Virginia Regulatory Town Hall

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Greater oversight of wholesale distributors
Document preparation date	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The Board of Pharmacy intends to increase its oversight of the wholesale distribution market in order to prevent opportunities for counterfeiting of drugs and ensure the integrity, safety and efficacy of drugs or devices distributed in the Commonwealth. While current regulations require persons engaged in the wholesale distribution of drugs to hold a permit issued by the Board and to adhere to certain rules for safeguarding drugs from diversion, additional requirements are needed to adequately protect the public from the distribution of counterfeit, misbranded, or otherwise unfit drugs.

Since regulations governing the practice of pharmacy have become so extensive and complex, the Board may consider the adoption of a new chapter for the regulation of wholesale distributors and the amending of applicable sections of Chapter 20 that reference their permitting by the Board.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly

chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

---

18 VAC 110-20-10 et seq. Regulations Governing the Practice of Pharmacy are promulgated under the general authority of Title 54.1, Chapter 24 of the Code of Virginia. Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations in accordance with the Administrative Process Act.

> ***§ 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 (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. 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.) of this title. …*

The specific statutory authority for the Board to regulate the practice of pharmacy including the distribution of controlled substances is found in § 54.1-3307 of the Code of Virginia.

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

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 which do not conform to the requirements of law. In so regulating the Board shall consider any of the following criteria as they are applicable:

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 Board may collect and examine specimens of drugs, devices and cosmetics which are manufactured, stored or dispensed in this Commonwealth.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed. Include the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. Delineate any potential issues that may need to be addressed as the regulation is developed.

It is likely that the Board will adopt requirements for the licensure and regulations of wholesale distributors as a new chapter – Chapter 25, Regulations Governing the Licensure of Wholesale Distributors. In doing so, current rules for permits, fees, and security for wholesale distributors would be eliminated in Chapter 20 and moved to the new chapter.

The proposed action will likely follow the outline of the Model Rules of the National Association of Boards of Pharmacy and may include definitions for terms not currently defined in the Drug Control Act, specific criteria for an application for licensure to include detailed information about the distribution operation, provisions for inspections and requirements for personnel, security, anti-counterfeiting measures, recordkeeping, and quality control.

In an increasingly complex environment for the marketing and distribution of prescription drugs and devices, the Board of Pharmacy has an obligation to be proactive in ensuring the safety, integrity and quality of controlled substances that are distributed in the Commonwealth. In instances where due diligence has not been observed in other states, drugs that were adulterated or counterfeited have entered the consumer market and resulted in harm to the public. Harm may come from an adulterated or counterfeited drug or device to which a patient has an adverse reaction or which does not have the strength or quality to achieve the intended result from pharmacotherapy.

It is the Board's responsibility to set out rules that will ensure that the drug supply is safe and efficacious, that records are being adequately maintained, and that there is sufficient oversight to deter adulteration or counterfeiting. With the adoption of new regulations for wholesale distributors, the Board intends to add rules that offer clear standards of practice that provide for both deterrence and enforcement.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action.

In order to set out rules that are enforceable through inspections and disciplinary proceedings conducted by the Board, it is necessary to adopt regulations. While the Board could issue a guidance document that expresses its intent regarding the practices of wholesale distributors, it would not have legal standing to enforce the guidance as requirements of law and regulation. In recognition of the need to address actual and potential problems with distribution of drugs that do that meet standards for purity, quality and safety, the National Association of Boards of Pharmacy has recently issued Model Rules for the Licensure of Wholesale Distributors. Effective February 20, 2004, the Model Rules establish definitions used in regulation, requirements for licensure, minimum qualifications for persons who engage in wholesale distribution of drugs or devices, minimum requirements for storage, handling, transport and shipment and for maintenance of records, requirements for security and anti-counterfeiting, storage of drugs and devices, returned, damaged or outdated drugs, and recordkeeping. Model Rules also require the development of policies and procedures and sets out prohibited acts that are unlawful for a person to perform or to aid in the performance.

It is the Board's intent to use the Model Rules as a guideline rather than to adopt them by reference or incorporate wholly into its regulation. In addition, the Board will look at regulations in other states for wholesale distribution of drugs and devices and will involve advisors who have familiarity with the business in the development of rules that will achieve the goal of protecting the integrity and safety of prescription drugs and devices but avoid requirements that may be onerous and without justification.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability.

There is no potential impact on the family and family stability.