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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	Pharmaceutical processor regulation changes pursuant to 2022 legislation
Final agency action date	September 6, 2022
Date this document prepared	September 6, 2022

This information is required for executive branch review pursuant to Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19. In addition, this information is required by the Virginia Register of Regulations pursuant to the Virginia Register Act (§ 2.2-4100 et seq. of the Code of Virginia). Regulations must conform to the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), 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.

Chapters 391 and 392 of the 2022 Acts of Assembly required the Board of Pharmacy to promulgate regulations to reflect the changes contained in those Acts to the pharmaceutical processor program. Enactment clause 12 of Chapters 391 and 392 stated that the promulgation of required regulations would be exempt from the Virginia Administrative Process Act, Va. Code § 2.2-4000 *et seq.* Enactment clause 13 required the Board to promulgate regulations by September 15, 2022.

The Board therefore promulgated regulations pursuant to the 2022 legislation to eliminate mandatory patient registration, change allowable manufacturing and extraction of cannabis products, wholesale transactions of bulk cannabis, and marketing of cannabis products.

Mandate and Impetus

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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). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "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."

Chapters 391 and 392 of the 2022 Acts of Assembly mandate that the Board promulgate these regulations.

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 September 6, 2022, the Board of Pharmacy amended the Regulations Governing Pharmaceutical Processors in accordance with Chapters 391 and 392 of the 2022 Acts of Assembly.