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Exempt Action: Final Regulation 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	Changes relating to 2021 legislation and previous actions
Final agency action date	December 7, 2021
Date this document prepared	December 7, 2021

Although a regulatory action may be exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the *Code of Virginia*, the agency is still encouraged to provide information to the public on the Regulatory Town Hall using this form. However, the agency may still be required to comply with the Virginia Register Act, 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 this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The amended regulations will:

- 1) Delete reference to cannabis “oil” and use the term cannabis “product” in section 10 for consistency with the Code.
- 2) Add “cannabis dispensing facility” to #6 in section 160 to correct an oversight in the regulation and for consistency with the Code.
- 3) Amend section 190 to correct placement of the phrase “in a cannabis dispensing facility.”
- 4) Add “cannabis dispensing facility” to subsection D in section 230 to correct an oversight in the regulation and for consistency with the Code.
- 5) Eliminate references in laboratory requirements in subsections B and G in section 300 to botanical cannabis since there are separate subsections for testing of those products.

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, internal staff review, petition for rulemaking, periodic review, or board decision). "Mandate" is defined as "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the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The impetus for this action is to correct and clarify the regulations that became effective on September 1, 2021.

Subsection N of § 54.1-3442.6 was added to authorize the adoption of regulations that are exempt from certain provisions of the Administrative Process Act provided the process of notification and public comment period are followed.

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

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.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On December 7, 2021, the Board of Pharmacy adopted final amendments to 18VAC110-60-10 et seq., Regulations Governing Pharmaceutical Processors.