SENATE BILL NO. 1337

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the Senate Committee on Education and Health

on _____)

(Patron Prior to Substitute--Senator Dunnavant)

A BILL to amend and reenact §§ 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia and to amend the Code of Virginia by adding sections numbered 54.1-3442.7:1, 54.1-3442.7:2, and 54.1-3442.7:3, relating to medical marijuana program; product, registration, dispensing, and recordkeeping requirements; advertising.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding sections numbered 54.1-3442.7:1, 54.1-3442.7:2, and 54.1-3442.7:3 as follows:

§ 54.1-3408.3. Certification for use of cannabis products for treatment.

A. As used in this section:

"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 the same as that term is defined in § 54.1-3442.5.

"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 § 54.1-3442.6, or a dilution of the resin of the Cannabis plant that contains, except as otherwise provided in Article 4.2 (§ 54.1-3442.5 et seq.), no more than 10 milligrams of delta-9-tetrahydrocannabinol per dose. "Cannabis oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, 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 ~~is~~ (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 Article 4.2 (§ 54.1-3442.5 et seq.), no more than 10 milligrams of delta-9-tetrahydrocannabinol per dose; and (v) is compliant with testing requirements ~~and (ii) composed of cannabis oil or botanical cannabis~~.

"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 care center licensed pursuant to § 63.2-1701.

"Pharmaceutical processor" means the same as that term is defined in § 54.1-3442.5.

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

"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 G.

"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, or derivative, mixture, or preparation of the mature stalks; or (iii) oil or cake made from the seeds of the plant.

B. A practitioner in the course of his professional practice may (i) issue a written certification for the use of cannabis products for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use and (ii) confirm his patient's diagnosed condition or disease upon request by a pharmacist pursuant to this subsection. The practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation and may

employ the use of telemedicine, provided that the use of telemedicine includes the delivery of patient care through real-time interactive audio-visual technology. The practitioner or patient may be located at the pharmaceutical processing or cannabis dispensing facility at the time of the certification. If a practitioner determines it is consistent with the standard of care to dispense botanical cannabis to a minor, the written certification shall specifically authorize such dispensing. If not specifically included on the initial written certification, authorization for botanical cannabis may be communicated verbally or in writing to the pharmacist at the time of dispensing.

A pharmacist employed or contracted by a pharmaceutical processor or cannabis dispensing facility may issue a written certification for the use of cannabis products if the pharmacist (a) is acting as the agent of a practitioner, including a practitioner who contracts with a pharmaceutical processor or cannabis dispensing facility to serve as the medical director of such pharmaceutical processor or cannabis dispensing facility, (b) is acting pursuant to policies established by a practitioner who has contracted with a pharmaceutical processor or cannabis dispensing facility to serve as the medical director of such pharmaceutical processor or cannabis dispensing facility, and (c) has verified the patient's diagnosis with a practitioner with whom the patient has a bona fide practitioner-patient relationship. Pharmacists shall retain records of all verifications received pursuant to clause (c).

C. The written certification shall be on a form provided by the Board of Pharmacy. Such written certification shall contain the name, address, and telephone number of the practitioner or pharmacist, as applicable; the name and address of the patient issued the written certification; the date on which the written certification was made; and the signature or authentic electronic signature of the practitioner. Such written certification issued pursuant to subsection B shall expire ~~no later than~~ one year after its issuance unless the practitioner provides in such written certification an earlier expiration. A written certification shall not be issued to a patient by more than one practitioner during any given time period.

D. No practitioner or pharmacist shall be prosecuted under § 18.2-248 or 18.2-248.1 for the issuance of a certification for the use of cannabis products for the treatment or to alleviate the symptoms of a patient's diagnosed condition or disease pursuant to a written certification issued pursuant to subsection B. Nothing in this section shall preclude ~~the Board of Medicine~~ a practitioner's professional

licensing board from sanctioning ~~a~~ the practitioner for failing to properly evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for evaluating or treating medical conditions.

E. A practitioner or pharmacist who issues a written certification to a patient pursuant to this section ~~shall register with the Board and~~ (i) shall hold sufficient education and training to exercise appropriate professional judgment in the certification of patients; (ii) shall not offer a discount or any other thing of value to a patient or a patient's parent, guardian, or registered agent that is contingent on or encourages the person's decision to use a particular pharmaceutical processor or cannabis product; (iii) shall not issue a certification to himself or his family members, employees, or coworkers; (iv) shall not provide product samples containing cannabis other than those approved by the U.S. Food and Drug Administration; (v) shall not accept compensation from a pharmaceutical processor or cannabis dispensing facility unless the practitioner is serving as the medical director of such pharmaceutical processor or cannabis dispensing facility or, in the case of a pharmacist, is employed or contracted by such pharmaceutical processor or cannabis dispensing facility; and (vi) in the case of a pharmacist employed or contracted by a pharmaceutical processor or cannabis dispensing facility, shall not charge a fee for any certification issued at such pharmaceutical processor facility or cannabis dispensing facility. The Board shall not limit the number of patients to whom a practitioner may issue a written certification. The Board may report information to the applicable licensing board on unusual patterns of certifications issued by a practitioner.

