to § 4.1-1602 and (ii) cultivates Cannabis plants intended only for the production of cannabis oil, botanical cannabis, and usable cannabis, produces cannabis products, and dispenses cannabis products to a patient pursuant to a written certification, 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.

"Pharmacist" means the same as that term is defined in § 54.1-3300.

"Pharmacy intern" means the same as that term is defined in § 54.1-3300.

"Pharmacy technician" means the same as that term is defined in § 54.1-3300.

"Pharmacy technician trainee" means the same as that term is defined in § 54.1-3300.

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine, a physician assistant licensed by the Board of Medicine, or an advanced practice registered nurse jointly licensed by the Boards of Nursing and Medicine.

"Registered agent" means an individual designated by a patient who has been issued a written certification, or, if such patient is a minor or a vulnerable adult as defined in § 18.2-369, designated by such patient's parent or legal guardian, and registered with the Board pursuant to subsection F of § 4.1-1601.

"Topical cannabis product" means a cannabis product that is intended to be applied topically to the skin

and is (i) formulated with cannabis oil or botanical cannabis, (ii) produced by a pharmaceutical processor and sold by a pharmaceutical processor or cannabis dispensing facility, (iii) registered with the Board, and (iv) compliant with testing requirements.

"Usable cannabis" means any cannabis plant material, including seeds, but not (i) resin that has been extracted from any part of the cannabis plant, its seeds, or its resin; (ii) the mature stalks, fiber produced from the stalks, or any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks; or (iii) oil or cake made from the seeds of the plant.

§ 4.1-1602. 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 Authority 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 pharmaceutical processor and up to five cannabis dispensing facilities for each health service area established by the Board of Health. 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 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 products that provide that each dispensed dose of a cannabis product not exceed 10 milligrams of total tetrahydrocannabinol, except as permitted under § 4.1-1603.2; (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 processor 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 N; (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 disposal of agricultural waste, and (c) a process for registering cannabis products.

D. The Board shall require pharmaceutical processors, after processing and before dispensing any cannabis products, to make a sample available from each batch of cannabis product for testing by an independent laboratory that is located in *the* Commonwealth and meets 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 certified testing laboratory, from each batch of botanical cannabis is required to achieve a representative botanical cannabis sample for analysis. Botanical cannabis products shall only be tested for the following: total cannabidiol (CBD), total tetrahydrocannabinol (THC), terpenes, pesticide chemical residue, heavy metals, mycotoxins, moisture, and microbiological contaminants. Testing thresholds shall be consistent with generally accepted cannabis industry thresholds. The pharmaceutical processor may remediate botanical cannabis or cannabis oil that fails any quality testing standard except pesticides. Following remediation, all remediated botanical cannabis or cannabis oil shall be subject to laboratory testing, which shall not be more stringent than initial testing prior to remediation. Remediated botanical cannabis or cannabis oil that passes such quality testing may be packaged and labeled. If a batch of botanical cannabis fails retesting after remediation, it shall be considered usable cannabis and may be processed into cannabis oil. Stability testing shall not be required for any cannabis product with an expiration date assigned by the pharmaceutical processor of 12 months or less from the date of the cannabis product registration approval. Stability testing required for assignment of an expiration date longer than 12 months shall be limited to microbial testing, on a pass/fail basis, and potency

testing, on a 15 percent deviation basis, of total THC and total CBD. No cannabis product shall have an expiration date longer than 12 months from the date of the cannabis product registration approval unless supported by stability testing.

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

F. Every pharmaceutical processor's dispensing area or cannabis dispensing facility shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor or cannabis dispensing facility unless all cannabis products are contained in a vault or other similar container to which only the pharmacist has access controls. The pharmaceutical processor shall ensure that security measures are adequate to protect the cannabis from diversion at all times, and the pharmacist-in-charge shall have concurrent responsibility for preventing diversion from the dispensing area.

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

G. The Board shall require the material owners of an applicant for a pharmaceutical processor or cannabis dispensing facility permit to submit to fingerprinting and provide personal descriptive information to be forwarded along with his fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information regarding the applicant's material owners. The cost of fingerprinting and the criminal history record search shall be paid by the applicant. The Central Criminal Records Exchange shall forward the results of the criminal history background check to the Board or its designee, which shall be a governmental entity.

H. A pharmaceutical processor shall maintain evidence of criminal background checks for all employees and delivery agents of the pharmaceutical processor. Criminal background checks of employees and delivery agents may be conducted by any service sufficient to disclose any federal and state criminal convictions.

I. In addition to other employees authorized by the Board, a pharmaceutical processor may employ individuals who may have less than one year of experience (i) to perform cultivation-related duties under the supervision of an individual who has received a degree in a field related to the cultivation of plants or a certification recognized by the Board or who has at least one year of experience cultivating plants, (ii) to perform extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least one year of experience extracting chemicals from plants, (iii) to perform duties at the pharmaceutical processor and cannabis dispensing facility upon certification as a pharmacy technician, and (iv) to serve as pharmacy technician trainees.

J. A pharmaceutical processor to whom a permit has been issued by the Board may (i) establish up to five cannabis dispensing facilities, subject to the permit requirement set forth in subsection B, for the dispensing of cannabis products that have been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board and (ii) establish, if authorized by the Board, one additional location at which the pharmaceutical processor may cultivate cannabis plants. Each cannabis dispensing facility and the additional cultivation location shall be located within the same health service area as the pharmaceutical processor.

