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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)	18VAC110-20
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy
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.

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.

Permits, licenses, and registrations issued by the Board of Pharmacy are mandated by the Drug Control Act (Chapter 34 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.

This chapter was in effect as VR530-01-1 before the creation of the Virginia Administrative Code. It has been amended 40 times in the past five years. It continues to be effective in protecting the public by scheduling dangerous chemicals in Schedule I, by setting rules for the safety, efficacy, and integrity of prescription medications, and by updating rules as new technologies and techniques are introduced in the practice of pharmacy. 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. The Board has identified several sections that it will consider for amendments:

- Section 10, amend definition of "personal supervision" to allow audio-visual technology by pharmacist on premises for supervision of compounding in retail pharmacies
- Section 25, amend the unprofessional conduct section to add language
    - acting in a manner that causes an individual to feel threatened or intimidated so that such individual is discouraged from reporting a public safety concern in good faith or is discouraged from cooperating with an employee of the Department of Health Professions in the conduct of an investigation or inspection.
    - failure to provide a working environment for all pharmacy personnel that protects the health, safety, and welfare of a patient including:
        - sufficient personnel to prevent fatigue, distraction, or other conditions that interfere with a pharmacist's ability to practice with competency and safety or creates an environment that jeopardizes patient care;
        - appropriate opportunities for uninterrupted rest periods and meal breaks;
        - adequate time for a pharmacist to complete professional duties and responsibilities including:
            - drug utilization review;
            - immunization;
            - counseling;
            - verification of the accuracy of a prescription
    - introducing external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public;
    - incenting or inducing the transfer of a prescription absent professional rationale.
- Section 110, amend to address appropriate opportunities for uninterrupted rest periods and meal breaks which may or may not require the pharmacy to close.
- Section 110, amend to include additional information to be required on a pharmacy permit or nonresident pharmacy registration application and include a requirement to notify board of any changes within timeframe consistent with current laws.

- Section 110, subsection J, amend to require an applicant for a pharmacy permit to report to the Board any prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the practice of pharmacy
- Section 110, extending timeframe beyond 14 days for notification of a change in the PIC
- Section 270, allow a pharmacist to use his professional judgment to alter or adapt a prescription, to change dosage, dosage form or directions, to complete missing information, or to extend a maintenance drug.
- Including a requirement for an e-profile identification number for facilities
- Extending timeframe beyond 14 days for notification of a change in the PIC
- Section 275, subsections B, C, and F, consider including exemption to requirement for returning to initiating pharmacy any prescriptions not delivered to the patient if prohibited under federal law.
- Section 275, amend to include record requirement for an alternate delivery site further delivering the drug to a patient's home.
- Section 290, consider amendment to provision that allows dispensing of a Schedule II drug for up to six months after the date on which the prescription was issued
- Section 550, amend to remove the restriction that a stat-drug box contain no more than 20 solid dosage units per schedule of Schedules II through V drugs
- Section 690 to prohibit controlled substance registration from being issued to private dwelling or residence just as there is a current prohibition on such issuance of a pharmacy permit.
- Clarifying expectation regarding administration records, particularly if drug administered by someone other than the pharmacist whose initials are captured on the dispensing record.
- Including a requirement for an e-profile identification number for facilities

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.

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(1) There is a continued need for the regulation since the Code requires pharmacies and other entities to be permitted, registered or licensed by the Board;
(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) As stated above, the chapter has been amended 40 times in the last five years and has five additional regulatory actions in process, including amendments to incorporate allowances for newer technology in hospital pharmacies. The last periodic review began in 2016, but was only finalized in 2019, so the Board has continually updated regulations while protecting the safety, integrity, and efficacy of dispensing 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.