F. No patient shall be required to physically present the written certification after the initial dispensing by any pharmaceutical processor or cannabis dispensing facility under each written certification, provided that the pharmaceutical processor or cannabis dispensing facility maintains an electronic copy of the written certification. Pharmaceutical processors and cannabis dispensing facilities shall electronically transmit, on a monthly basis, all new written certifications received by the pharmaceutical processor or cannabis dispensing facility to the Board.

G. A patient, or, if such patient is a minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian, may designate an individual to act as his registered agent for the purposes

of receiving cannabis products pursuant to a valid written certification. Such designated individual shall register with the Board. The Board may set a limit on the number of patients for whom any individual is authorized to act as a registered agent.

H. Upon delivery of a cannabis product by a pharmaceutical processor or cannabis dispensing facility to a designated caregiver facility, any employee or contractor of a designated caregiver facility, who is licensed or registered by a health regulatory board and who is authorized to possess, distribute, or administer medications, may accept delivery of the cannabis product on behalf of a patient or resident for subsequent delivery to the patient or resident and may assist in the administration of the cannabis product to the patient or resident as necessary.

I. Information obtained under the patient certification or agent registration process shall be confidential and shall not be subject to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However, reasonable access to registry information shall be provided to (i) the Chairmen of the House Committee for Courts of Justice and the Senate Committee on the Judiciary, (ii) state and federal agencies or local law enforcement for the purpose of investigating or prosecuting a specific individual for a specific violation of law, (iii) licensed practitioners or pharmacists, or their agents, for the purpose of providing patient care and drug therapy management and monitoring of drugs obtained by a patient, (iv) a pharmaceutical processor or cannabis dispensing facility involved in the treatment of a patient, or (v) a registered agent, but only with respect to information related to such patient.

§ 54.1-3442.5. Definitions.

As used in this article:

"Botanical cannabis," "cannabis oil," "cannabis product," "designated caregiver facility," "practitioner," "registered agent," and "usable cannabis" have the same meanings as specified in § 54.1-3408.3.

"Cannabis dispensing facility" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3442.6; (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.

~~"Designated caregiver facility" has the same meaning as defined in § 54.1-3408.3.~~

"Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to §~~ 54.1-3408.3~~ 54.1-3442.6 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.

~~"Practitioner" has the same meaning as specified in § 54.1-3408.3.~~

~~"Registered agent" has the same meaning as specified in § 54.1-3408.3.~~

§ 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 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, 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~~ products that provide that each dispensed dose of a cannabis ~~oil~~ product not exceed 10 milligrams of ~~delta-9-tetrahydrocannabinol~~ total tetrahydrocannabinol, except as permitted under § 54.1-3442.7:2; (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 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 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 ~~and approved upon satisfaction of applicable testing standards~~, 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 ~~six~~ 12 months or less from the date of the cannabis product registration approval or the date of packaging and labeling, whichever is later. Stability testing required for assignment of an expiration date longer than ~~six~~ 12 months shall be limited to microbial testing, on a pass/fail basis, and potency testing, on a ~~10~~ 15 percent deviation basis, of ~~active ingredients~~ 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 or the date of packaging and labeling, whichever is later, 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 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 ~~oil~~ 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. 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.

H. In addition to other employees authorized by the Board, a pharmaceutical processor may employ individuals who may have less than two years 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 two years 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 two years of experience extracting chemicals from plants, and (iii) to perform duties at the pharmaceutical processor and cannabis dispensing facility upon certification as a pharmacy technician.

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

J. 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.

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

L. 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.

M. A pharmaceutical processor may acquire industrial hemp extracts grown and processed in Virginia, and in compliance with state or federal law, from a registered industrial hemp dealer or 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.~~

§ 54.1-3442.7. 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 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 practitioner and~~ 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. ~~The Board shall establish in regulation an amount of cannabis oil that constitutes a 90-day~~ supply to treat or alleviate the symptoms of a patient's diagnosed condition or disease. 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 dealer or processor pursuant to § 54.1-3442.6. 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 for Health, Welfare and Institutions and the Senate Committee on Education and Health on the operation of pharmaceutical processors and cannabis dispensing facilities issued a permit by the Board.

D. The concentration of ~~delta-9-tetrahydrocannabinol~~ total tetrahydrocannabinol in any cannabis product on site may be up to ~~10~~ 15 percent greater than or less than the level of ~~delta-9-tetrahydrocannabinol measured for labeling~~ 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 longer than 12 months.

§ 54.1-3442.7:1. Packaging and labeling; corrections; records.