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

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

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

N. A pharmaceutical processor may acquire from a registered industrial hemp handler or processor industrial hemp extracts that (i) are grown and processed in Virginia in compliance with state or federal law, and (ii) notwithstanding the tetrahydrocannabinol limits set forth in the definition of "industrial hemp extract" in § 3.2-5145.1, contain a total tetrahydrocannabinol concentration of no greater than 0.3 percent. 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 handler or processor shall provide such third-party testing results to the pharmaceutical processor before industrial hemp extracts may be acquired.

O. Product labels for all cannabis products and botanical cannabis shall be complete, accurate, easily

~~discernable~~ *discernible*, and uniform among different products and brands. Pharmaceutical processors shall affix to all cannabis products and botanical cannabis a label, which shall also be accessible on the pharmaceutical processor's website, that includes:

1. The product name;

2. All active and inactive ingredients, including cannabinoids, terpenes, additives, preservatives, flavorings, sweeteners, and carrier oils;

3. The total ~~percentage and~~ milligrams of tetrahydrocannabinol and cannabidiol included in the *edible cannabis product or topical cannabis* product ~~and~~, the number of milligrams of tetrahydrocannabinol and cannabidiol in each serving *of the edible cannabis product or topical cannabis product, and the total percentage of tetrahydrocannabinol and cannabidiol included in the inhalable cannabis product*;

4. The amount of product that constitutes a single serving and the amount recommended for use by the practitioner or dispensing pharmacist;

5. Information regarding the product's purpose and detailed usage directions;

6. Child and safety warnings in a conspicuous font; and

7. Such other information required by the Board.

P. A pharmaceutical processor or cannabis dispensing facility shall maintain an adequate supply of cannabis products that (i) contain cannabidiol as their primary cannabinoid and (ii) have low levels of or no tetrahydrocannabinol.

Q. 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 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 shall consider and keep on file all public comments received for any regulation adopted pursuant to this section.

§ 4.1-1603. Dispensing cannabis products; report.

A. A pharmaceutical processor or cannabis dispensing facility shall dispense or deliver cannabis products only in person to (i) a patient who is a Virginia resident or temporarily resides in Virginia and has been issued a valid written certification; (ii) such patient's registered agent; or (iii) if such patient is a minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident or temporarily resides in Virginia. *A pharmaceutical processor or cannabis dispensing facility may dispense or deliver cannabis products to such patient or such patient's registered agent, parent, or legal guardian at any residence, including a temporary residence, or business. Notwithstanding the foregoing, a pharmaceutical processor or cannabis dispensing facility shall not dispense or deliver cannabis products to any public gathering places, including sporting events, festivals, fairs, races, concerts, and terminals of public transportation companies.* A companion may accompany a patient into a pharmaceutical processor's dispensing area or cannabis dispensing facility. Prior to the initial dispensing of cannabis products pursuant to each written certification, a pharmacist or pharmacy technician employed by the pharmaceutical processor or cannabis dispensing facility shall make and maintain, on site or remotely by electronic means, for two years a paper or electronic copy of the written certification that provides an exact image of the document that is clearly legible; shall view, in person or by audiovisual means, a current photo identification of the patient, registered agent, parent, or legal guardian; and shall verify current board registration of the corresponding registered agent if applicable. Thereafter, an initial dispensing may be delivered to the patient, registered agent, parent, legal guardian, or designated caregiver facility. Prior to any subsequent dispensing of cannabis products pursuant to each written certification, an employee or delivery agent shall view a current photo identification of the patient, registered agent, parent, or legal guardian and the current board registration issued to the registered agent if applicable. No pharmaceutical processor or cannabis dispensing facility shall dispense more than a 90-day supply, as determined by the dispensing pharmacist or certifying practitioner, for any patient during any 90-day period. A pharmaceutical processor or cannabis dispensing facility may dispense less than a 90-day supply of a cannabis product for any patient during any 90-day period; however, a pharmaceutical processor or cannabis dispensing facility may dispense more than one cannabis product to a patient at one time. No more than four ounces of botanical cannabis shall be dispensed for each 30-day period for which botanical cannabis is dispensed. In determining the appropriate amount of a cannabis product to be dispensed to a patient, a pharmaceutical processor or cannabis dispensing facility shall consider all cannabis products dispensed to the patient and adjust the amount dispensed accordingly.

B. A pharmaceutical processor or cannabis dispensing facility shall dispense only cannabis products produced on the premises of a pharmaceutical processor permitted by the Board or cannabis products that

have been formulated with extracts from industrial hemp acquired by a pharmaceutical processor from a registered industrial hemp handler or processor pursuant to § 4.1-1602. A pharmaceutical processor may begin cultivation upon being issued a permit by the Board.

C. The Board shall report annually by December 1 to the Chairmen of the House Committee on General Laws and the Senate Committee on Rehabilitation and Social Services on the operation of pharmaceutical processors and cannabis dispensing facilities issued a permit by the Board.

D. The concentration of total tetrahydrocannabinol in any cannabis product on site may be up to 15 percent greater than or less than the level of total tetrahydrocannabinol listed in the approved cannabis product registration. A pharmaceutical processor and cannabis dispensing facility shall ensure that such concentration in any cannabis product on site is within such range. A pharmaceutical processor producing cannabis products shall establish a stability testing schedule of cannabis products that have an expiration date of longer than 12 months.