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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)	18VAC110-20
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy
Action title	Exclusion of private dwellings or residences from operating locations of controlled substance registrations
Date this document prepared	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), 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, 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 the subject matter, intent, and goals of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation).

The Board intends to amend 18VAC110-20-690 to prohibit issuance of a controlled substances registration at a location that is a private dwelling or residence. This would make 18VAC110-20-690 consistent with 18VAC110-20-110(J), which prohibits issuance of a pharmacy permit to locations that are private dwellings or residences, and 18VAC110-50-30(C), which prohibits issuance of a license, permit, or registration to a wholesale distributor, manufacturer, warehouser, nonresident warehouser, nonresident wholesale distributor, nonresident manufacturer, third-party logistics provider, or nonresident third-party logistics provider from operating out of a private dwelling or residence.

Acronyms and Definitions

Define all acronyms or technical definitions used in this form.

CSR = controlled substance registration

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 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."

In its 2021 periodic review of Chapter 20, the Board identified this potential amendment as needed to ensure safety of the public. Although the amendment was included in the notice of intended regulatory action following the periodic review of Chapter 20, the Board felt this exclusion was imperative to protect the health, safety, and welfare of the public, and so initiated a separate action.

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 of the Board of Pharmacy are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be "[t]o 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."

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 Board considers the operation of a controlled substances registration and maintenance of a stock of controlled substances in a private dwelling or residence not conducive to maintaining security and accountability of drugs. Similar prohibitions are in place for permitted pharmacies under 18VAC110-20-110(J), which subsection was created to prohibit pharmacy operation out of a private dwelling or residence for the same reasons. Similarly, 18VAC110-50-30(C) prohibits issuance of a license, permit, or registration to a wholesale distributor, manufacturer, warehouser, nonresident warehouser, nonresident wholesale distributor, nonresident manufacturer, third-party logistics provider, or nonresident third-party logistics provider from operating out of a private dwelling or residence.

There are currently a handful of CSRs issued to private dwellings or residences. Those CSRs will be grandfathered in by the Board so as not to impact existing businesses.

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 Board will amend 18VAC110-20-690 to include a provision similar to 18VAC110-20-110(J) and 18VAC110-50-30(C). The provision will state that a controlled substance registration shall not be issued to any person to operate from a private dwelling or residence.

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.

There is no alternative to regulation. The intended action is a prohibition on how CSRs are issued. It must be included in regulatory language. Small businesses cannot be exempted from the prohibition as that would entirely defeat the purpose of the amendment.

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 Erin Barrett, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or erin.barrett@dhp.virginia.gov or by fax to (804) 915-0382. 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 the proposed 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.