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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-60
VAC Chapter title(s)	Regulations Governing Pharmaceutical Processors
Action title	Petition for rulemaking
Date this document prepared	9/11/20

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation.

In response to a petition for rulemaking from the Virginia Medical Cannabis Coalition, the Board of Pharmacy decided to publish a Notice of Intended Regulatory Action in order to consider the requested amendments to regulations governing pharmaceutical processors. The amendments requested are relating to requirements for pharmacy technicians, visitor policy, inventory, labeling, expiration dates on products, remediation of samples, and access for non-licensed personnel.

Acronyms and Definitions

Define all acronyms or technical definitions used in this form.

N/A

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

There is no mandate for this regulatory change; the impetus is response to a petition for rulemaking from the organization representing the pharmaceutical processors.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:
6. To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.).

The specific statutory authority for the Board to promulgate these regulations is found in the following section:

§ 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 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) quarterly inspections; (viii) processes for safely and securely dispensing and delivering in person cannabis oil to a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) dosage limitations, which shall 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 cannabis oil products between pharmaceutical processors and between a pharmaceutical processor and a cannabis dispensing facility; (xi) an allowance for the sale of devices for administration of dispensed products; (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; and (xiii) a process for acquiring oil from industrial hemp extract and formulating such oil extract with Cannabis plant extract into allowable dosages of cannabis oil. 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 oil; (b) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (c) the secure disposal of plant remains; and (d) a process for registering cannabis oil products.

D. The Board shall require that, after processing and before dispensing cannabis oil, a pharmaceutical processor shall make a sample available from each homogenized batch of 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 is required to achieve a representative sample for analysis.

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 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. A pharmacist in charge of a pharmaceutical processor may

authorize certain employee access to secured areas designated for cultivation and other areas approved by the Board. No pharmacist shall be required to be on the premises during such authorized access. The pharmacist-in-charge shall ensure security measures are adequate to protect the cannabis from diversion at all times.

G. The Board shall require 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. 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. 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 horticulture or a certification recognized by the Board or who has at least two years of experience cultivating plants and (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.

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 oil that has 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 (i) a felony under the laws of the Commonwealth or another jurisdiction or (ii) within the last five years, any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 or a substantially similar offense under the laws of another jurisdiction 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 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.

M. Any person who proposes to use an automated process or procedure during the production of cannabis oil that is not otherwise authorized in law or regulation or at a time when a pharmacist

will not be on-site may apply to the Board for approval to use such process or procedure pursuant to subsections B through E of § 54.1-3307.2.

N. A pharmaceutical processor may acquire oil from industrial hemp extract 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 oil extract with cannabis plant extract into an allowable dosage of cannabis oil. Oil from industrial hemp acquired by a pharmaceutical processor is 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. The industrial hemp dealer or processor shall provide such third-party testing results to the pharmaceutical processor before oil from industrial hemp may be acquired.

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

The intent of the petitioner's requested amendments is to remove requirements that are considered burdensome or costly. Amendments adopted by the Board would be those that facilitate the operation of a pharmaceutical processor without imposing any additional risk of harm or diversion in order to protect the health and safety of the public.

Substance

Briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

The petitioner has requested the following amendments:

18VAC110-60-170: Remove the two-year requirement for pharmacy technicians employed by a pharmaceutical processor

18VAC110-60-220(F,G): Visitors Policy: Remove the requirement that the Board must approve or waive all visitors. Also, allow younger minor children to accompany their parent into the dispensing area and allow visitors to assist someone into the facility that might have mobility issues.

18VAC110-60-230(A)(1), (B): Inventory: Remove requirement that a pharmacist or pharmacy technician must conduct inventory. Change to require a pharmacist or pharmacy technician to verify the inventory, not conduct.

18VAC110-60-290: Product Label: Remove requirements for duplicative information between the product label and patient label.

18VAC110-60-290(B)(2)(e): Expiration Dates: Set a specific expiration date range for products until stability testing is feasible. Specifically consider between 6 and 12 months

18VAC110-60-300(F): Remediation: Allow for remediation if a sample does not pass testing requirements.

18VAC110-60-310(A)(1): VCPRL: Allow non-licensed personnel to access the VCPRL to allow access to the processor.

18VAC110-60-310(C): Patient Labels: Remove requirements for duplicative information between the product label and patient label (same request as product label).

The Board has referred these specific requests for amendments to the Regulation Committee; that committee will review and recommend language for consideration at the proposed stage.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

All of the issues addressed in the petition are requirements set out in regulation and can only be revised by amending regulations. There are no alternatives.

Periodic Review and Small Business Impact Review Announcement

This NOIRA is not being used to announce a periodic review or a small business impact review.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

The Board of Pharmacy is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, and (iii) the potential impacts of the regulation.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Elaine Yeatts, 9960 Mayland Drive, Suite 300, Richmond, VA 23233; phone (804) 367-4688; fax (804) 527-4434; Elaine.yeatts@dhp.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage, and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (https://townhall.virginia.gov) and on the Commonwealth Calendar website (https://commonwealthcalendar.virginia.gov/). Both oral and written comments may be submitted at that time.