



townhall.virginia.gov

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	July 6, 2021
Date this document prepared	July 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 proposed regulations:

1) Amend regulations as required by the 2021 legislation, to include:

- Allowance for pharmaceutical processors to dispense botanical cannabis and requirement to establish testing standards establish testing, disposal, and security standards for botanical cannabis and a registration process for botanical cannabis products;
- Elimination of the limitation on the number of patients for whom a practitioner can write certification;

- Elimination of the requirement that a pharmacist have oversight of the cultivation and processing areas of a pharmaceutical processor and establishment of requirements for a responsible party to oversee those areas;
- Establishment of reasonable requirements for advertising of botanical cannabis and cannabis products;
- Allowance for the use of telemedicine; and
- Allowance for dispensing of botanical cannabis to a minor.

2) Incorporate other amendments that are currently in effect as emergency regulations to include:

- Amendments that: 1) include in regulation provisions for cannabis dispensing facilities; 2) provide for patients who are temporary residents to register; 3) allow for access to cultivation areas of the processor when a pharmacist is not present; 4) set out standards for laboratories that provide testing to obtain a controlled substance registration; 5) allow for sale of devices and inert sample products; 5) provide for wholesale distribution between processors and dispensing facilities; and 6) modify other provisions as applicable to changes in the Code of Virginia pursuant to SB976 of the 2020 General Assembly.
- Amendments for 1) registration of agents for patients certified to receive cannabidiol or THC-A oil, so all sections that reference registered individuals are amended to include registered agents; and 2) wholesale distribution of oils between processors.
- Amendment to prohibit the production of an oil intended to be vaporized or inhaled from containing vitamin E acetate.

3) Replace the references to “cannabis oil” with “cannabis 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 mandate for this action is in the enactment clauses of legislation passed by the 2021 General Assembly:

HB1988:

2. That the Board of Pharmacy (the Board) shall promulgate regulations implementing the provisions of this act. The Board’s initial adoption of regulations shall be exempt from the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), except that the Board shall provide an opportunity for public comment on the regulations prior to adoption. The Board shall complete work on such regulations in order that they will be implemented no later than September 1, 2021.

HB2218 and SB1333:

3. That the Board of Pharmacy shall promulgate regulations implementing the provisions of this act including its enactment clauses. The Board's adoption of regulations shall be exempt from the Administrative Process Act (§ [2.2-4000](#) et seq. of the Code of Virginia), except that the Board shall provide an opportunity for public comment on the regulations prior to adoption. The Board shall complete work on such regulations in order that they will be implemented no later than 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 July 6, 2021, the Board of Pharmacy adopted final amendments to 18VAC110-60-10 et seq., Regulations Governing Pharmaceutical Processors.