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Fast-Track Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-50
Regulation title(s)	Regulations Governing Wholesale Distributors, Manufacturers, Warehousers, and Third-party Logistics Providers
Action title	Registration of nonresident warehousers and third-party logistics providers
Date this document prepared	9/6/18

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 (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

Pursuant to Chapter 96 of the 2018 Acts of the Assembly (HB520), the Board of Pharmacy has adopted amendments to 18VAC110-50-10 et seq., relating to a requirement for registration of nonresident warehousers and third-party logistics providers. Regulations will establish fees and requirements for nonresident warehousers and third-party logistics providers consistent with those for resident entities of the same type.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

N/A

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On June 21, 2018, the Board of Pharmacy amended 18VAC110-50-10 et seq., Regulations Governing Wholesale Distributors, Manufacturers, Warehousers, and Third-party Logistics Providers, to conform to provisions of Chapter 96 of the 2018 Acts of the Assembly to be effective after July 1, 2018. The action was adopted as exempt action, but the Board was subsequently advised by the Office of the Attorney General to submit it as a fast-track action.

Mandate and Impetus

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

As required by Virginia Code § 2.2-4012.1, please also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

The mandate for registration of nonresident warehousers and third-party logistics providers is found in Chapter 96 of the 2018 Acts of the Assembly (HB520). Regulations pertaining to nonresident warehousers and third-party logistics providers are the same as those for the resident entities of the same type. Therefore, they should not be controversial and may be fast-tracked.

Legal Basis

Please identify (1) the agency or other promulgating entity, 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 entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity'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:

1. To establish the qualifications for registration, certification, licensure or the issuance of a multistate licensure privilege in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.

2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.

3. To register, certify, license or issue a multistate licensure privilege to qualified applicants as practitioners of the particular profession or professions regulated by such board.

4. To establish schedules for renewals of registration, certification, licensure, and the issuance of a multistate licensure privilege.

5. To levy and collect fees for application processing, examination, registration, certification or licensure or the issuance of a multistate licensure privilege and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.

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 specific statutory mandate for these regulations is found in § 54.1-3435.4:01 and § 54.1-3435.4:2

§ 54.1-3435.4:01. Registration to act as a nonresident warehouser; regulations.

A. Any warehouser located outside the Commonwealth that ships prescription drugs or devices into the Commonwealth shall be registered with the Board. Such nonresident warehouser shall renew such registration annually on a date determined by the Board and shall notify the Board within 30 days of any substantive change in the information previously submitted.

B. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs and devices by nonresident warehousers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices, and to protect the public.

C. The nonresident warehouser shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located that authorizes the possession and distribution of

such prescription drugs and devices and shall furnish proof of such upon application and at each renewal.

D. Records of prescription drugs and devices distributed into the Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distributions into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of State Police upon request within seven days of receipt of such request.

§ 54.1-3435.4:2. Registration of nonresident third-party logistics provider; renewal.

A. Any third-party logistics provider located outside the Commonwealth that ships prescription drugs or devices into the Commonwealth shall be registered with the Board. Such nonresident third-party logistics provider shall renew such registration annually on a date determined by the Board and shall notify the Board within 30 days of any substantive change in the information previously submitted.

B. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs and devices by nonresident third-party logistics providers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices, and to protect the public.

C. The nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located or current licensure as a third-party logistics provider with the FDA and shall furnish proof of such upon application and at each renewal.

D. Records of prescription drugs and devices distributed into the Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distributions into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of State Police upon request within seven days of receipt of such request.

Purpose

Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

Regulations pertaining to nonresident warehousers and nonresident third-party logistics providers are the same as those for the resident entities of the same type. Requirements for security, storage, policies and procedures, handling of adulterated drugs, and safeguards against diversion are necessary to ensure the safety and integrity of the supply of prescription drugs and devices shipped into the Commonwealth by nonresident entities.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

Regulations for nonresident warehousers and nonresident third-party logistics are identical to those for resident warehousers and third-party logistics providers, including fees for initial applications and renewal. The functions performed, the security protections, and the need to safeguard the drug supply are the same, regardless of whether the entity is located in Virginia or is shipping drugs and devices for Virginia patients.

Issues

Please identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

1) The primary advantage to the public is protection of drugs and devices to ensure their efficacy and integrity and to guard against diversion. There are no disadvantages.
2) The primary advantage to the agency is compliance with a statutory mandate for regulation; there are no disadvantages.
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 to "*promulgate regulations in accordance with the Administrative Process Act (§2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system.*" There is no restraint on competition as a result of promulgating this regulation; resident and nonresident warehousers and third-party logistics providers are being regulated equally.

