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# Exempt Action: Final Regulation
# Agency Background Document

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| **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 to access and labeling requirements |
| **Final agency action date** | March 15, 2022 |
| **Date this document prepared** | March 15, 2022 |

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) Amend section 210 to clarify the process by which a pharmacist, pharmacy technician, or an employee of the pharmaceutical processor or cannabis dispensing facility who has routine access to confidential patient data and who has signed a patient data confidentiality agreement with the processor or dispensing facility, may determine eligibility for access to the processor or facility.

2) Amend section 310 to eliminate certain requirements to be included on a product label if the information is found on the batch label.

## 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the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."*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 address two remaining issues that were initially included in a NOIRA (Action 5611 / Stage 9081) that was subsequently withdrawn.

Subsection N of § 54.1-3442.6 authorizes 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 March 15, 2022, the Board of Pharmacy adopted final amendments to 18VAC110-60-10 et seq., Regulations Governing Pharmaceutical Processors.