Virginia Regulatory Town Hall

townhall.virginia.gov

Fast Track Proposed Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-50
Regulation title	*Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers*
Action title	Regulatory reform
Date this document prepared	December 28, 2012

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

The Board of Pharmacy has conducted a periodic review of its regulations governing Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers. In response to the Governor's regulatory reform project, the Board proposes to make the information required in the application process more reasonable and less restrictive.

Statement of final agency action

On December 12, 2012, the Board of Pharmacy adopted amended regulations for 18 VAC 110-50-10 et seq., Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers to implement changes recommended in a periodic review of regulations.

Legal basis

18 VAC 110-30-10 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.

The specific statutory authority for the Board of Pharmacy to regulate the practice of pharmacy including the dispensing 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.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the amended regulation is elimination of certain information currently required for an application for licensure as a wholesale distributor. Information about the responsible parties is necessary to ensure the integrity of a wholesale distributor business; the Board is able to eliminate certain burdensome requirements without jeopardizing the enforceability of

regulations or compromising the health and safety of persons who are the ultimate recipients of drugs being distributed for dispensing.

Rationale for using fast track process

The Board has opted to use the fast-track process for two reasons: 1) the action is consistent with the Governor's project to reform regulations that are unnecessarily burdensome; and 2) it does not anticipate any objection to the changes.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

The substantive changes are: 1) modification of the required information on an application for licensure as a wholesale distributor; and 2) elimination of the requirement for notarization of a sworn statement on criminal convictions.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.
If there are no disadvantages to the public or the Commonwealth, please indicate.

1) The primary advantage of the regulatory action is less burdensome and costly regulation for an application for licensure as a wholesale distributor. There are no disadvantages.
2) There are no advantages or disadvantages to the Commonwealth.
3) The action is the result of a periodic review conducted pursuant to the Governor's Regulatory Reform Project.

Requirements more restrictive than federal

There are no applicable federal requirements.

Localities particularly affected

The proposed regulation does not affect any locality.

Regulatory flexibility analysis

Since the intent is to promulgate a less burdensome and costly regulation, there are no alternative methods for accomplishing the objective of reducing the regulatory burden.

Economic impact

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners or entities for necessary functions of regulation. There would be little or no additional expense for promulgation of the amended rule. Consideration of the proposed rule has been during a regularly scheduled board meeting, and to the extent possible, all notifications would be done electronically to minimize the cost. There are no on-going expenditures for the agency related to amendments to regulations.
Projected cost of the *new regulations or changes to existing regulations* on localities.	There are no costs to localities.
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	The businesses that would be affected would be wholesale distributors; there are no changes affecting warehousers or manufacturers.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are currently 768 non-resident wholesale distributors and 116 Virginia wholesale distributors that are licensed to do business in the Commonwealth. It is unknown how many are small businesses.
All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	The changes to regulations will make the provision of information for licensure less burdensome. They will not affect those wholesale distributors who have already obtained a license.
Beneficial impact the regulation is designed to produce.	The amended regulation should make it less burdensome to apply for licensure as a wholesale distributor.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

Following the close of comment on the periodic review, staff of the Board reviewed the regulation in light of current practices and interpretation of regulations as set forth in Guidance Document 110-34. Staff recommendations were presented to the Regulation Committee on December 11th and to the full Board on December 12th. There was no public comment on the regulation at either of the meetings.

Periodic review/small business impact review result

The Notice of Periodic Review was published in the Register of Regulations, posted on Townhall and sent to the public participation mailing list for the Board of Pharmacy with the opportunity for comment from November 5th to December 5th. There were no comments.

The regulation meets the criteria in Executive Order 14 as it is necessary for public health and the safety of prescription medications; it is clearly written and easily understandable. There have been no complaints, no concerns about complexity and no conflict with state or federal law or regulation. It was last reviewed and amended in 2006 and has been amended two times since then. Changes to Chapter 50 make the application process less restrictive and reflect guidance of the Board in its interpretation of regulations.

Family impact

There is no impact on the family.

Detail of changes

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
40	Sets out requirements for safeguards against diversion of drugs in facilities	The regulation is amended just to clarify that the *license* referenced in section 40 applies to a *wholesale distributor* and a *permit* applies to a *manufacturer or warehouse.*
70	In Part II on licensure of wholesale distributors, section 70 sets out the	Subdivision 4 under subsection A specifies that the application must include the type of ownership and name(s) of the owner.

	required minimum information for an application to be licensed as a wholesale distributor.	If a partnership, the regulation requires the name, address, and social security number or control number of *each* partner, and the name of the partnership and federal employer identification number. The amended regulation would specify that the information is only required for the partner who is specifically responsible for the operations of the facility listed on the application. Likewise, if the ownership is a corporation, the regulation requires the name, address, social security number or control number, and title of *each* corporate officer and director. The amended regulation would specify that the information is only required for the officer or director who is specifically responsible for the operations of the facility listed on the application. *The Board does not believe it is reasonable to require social security or control numbers for all partners or all officers or directors of a corporation unless the individuals are directly involved in the operation of the distributorship. The intent of the regulation is accountability to ensure the integrity of wholesaled drugs.*
80	Sets out the minimum qualifications, eligibility and responsible party for a wholesale distributorship	Subsection C requires that the person who is named as the responsible party submit, among other things, a "*sworn statement or affirmation*" disclosing whether he has a criminal conviction or is the subject of any pending criminal charges. The amendment will change the language to "*attestation."* *Practically speaking, a sworn statement or affirmation is achieved by having a notary public sign the affirmation. Witnessing the attestation and signature by a notary public provides no assurance that the applicant is truthfully replying to the question. It appears to be an unnecessary step in the application process. In addition to the attestation about criminal convictions, the applicant must have a criminal history record check, so the Board is not concerned about replacing "sworn statement" with "attestation."*