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Periodic Review and Small Business Impact Review Report of Findings

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-30
VAC Chapter title(s)	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances
Date this document prepared	12/8/21

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***.

Acronyms and Definitions

Define all acronyms used in this Report, and any technical terms that are not also defined in the "Definitions" section of the regulation.

N/A

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 or 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 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.

Alternatives to Regulation

Describe any viable alternatives for achieving the purpose of the regulation that were considered as part of the periodic review. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving its purpose.

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 Comment

Summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency response. Be sure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. Indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

The Notice of Periodic Review was published in the Register on January 4, 2021 with public comment was requested until January 25, 2021 on any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economic performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable. There are over 270 persons on the Townhall notification list for the Board of Pharmacy; there were no comments during the comment period.

The Board is publishing the results of its periodic review and seeking comment on the Decision prior to adopting a Notice of Intended Regulatory Action.

Effectiveness

Pursuant to § 2.2-4017 of the Code of Virginia, indicate whether the regulation meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), including why the regulation is (a) necessary for the protection of public health, safety, and welfare, and (b) is clearly written and easily understandable.

All of the provisions of Chapter 30 were included as VR530-01-2 before the creation of the Virginia Administrative Code. It has been amended 12 times since 2001 as changes in practice and statutory authority have changed. It continues to be effective in protecting the public by setting rules for the security and integrity of drugs being sold by practitioners of the healing arts in their practices. Whenever amendments are promulgated, language is reviewed to ensure that it is clearly written and easily understandable.

Decision

Explain the basis for the promulgating agency's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

The Board will amend the regulation. While there was no public comment on this chapter resulting from the Notice of Periodic Review, 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.

After further opportunity for comment and recommendations for amendments, the Board will publish a Notice of Intended Regulatory Action.

Small Business Impact

As required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

(1) There is a continued need for the regulation since § 54.1-3302 of the Code of Virginia provides: *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*. § 54.1-3302 specifically authorizes the Board "*authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts."* Such regulation can only occur through the continuation of Chapter 30;
(2) The Board has not received any of complaints or comments concerning the regulation;
(3) Practitioners do not find the regulation to be overly complex, but the Board will consider whether requirements could be simplified or clarified;
(4) There is no overlap duplication, or conflict with federal or state law or regulation; and
(5) The Board has continually updated regulations while protecting the safety, integrity, and efficacy of dispensing medications. There is a current regulatory action (replacing emergency regulations) expanding the authority for nurse practitioners and physician assistants in free clinics to dispense Schedule VI medications.

In its review, the Board will consider any additional amendments that are recommended that will streamline or clarify regulations in order to minimize the economic impact on small businesses.