Requirements More Restrictive than Federal

Please identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material

impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

There are no state agencies affected.

Localities Particularly Affected

There are no localities affected.

Other Entities Particularly Affected

There are no other entities affected.

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	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 for necessary functions of regulation. The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Any on-going costs for issuance of registration or conducting investigations and adjudicating cases will be offset by revenue generated from registration fees.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no costs to other state agencies.
For all agencies: Benefits the regulatory change is designed to produce.	The benefit is compliance with the Code.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no projected costs.

Benefits the regulatory change is designed to produce.	No direct benefit.

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Nonresident warehousers and nonresident third-party logistics providers
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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	The agency has no estimate of the number of entities or of the number that may be small businesses.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	There will be costs associated with registration in order to do business in Virginia. Those costs include a $270 fee for applying for registration and a $270 annual renewal fee. There are costs for security, record-keeping, storage, etc., but those requirements would likely be the same as those of the resident state and would have already been incurred in order to operate in that jurisdiction.
Benefits the regulatory change is designed to produce.	The benefit is public protection for the integrity and security of drugs and devices coming from out-of-state entities.

Alternatives

Please describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

The Board is mandated to promulgate regulations for registration of nonresident warehousers and nonresident third-party logistics providers. As applicable, the regulations for resident facilities and nonresident facilities are identical and are necessary to protect public health and safety of prescription drugs and devices.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

There are no alternative regulatory methods; the Board is mandated to promulgate regulations for registration of nonresident warehousers and nonresident third-party logistics providers.

Public Participation

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Detail of Changes

Current section number	Current requirement	Change, intent, rationale, and likely impact of new requirements
20	Sets out fees for permits, licenses, or registrations	Fees for initial application, renewals, late fees, or reinstatement are established for nonresident warehousers and nonresident third-party logistics providers. They are identical to those for resident warehousers and resident third-party logistics providers - $270 for application and renewal.
30	Sets out requirements for filing an application; location of business; inspection requirement	Subsection A, requiring an application for issuance of a new registration is amended to include nonresident warehousers and nonresident third-party logistics providers. Subsection C, prohibiting establishment of a business in a private dwelling or a residence or to operate without meeting applicable facility requirements for storage and distribution of drugs and devices is amended to include nonresident warehousers and nonresident third-party logistics providers.
40	Sets out requirements for safeguards against diversion of drugs	Subsection A, setting out security measure for storage and access, is amended to include nonresident warehousers and nonresident third-party logistics providers.

60	Sets out allowance for issuance of special or limited-use licenses	The allowance in section 60 for the board to waive certain requirements for wholesale distributors or third-party logistics providers is amended to include nonresident third-party logistics providers.
70	Sets out minimum required information for a third-party logistics provider or a wholesale distributor	Subsection A, which includes the information necessary to issue a registration as a third-party logistics provider is amended to include a nonresident third-party logistics provider.
80	Sets out the minimum qualifications, eligibility and responsible party for a third-party logistics provider or a wholesale distributor	Subsection A, which includes the factors used to determine eligibility for licensure as a wholesale distributor or registration as a third-party logistics provider, is amended to include a nonresident third-party logistics provider. Subsection B, which includes the requirements for the person named as the responsible party for a wholesale distributor or a third-party logistics provider, is amended to include a nonresident third-party logistics provider. Subsection E, which sets out the requirement for a nonresident wholesale distributor to designate registered agent in Virginia for service of legal documents, is amended to include a nonresident third-party logistics provider.
100	Sets out requirement for examination of drug shipments and accompanying documents	Subsection B is amended to include a nonresident third-party logistics provider in the requirement for a review of records.
110	Sets out rules for returned, damaged and counterfeit drugs	Subsections C and D, which establish the required process for problematic drugs or devices and require cooperation with authorities in conducting an investigation, are amended to include a nonresident third-party logistics provider.
120	Sets out the requirements for policies and procedures	Section 120, which currently sets out requirements for policies and procedures for wholesale distributors, nonresident wholesale distributors and third-party logistics providers, is amended to include nonresident third-party logistics providers.
130	Sets out requirements for recordkeeping	Section 130, which currently sets out requirements for recordkeeping for wholesale distributors, nonresident wholesale distributors and third-party logistics providers, is amended to include nonresident third-party logistics providers