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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)	18VAC110-50
VAC Chapter title(s)	Regulations Governing Wholesale Distributors, Manufacturers, Third-Party Logistics Providers, and Warehousers
Date this document prepared	2/10/22

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***.

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 manufacturing, dispensing, selling, distributing, or processing of drugs and devices 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 for wholesale distributors, manufacturers, third-party logistics providers, and warehousers is found in Articles 3 and 4 of Chapter 34 of Title 54.1 (Drug Control Act).

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.

The Board of Pharmacy has been authorized in the Drug Control Act (Chapter 34 of Title 54.1 of the Code of Virginia) to promulgate regulations for the licensure of wholesale distributors and permitting of warehousers and manufacturers. Most recently, in 2016, the Code was amended to require permitting of third party logistic providers in § 54.1-3435.4:1. Subsection B provides: "The Board shall adopt such regulations relating to the requirements to operate as a third-party logistics provider, including the storage, handling, and distribution of prescription drugs by third-party logistics providers, as it deems necessary to prevent diversion of prescription drugs and to protect the public."

There are no alternatives for implementation of the mandates for licenses and permits 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.

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.

In 2006, it was determined that regulations governing the practice of pharmacy (Chapter 20) had become so extensive and complex that the Board proposed the adoption of a new chapter (Chapter 50) to incorporate the regulations for wholesale distributors, manufacturer, and warehousers and to delete requirements for those entities in the regulations governing the practice of pharmacy.

The chapter has been amended 12 times since 2006 to clarify provisions, add protections against counterfeiting of drug in the wholesale market, and regulate third party logistic providers as mandated by the Code. 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 has recommended that the chapter be retained without amendments at this time.

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 as the Code requires these facilities to be regulated and for the Board to promulgate such regulations relating to the storage, handling, and distribution of prescription drugs as necessary to prevent diversion of prescription drugs, and to protect the public. Such regulation can only occur through the continuation of Chapter 50;
(2) The Board has not received any of complaints or comments concerning the regulation;
(3) Facilities regulated by Chapter 50 do not find the regulation to be overly complex, but the Board is always open to comment on whether requirements could be simplified or clarified;
(4) There is no overlap duplication, or conflict with federal or state law or regulation. Manufacturers are required to follow the federal rule, Good Manufacturing Practice for Finished Pharmaceuticals regulations set forth in 21 CFR Part 211; and
(5) The Board has continually updated regulations while protecting the safety, integrity, and efficacy of dispensing medications.