A. Pharmaceutical processors shall comply with all packaging and labeling requirements set forth in this article and Board regulations.

B. No cannabis product shall be packaged in a container or wrapper that bears, or is otherwise labeled to bear the trademark, trade name, famous mark as defined in 15 U.S.C. § 1125, or other identifying mark, imprint, or device, or any likeness thereof, of a manufacturer, processor, packer, or

distributor of a product intended for human consumption other than the manufacturer, processor, packer, or distributor that did in fact so manufacture, process, pack, or distribute such cannabis product.

C. Pharmaceutical processors may correct typographical errors made on cannabis product labels and any documents generated as the result of a wholesale transaction.

§ 54.1-3442.7:2. Cannabis product registration; approval, deviation, and modification.

A. A pharmaceutical processor shall register with the Board each cannabis product it manufactures. Applications for cannabis product registration shall be submitted to the Board on a form prescribed by the Board.

B. An application for cannabis product registration shall include:

1. The total tetrahydrocannabinol and total cannabidiol in such cannabis product, based on laboratory testing results for the cannabis product formulation;

2. A product name;

3. A proposed product package; and

4. A proposed product label, which shall not be required to contain an expiration date at the time of application.

C. The Board shall register all cannabis products that meet testing, labeling, and packaging standards within 14 days after an application for registration is submitted. If the cannabis product fails to meet such standards or the application was deficient, the Board shall notify the applicant of the specific reasons for such failure or deficiency within 14 days of the date the application for registration was submitted. If the Board fails to respond within 14 days, the application shall be deemed approved.

D. Within two business days of the Board's approval or deemed approval, the Board shall enter the cannabis product's national drug code number into the Prescription Monitoring Program.

E. The following cannabis product deviations from an approved cannabis product registration shall be permitted without any requirement for a new cannabis product registration or notice to the Board:

1. A deviation in the concentration of total tetrahydrocannabinol (THC) or total cannabidiol (CBD) in a cannabis product or dose thereof of up to 15 percent greater than or less than the concentration of total tetrahydrocannabinol or total cannabidiol, either or both, listed in the approved cannabis product

registration; however, for a cannabis product with five milligrams or less of total THC or total CBD per dose, the total THC or total CBD concentration shall be within 0.5 milligrams of the single dose total THC or total CBD concentrations approved for that cannabis product;

2. A variation in packaging, provided that the packaging is substantially similar to the approved packaging and otherwise complies with applicable packaging requirements;

3. A deviation in labeling, including a variation made in accordance with § 54.1-3442.7:1, that reflects allowable deviations in total THC or total CBD or that makes a minor text, font, design, or similar modification, provided that the labeling is substantially similar to the approved labeling and otherwise complies with applicable labeling requirements; and

4. Any other insignificant changes.

F. A pharmaceutical processor may submit a request to modify an existing cannabis product registration in the event of a cannabis product deviation that is not set forth in subsection E. Upon receipt, the Board shall respond to such request within 14 days. The Board may grant or deny the request, propose a reasonable revision, or require the pharmaceutical processor to provide additional information. If the Board fails to respond to a request for modification within 14 days of its submission, the proposed modification shall be deemed approved.

§ 54.1-3442.7:3. Advertising and marketing.

A. Pharmaceutical processors and cannabis dispensing facilities may (i) advertise and promote products and operations and (ii) provide educational material to practitioners, patients, and the public.

B. Pharmaceutical processors and cannabis dispensing facilities may engage in advertising or marketing that does not:

1. Include false or misleading statements;

2. Promote overconsumption;

3. Depict a person younger than 21 years of age;

4. Appeal particularly to persons younger than 21 years of age, including by using cartoons in any way;

5. Associate cannabis products with candy or similar products or depicts any images that bear a reasonable resemblance to a candy or similar product; or

6. Contain any seal, flag, crest, coat of arms, or other insignia that is likely to mislead patients or the public to believe that the cannabis product is made or endorsed by the Commonwealth.

C. All advertising and marketing by pharmaceutical processors and cannabis dispensing facilities shall (i) accurately and legibly identify the pharmaceutical processor or cannabis dispensing facility responsible for its content and (ii) include a statement that cannabis products are for use by certified patients only.

2. That pharmaceutical processors and cannabis dispensing facilities shall collect and provide to the Board of Pharmacy by July 1, 2024, data regarding the impact of this act on program participation, reductions in the price of cannabis products, and improved operational efficiencies.

3. That the Board of Pharmacy shall amend its regulations, including 18VAC110-60-270, 18VAC110-60-285, 18VAC110-60-290, and 18VAC110-60-310, to replace any references to "brand" with "registered cannabis product name."

4. That the Board of Pharmacy may assess and collect regulatory fees from each pharmaceutical processor and cannabis dispensing facility in an amount sufficient to implement the provisions of this act.

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