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## Notice of Intended Regulatory Action (NOIRA) Agency Background Document

<b>Agency name</b>	Board of Pharmacy, Department of Health Professions
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	18VAC110-30
<b>VAC Chapter title(s)</b>	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances
<b>Action title</b>	Periodic review
<b>Date this document prepared</b>	3/15/22

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), 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 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 has identified at least two sections that it will consider for amendments:

- Insertion of requirements, similar to other facilities permitted by the Board of Pharmacy, to declare hours of operation the location will be open to service the public and report changes in the hours of operation expected to last for more than one week to the board and the public at least 14 days prior to the anticipated change. Include exemptions for emergency circumstances beyond control of the owner or responsible party or expansion of hours.
- Section 80 to prohibit license and permit from being issued to private dwelling or residence.

## Acronyms and Definitions

*Define all acronyms or technical definitions used in this form.*

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N/A

## 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 Executive Order 14 (as amended, July 16, 2018), “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the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part.”*

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The impetus for this regulatory action is implementation of recommendations from the Board’s periodic review of regulations. A General Notice was published with comment on the report of results requested from January 17, 2022 to February 25, 2022. No comment on this chapter was received.

## 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.*

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Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

**§ 54.1-2400. General powers and duties of health regulatory boards.**

*The general powers and duties of health regulatory boards shall be:*

*...6. To 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, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100 et seq.](#)) and Chapter 25 (§ [54.1-2500 et seq.](#)).*

The statutory authority for the Board to promulgate regulations to regulate the practice of pharmacy is found in:

**§ 54.1-3307. Specific powers and duties of Board.**

*A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.*

*The Board's regulations shall include criteria for:*

- 1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.*
- 2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.*
- 3. Controls and safeguards against diversion of drugs or devices.*
- 4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.*
- 5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.*
- 6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.*
- 7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.*
- 8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.*
- 9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.*

The statutory authority for the Board to promulgate regulations to regulate practitioners of the healing arts who are selling drugs:

**§ 54.1-3302. Restrictions on practitioners of the healing arts.**

*A practitioner of the healing arts shall not sell or dispense controlled substances except as provided in §§ [54.1-2914](#) and [54.1-3304.1](#). Such exceptions shall extend only to his own patients unless he is licensed to practice pharmacy.*

**§ 54.1-3304.1. Authority to license and regulate practitioners; permits.**

*A. The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any practitioner of the healing arts to dispense controlled substances within the Commonwealth unless licensed by the Board to sell controlled substances.*

*B. Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances. Facilities in which only one practitioner of the healing arts is licensed by the Board to sell controlled substances shall be exempt from fees associated with obtaining and renewing such permit.*

*C. The Board of Pharmacy may issue a limited-use license for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances to a doctor of medicine, osteopathic medicine, or podiatry, a nurse practitioner, or a physician assistant, provided that such limited-use licensee is practicing at a nonprofit facility. Such facility shall obtain a limited-use permit from the Board and comply with regulations for such a permit.*

**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 amendments being considered are necessary to protect public health and safety by ensuring patients have sufficient information to know when pharmaceutical services are going to be available at the location where a practitioner is permitted to sell controlled substances and by prohibiting the conduct of such a practice in one’s private residence which could jeopardize the integrity and security of such substances.

**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 has identified at least two sections that it will consider for amendments:

- Insertion of requirements, similar to other facilities permitted by the Board of Pharmacy, to declare hours of operation the location will be open to service the public and report changes in the hours of operation expected to last for more than one week to the board and the public at least 14 days prior to the anticipated change. Include exemptions for emergency circumstances beyond control of the owner or responsible party or expansion of hours.
- Section 80 to prohibit license and permit from being issued to 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.*

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Licenses and controlled substance registrations issued by the Board of Pharmacy are mandated by Chapter 33 of Title 54.1 of the Code of Virginia. There are no alternatives for implementation of the mandates other than the promulgation of reasonable regulations that are enforceable and protect the public health and safety.

### 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.*

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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, 9960 Mayland Drive, Suite 300, Henrico, VA 23233; (804) 367-4688; FAX (804) 527-4434; [erin.barrett@dhp.virginia.gov](mailto:erin.barrett@dhp.virginia.gov). 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 this 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.